

CORNERSTONE THERAPEUTICS INC

Form 8-K

December 20, 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):

December 14, 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

(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 1.01. Entry into a Material Definitive Agreement.

On December 14, 2012, Cornerstone Therapeutics Inc. (the "Company") entered into an amendment to the License and Distribution Agreement (the "Amendment") with its majority stockholder, Chiesi Farmaceutici S.p.A ("Chiesi"). The Amendment amends the license and distribution agreement the parties originally entered into on May 6, 2009 (the "Distribution Agreement"). Under the Distribution Agreement, the Company distributes and markets, in the United States, Chiesi's CUROSURF® product, a natural lung surfactant used for the treatment of respiratory distress syndrome in premature infants.

The Amendment extends the initial term of the Distribution Agreement a further five years to 15 years starting from September 1, 2009. After such time, the Distribution Agreement will automatically renew for successive one-year periods, unless earlier terminated by either party by giving at least six months written notice prior to the automatic renewal date.

The Amendment also provides for certain modifications to the financial terms of the Distribution Agreement, including supply price and commercial incentives, which the Company anticipates will improve the Company's gross and operating margins on the product.

Chiesi is the Company's majority stockholder and 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 Company's proxy statement for its 2012 annual meeting of stockholders, which was filed with the Securities and Exchange Commission (the "SEC") on April 23, 2012. In addition, as previously disclosed on a Form 8-K filed with the SEC on June 27, 2012, on June 21, 2012 the Company entered into a senior secured term loan facility with Chiesi, pursuant to which the Company borrowed \$90 million from Chiesi, and as disclosed on a Form 8-K filed with the SEC on November 13, 2012, on November 6, 2012, the Company and Chiesi entered into a license and distribution for BETHKIS®, an inhaled tobramycin-based product for the management of cystic fibrosis patients with *Pseudomonas aeruginosa*. As required by the Company's Related Person Transaction Policy, the terms of the Amendment have been approved by the Company's Audit Committee.

Cautionary Statement Regarding Forward-Looking Statements

This Current Report on Form 8-K includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. For this purpose, any statements contained herein, other than statements of historical fact, including statements regarding the Company's anticipated gross and operating margins with respect to sales of CUROSURF and any other statements about management's future expectations, beliefs, goals, plans or prospects, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including the risks and uncertainties described in Item 1A (Risk Factors) of the Company's Annual Report on Form 10-K filed with the SEC on March 6, 2012 and in its subsequent filings with the SEC. In addition, any forward-looking statements in this Current Report on Form 8-K represent the Company's views only as of the date of this Current Report on Form 8-K and should not be relied upon as representing its views as of any subsequent date. While the Company may elect to update these forward-looking statements publicly at some point in the future, it specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise, except as may be required by law. The Company's forward-looking statements do not reflect the potential impact of any acquisitions, mergers, dispositions, business development transactions, joint ventures or investments that it may make or enter into.

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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.

Cornerstone Therapeutics Inc.

December 20, 2012

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

Name: Andrew K. W. Powell

*Title: Executive Vice President, General Counsel and
Secretary*