

Altus Pharmaceuticals Inc.
Form 8-K
July 03, 2007

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):

June 28, 2007

Altus Pharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

Delaware

0-51711

04-3573277

(State or other jurisdiction
of incorporation)

(Commission
File Number)

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

125 Sidney Street, Cambridge, Massachusetts

02139

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

617-299-2900

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.

On June 28, 2007, Altus Pharmaceuticals Inc. (the "Company") was notified by the Office of Orphan Products Development of the Food and Drug Administration ("FDA") that the orphan drug designation granted in 2002 to ALTU-135 for the treatment of pancreatic insufficiency was being revoked. The FDA based its decision on a finding that if one includes all patients with HIV/AIDS who suffer from fat malabsorption in this indication, the patient population in the United States appears to exceed 200,000 persons and is thus ineligible for orphan drug designation. We believe that only a subset of patients with HIV/AIDS have fat malabsorption due to pancreatic insufficiency and that our original filing was intended to be within the 200,000 person limit for this disease condition, however, the FDA concluded otherwise.

The principal anticipated advantage to the Company of an orphan drug designation is the availability of tax credits and the abatement of new drug application filing fees. In addition, the holder of the first new drug application approval also receives marketing exclusivity for a period of seven years over other products that contain the same drug or active ingredient. We are not aware of other products in development that are the same drug as ALTU-135 for orphan drug purposes. Given these facts and circumstances, the Company may consult with the Office of Orphan Products Development. If we conclude that re-filing with a more precisely defined indication has merit, we have the right to submit an application on or before the filing of a new drug application. We may also conclude that the advantages of continuing to seek orphan drug designation may not be warranted.

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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.

Altus Pharmaceuticals Inc.

July 3, 2007

By: Sheldon Berkle

Name: Sheldon Berkle

Title: President and Chief Executive Officer