CORCEPT THERAPEUTICS INC
Form 8-K
April 08, 2011

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): March 31, 2011

Corcept Therapeutics Incorporated
(Exact name of registrant as specified in its charter)

000-50679
(Commission File Number)

Delaware	77-0487658
(State or other jurisdiction of incorporation)	(I.R.S. Employer Identification No.)

149 Commonwealth Drive
Menlo Park, CA 94025
(Address of principal executive offices, with zip code)

(650) 327-3270
(Registrant's telephone number, including area code)

(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 (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On March 31, 2011, we issued a press release announcing that we will submit our New Drug Application (NDA) for the use of CORLUX in Cushing's Syndrome to the FDA the week of April 11, 2011.

The completion of the NDA submission is a critical milestone for Corcept on our path to making CORLUX available to Cushing's Syndrome patients. Additional initiatives in support of this objective include the following:

- We plan to submit a request to the FDA for Priority Review along with our NDA submission. According to the FDA, "Priority Review" designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. The FDA's goal for completing a Priority Review is six months. The FDA will notify us within 45 days of our request whether our NDA has been assigned a Priority Review or a Standard Review (for which the FDA's goal is a ten month review time).

- We expect that the FDA will notify us whether our NDA submission has been accepted for filing within 74 days of submission, which the FDA bases on their initial 60-day review of the completeness of our application.

- We expect to make detailed data from our Phase 3 trial of CORLUX in Cushing's Syndrome available to the endocrinologists who treat the disorder at the Endocrine Society Annual Meeting, June 4-7 in Boston.

    - We are developing plans and engaging third-party vendors to support a commercial launch of CORLUX in the United States, if approved by the FDA.

Statements made in this current report on Form 8-K, other than statements of historical fact, are forward-looking statements, including, for example, statements relating to the timing of submission of the NDA and the FDA's response, plans to submit a request for Priority Review along with the NDA, the release of detailed data from our Phase 3 trial of CORLUX in Cushing's Syndrome and our development and commercialization plans. Forward-looking statements are subject to a number of known and unknown risks and uncertainties that might cause actual results to differ materially from those expressed or implied by such statements. For example, we cannot assure you that the FDA's review of the NDA will be favorable or that we will pursue further activities with respect to the development of CORLUX. These and other risk factors are set forth in our annual report on Form 10-K for the fiscal year ended December 31, 2010 and subsequent SEC filings. We disclaim any intention or duty to update any forward-looking statement made in this current report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

Exhibit 99.1 Press Release dated March 31, 2011

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.

CORCEPT THERAPEUTICS INCORPORATED

Date: April 8, 2011

By:/s/ Caroline M. Loewy
Caroline M. Loewy
Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated March 31, 2011