

CORNERSTONE THERAPEUTICS INC
Form 8-K
July 26, 2013

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):

July 24, 2013

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 8.01 Other Events.

Cornerstone Therapeutics Inc. (the "Company") announced on July 24, 2013 that it had filed a Complaint in the United States District Court for the District of Delaware alleging that Exela Pharma Sciences, LLC, Exela PharmSci, Inc., and Exela Holdings, Inc. (collectively "Exela") infringed its U.S. Patent Nos. 7,612,102 and 7,659,291 by filing a supplemental New Drug Application with the U.S. Food and Drug Administration (the "FDA") seeking approval to market a ready to use injectable formulation of 0.1 mg/ml and 0.2 mg/ml nicardipine hydrochloride in 0.9% sodium chloride. The Company markets a ready to use injectable formulation of 0.1 mg/ml and 0.2 mg/ml nicardipine hydrochloride in 0.86% and 0.83% sodium chloride under the name CARDENE® I.V. (nicardipine hydrochloride) Premixed Injection. U.S. Patent Nos. 7,612,102 and 7,659,291 do not expire until December 26, 2027 and April 18, 2027, respectively.

As previously disclosed, the Company received a Paragraph IV Notice Letter (the "Notice") from Exela advising the Company of the filing by Exela of the supplemental New Drug Application. By filing suit to enforce its patents within 45 days from the Company's receipt of the Notice, under the Hatch-Waxman Act, the FDA may not approve Exela's product for a period of 30 months from the Company's receipt of the Notice, or until an earlier court decision adverse to the Company's patents. The Company intends to vigorously defend the intellectual property rights covering CARDENE I.V.

Safe Harbor Statement

This Current Report on Form 8-K ("Form 8-K") includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. For this purpose, any statements contained herein, other than statements of historical fact, including our strategy and our future operations and opportunities, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including our ability to satisfy FDA and other regulatory requirements, our ability to develop and maintain the necessary sales, marketing, supply chain and distribution capabilities to successfully commercialize our products, our ability to obtain, maintain and enforce patent and other intellectual property protection for our products, including CARDENE, and our product candidates and the other factors described in Item 1A (Risk Factors) of our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 14, 2013 and in our subsequent filings with the SEC. In addition, the statements in this Form 8-K reflect our expectations and beliefs only as of the date hereof. We anticipate that subsequent events and developments may cause our expectations and beliefs to change. However, while we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so, whether as a result of new information, future events or otherwise, except as may be required by law. Our forward-looking statements do not reflect the potential impact of any acquisitions, mergers, dispositions, business development transactions, joint ventures or investments that we may make or enter into. These forward-looking statements should not be relied upon as representing our views as of any date after the date of this Form 8-K.

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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.

July 26, 2013

Cornerstone Therapeutics Inc.

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

Name: Andrew K. W. Powell

Title: EVP, General Counsel and Secretary