CORNERSTONE THERAPEUTICS INC
Form 8-K
August 20, 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): August 15, 2013

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 8.01 Other Events.

On August 15, 2013, Cornerstone Therapeutics Inc. (the "Company") received a notice letter (the "Notice Letter") from a generic applicant (the "Generic Applicant") stating that the Generic Applicant filed an Abbreviated New Drug Application ("ANDA") containing a "Paragraph IV" patent certification with the U.S. Food and Drug Administration (the "FDA") seeking approval to market a generic version of the Company's drug, CARDENE® I.V. (nicardipine hydrochloride) Premixed Injection (0.1 mg/ml and 0.2 mg/ml nicardipine hydrochloride in 0.86% and 0.83% sodium chloride). The Notice Letter states that the "Paragraph IV" certification was made with respect to the Company's three patents covering CARDENE I.V. listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluation, commonly known as the Orange Book. Those three patents -- U.S. Patent Nos. 7,612,102, 7,659,291 and 8,455,524 -- have expiration dates ranging from April 18, 2027 to December 27, 2027.

The Company is currently evaluating the Notice Letter and intends to vigorously enforce its intellectual property rights relating to CARDENE I.V., including the three Orange Book patents identified above. By filing suit to enforce its patents within 45 days from the Company's receipt of the Notice Letter, under the Hatch-Waxman Act, the FDA may not approve the Generic Applicant's product for a period of 30 months from the Company's receipt of the Notice Letter, or until an earlier court decision adverse to the Company's patents. The Company cannot predict the outcome of this matter or guarantee the outcome of any litigation.

The Notice Letter from the Generic Applicant is the first Paragraph IV notice letter received from an ANDA filer for CARDENE I.V. In July 2013, the Company initiated a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Exela Pharma Sciences, LLC, Exela PharmSci, Inc., and Exela Holdings, Inc. (collectively "Exela") in connection with Exela's filing of a supplemental New Drug Application 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.

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 I.V., 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.

Cornerstone Therapeutics Inc.

August 20, 2013

By: /s/ Craig A. Collard

Name: Craig A. Collard
Title: Chief Executive Officer