

**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:

- ☐ 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))

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 hypercortisolism 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

FDA Will Not Require a Risk Evaluation and Mitigation Strategy in Connection With Corcept's Proposed Distribution of Korlym(TM) for Cushing's Syndrome

MENLO PARK, CA -- (Marketwire - December 15, 2011) - Corcept Therapeutics Incorporated (NASDAQ: CORT), a pharmaceutical company engaged in the discovery, development and commercialization of drugs for the treatment of severe metabolic and psychiatric disorders, today announced that it has 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 its 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 hypercortisolism 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, which remains February 17, 2012.

"We are focused intently on developing the commercial and logistical capabilities we will need to make Korlym available to patients suffering from Cushing's Syndrome, should the FDA approve our drug for this indication," said Joseph K. Belanoff, M.D., Chief Executive Officer at Corcept.

About Cushing's Syndrome

Endogenous Cushing's Syndrome is caused by prolonged exposure of the body's tissues to high levels of the hormone cortisol and is generated by tumors that produce cortisol or ACTH. Cushing's Syndrome is an orphan indication which most commonly affects adults aged 20 to 50. An estimated 10 to 15 of every one million people are newly diagnosed with this syndrome each year, resulting in over 3,000 new patients in the United States. An estimated 20,000 patients in the United States have Cushing's Syndrome. Symptoms vary, but most people have one or more of the following manifestations: high blood sugar, diabetes, high blood pressure, upper body obesity, rounded face, increased fat around the neck, thinning arms and legs, severe fatigue and weak muscles. Irritability, anxiety, cognitive disturbances and depression are also common. Cushing's Syndrome can affect every organ system in the body and can be lethal if not treated effectively.

About Korlym

Corcept's first-generation compound, Korlym, also known as mifepristone, directly blocks the cortisol (GR-II) receptor and the progesterone (PR) receptor. Intellectual property protection is in place to protect important methods of use for Korlym. Corcept retains worldwide rights to its intellectual property related to Korlym.

About Corcept Therapeutics Incorporated

Corcept is a pharmaceutical company engaged in the discovery, development and commercialization of drugs for the treatment of severe metabolic and psychiatric disorders. The company has completed its Phase 3 study of Korlym for the treatment of Cushing's Syndrome, and has an ongoing Phase 3 study of Korlym for the treatment of the psychotic features of psychotic depression. Corcept also has a developed a portfolio of new selective GR-II antagonists that block the effects of cortisol but not progesterone and has an extensive intellectual property portfolio covering the use of GR-II antagonists in the treatment of a wide variety of psychiatric and metabolic disorders, including the prevention of weight gain caused by the use of antipsychotic medication, as well as composition of matter patents for our selective GR-II antagonists.

Statements made in this news release, 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 potential outcome of the FDA's review of our NDA filing, Corcept's clinical development and research programs, the timing of introduction of Korlym and future product candidates and the ability to create value from Korlym or other future product candidates. 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, there can be no assurances with respect to the timing of completion and outcome of the FDA's review of our NDA filing, the cost, rate of spending, completion or success of clinical trials; or that Corcept will pursue further activities with respect to the development of Korlym or any of its other selective GR-II antagonists. These and other risk factors are set forth in the Company's SEC filings, all of which are available from our website (www.corcept.com) or from the SEC's website (www.sec.gov). We disclaim any intention or duty to update any forward-looking statement made in this news release.

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