CORCEPT THERAPEUTICS INC
Form 8-K
December 15, 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: December 15, 2011
(Date of earliest event reported)

Corcept Therapeutics Incorporated
(Exact name of registrant as specified in its charter)
DE
(State or other jurisdiction
of incorporation) 000-50679
(Commission File Number) 77-0487658
(IRS Employer
Identification Number)
149 Commonwealth Drive, Menlo Park, CA
(Address of principal executive offices) 94025
(Zip Code)
650-327-3270
(Registrant's telephone number, including area code)
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:

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 December 15, 2011, we announced that we have been advised by the U.S. Food and Drug Administration (FDA) that no Risk Evaluation and Mitigation Strategy (commonly known as a "REMS" program) will be required in connection with Corcept's proposed distribution of our lead product candidate, mifepristone, to which Corcept has given the brand name Korlym. The FDA is currently reviewing Corcept's New Drug Application (NDA) for Korlym, a glucocorticoid receptor type II (GR-II) antagonist that blocks the cortisol receptor, for the treatment of the clinical and metabolic effects of hypercorticolism in patients with endogenous Cushing's Syndrome. The FDA's decision with respect to REMS does not alter the Prescription Drug User Fee Act (PDUFA) date for completion of FDA review of the NDA, which remains February 17, 2012.

The press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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 potential benefit of Korlym for patients diagnosed with Cushing's Syndrome, the timing of completion and outcome of FDA review of the NDA, our clinical development and research programs and the timing of introduction of Korlym. 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 with respect to the timing of completion and outcome of the FDA's review of our NDA filing or that we will pursue further activities with respect to the development of Korlym. 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

(a) Financial statements:
None
(b) Pro forma financial information:
None
(c) Shell company transactions:
None
(d) Exhibits
99.1 Press Release of Corcept Therapeutics Incorporated dated December 15, 2011

SIGNATURE

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.

Dated: December 15, 2011
CORCEPT THERAPEUTICS INCORPORATED

By: /s/ G. Charles Robb
G. Charles Robb

Chief Financial Officer

Exhibit Index **Exhibit No.** **Description** 99.1 Press Release of Corcept Therapeutics Incorporated dated December 15, 2011