CORNERSTONE THERAPEUTICS INC
Form 8-K
May 09, 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): May 9, 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))

Top of the Form

Item 1.01. Entry into a Material Definitive Agreement.

On May 9, 2013, Cornerstone Therapeutics Inc. (the Company) announced it had entered into a License and Distribution Agreement (the License Agreement) with Digestive Care, Inc. (DCI) pursuant to which the Company acquired exclusive U.S. rights to market PERTZYE® (pancrelipase), a unique pancreatic enzyme product, approved by the U.S. Food and Drug Administration (the FDA) for the treatment of Exocrine Pancreatic Insufficiency (EPI) due to cystic fibrosis (CF). The PERTZYE formulation was previously marketed by DCI for more than a decade under the trade name PANCRECARB® MS-16. The License Agreement includes the right of first refusal to negotiate a license to any alternative, substitute, successor or improvement to PERTZYE that DCI may develop. The License Agreement contains a non-competition covenant under which the Company may not manufacture, promote, market, sell or distribute in the United States any pancreatic enzyme product that is indicated for the treatment of patients with CF for the duration of the License Agreement.

The License Agreement will remain in force for an initial term of ten years from the effective date, or May 9, 2023. Thereafter, the License Agreement will automatically renew for successive additional terms of two years, each such term an extension term, unless either the Company or DCI provides written notice six months prior to an end of the initial term or an extension term. Provisions within the Agreement allow for DCI to terminate the Agreement, if a certain amount of annual net sales are not achieved by July 2016 and July 2018, provided that the right to terminate will trigger a refund of certain milestone payments. The Company s rights to terminate include but are not limited to, the right to terminate if DCI is unable to manufacture or supply product for a defined period of time or if there are certain observations or uncorrected actions following the good manufacturing practice audit of DCI s raw material supplier, or the GMP Audit.

In consideration for the grant of rights under the License Agreement, the Company will make an initial payment of $10 million into an escrow fund which amount shall be released from escrow upon fulfillment of certain conditions provided in the Agreement, including the satisfactory completion of the GMP Audit. The Company will be required to make minimum investments in promotion during the first three years of the initial term, to pay quarterly royalties based on a percentage of net sales, and also to make milestone payments up to a further $20 million when certain net sales targets are met.

The License Agreement will be filed by the Company as an exhibit to its quarterly report on Form 10-Q for the quarter ending June 30, 2013, with portions omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

A copy of the Company s press release is filed as an exhibit to this Report and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

See the Exhibit Index attached hereto.

Top of the Form

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.

May 9, 2013

By: /s/ Andrew K.W. Powell

Name: Andrew K.W. Powell
Title: Executive Vice President, General Counsel and Secretary

Top of the Form

Exhibit Index

Exhibit No.	Description
99.1	Press release dated May 9, 2013