

CORNERSTONE THERAPEUTICS INC
Form 8-K
October 18, 2012

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):

October 18, 2012

Cornerstone Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware

000-50767

04-3523569

(State or other jurisdiction
of incorporation)

(Commission
File Number)

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

1255 Crescent Green Drive, Suite 250, Cary,
North Carolina

27518

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

919-678-6611

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 7.01 Regulation FD Disclosure.

On October 12, 2012, the U.S. Food and Drug Administration (the "FDA") approved the New Drug Application by Chiesi Farmaceutici S.p.A, Cornerstone Therapeutics Inc.'s (the "Company") majority stockholder, for Bethkis®, an inhaled tobramycin-based product indicated for the management of cystic fibrosis patients with Pseudomonas aeruginosa (the "Product"). The Company and Chiesi are currently in final discussions concerning the potential licensing of the Product to the Company in the United States. The terms and conditions of any such license are subject to review and approval by the Audit Committee of the Company's Board of Directors, pursuant to the terms of the Company's Related Person Transaction Policy.

As a result of extensive discussions and analysis of a proposed license transaction in 2011, the Company agreed to permit Chiesi to reference the Company as the labeler in the draft Bethkis labeling Chiesi previously submitted to the FDA. Delays in the approval of Bethkis resulted in the Company deciding not to proceed with a licensing transaction for Bethkis in 2011, and there can be no assurance that the Company and Chiesi will be able to agree upon the terms of a definitive license agreement, nor how long such negotiations may take. In the event that the Company and Chiesi are not able to agree upon the terms of a definitive license agreement, the Company has acknowledged to Chiesi that it will have no right or obligation with respect to Bethkis, and Chiesi has agreed to take immediate steps to identify a replacement labeler.

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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.

October 18, 2012

Cornerstone Therapeutics Inc.

By: */s/ Andrew K. W. Powell*

Name: Andrew K. W. Powell

Title: Executive Vice President, General Counsel and Secretary