

CORNERSTONE THERAPEUTICS INC

Form 8-K

November 13, 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): November 6, 2012

Cornerstone Therapeutics Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

000-50767
(Commission File Number)

04-3523569
(IRS Employer Identification No.)

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1255 Crescent Green Drive, Suite 250, Cary, NC

(Address of Principal Executive Offices)

27518

(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))

Item 1.01. Entry into a Material Definitive Agreement.

As previously announced, on November 6, 2012, Cornerstone Therapeutics Inc. (the Company) and its majority stockholder, Chiesi Farmaceutici S.p.A (Chiesi), entered into a License and Distribution Agreement (the Distribution Agreement) pursuant to which Chiesi granted the Company an exclusive license to market and sell Chiesi's Bethkis® product in the United States. Bethkis is an inhaled tobramycin-based product approved by the U.S. Food and Drug Administration (the FDA) for the management of cystic fibrosis patients with Pseudomonas aeruginosa. The Distribution Agreement contains a customary non-competition covenant under which the Company may not sell in the United States any competing product to Bethkis for the duration of the Distribution Agreement.

The Distribution Agreement will remain in force for an initial term until the last date on which the sale of Bethkis in the United States would infringe a valid claim of any of the patents that are licensed under the Distribution Agreement. Thereafter, the Distribution Agreement will automatically renew for an additional period of five years, during which time it may be terminated by either party with effect on December 31st of any year, by giving at least twelve months prior written notice. The Distribution Agreement will automatically terminate if the Company fails to make the first commercial sale of the product in the United States within nine months after obtaining approval by the FDA of a label for the product that includes a registered trademark for Bethkis, subject to extension for certain specified product supply failures outside of the Company's control.

In consideration for the grant of the license, the Company will make an initial payment to Chiesi of \$1.0 million and will make a milestone payment of \$2.5 million upon the first commercial sale of the product in the United States. The Company will also be required to pay certain costs related to a Phase IV clinical trial with respect to the product and quarterly royalties based on a percentage of net sales.

As disclosed in the Company's proxy statement for its 2012 annual meeting of stockholders, which was filed with the Securities and Exchange Commission (SEC) on April 23, 2012 (the Proxy Statement), as of April 5, 2012, Chiesi is the Company's majority stockholder, and Chiesi currently is the beneficial owner of approximately 65% of the Company's outstanding common stock. In addition, the Company and certain of its stockholders have entered into a series of transactions and agreements with Chiesi that are described in the Proxy Statement, including a License and Distribution Agreement for CUROSURF®, a natural lung surfactant used for the treatment of respiratory distress syndrome in premature infants. In addition, as previously disclosed on a Form 8-K filed on June 27, 2012 with the SEC, on June 21, 2012, the Company borrowed \$90 million from Chiesi pursuant to a senior secured term loan facility. As required by the Company's Related Person Transaction Policy, the terms of the Distribution Agreement have been approved by the Company's Audit Committee.

A copy of the Distribution Agreement is attached as Exhibit 10.1 to this Current Report on Form 8-K, and the Company refers you to such exhibit for the complete terms of the Distribution Agreement, which are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

See the Exhibit Index attached hereto.

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.

CORNERSTONE THERAPEUTICS INC.

Date: November 13, 2012

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

Executive Vice President, General Counsel and Secretary

EXHIBIT INDEX

Exhibit No.	Description of Document
Exhibit 10.1	License and Distribution Agreement between Chiesi Farmaceutici S.p.A. and the Registrant dated November 6, 2012.