

**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: April 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 April 15, 2011, we issued a press release announcing that we submitted our New Drug Application (NDA) for the use of CORLUX in Cushing's Syndrome to the U.S Food and Drug Administration (FDA) on April 15, 2011.

We included a proposal for our Risk Evaluation and Mitigation Strategies (REMS) along with our NDA submission for consideration as part of the NDA review process. We have also submitted a request to the FDA for Priority Review, which 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 and 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 previously announced positive results from our primary endpoints in our Phase 3 Cushing's Syndrome study in December 2010 and from our key secondary endpoint in January 2011. We expect to make detailed data available to the endocrinologists who treat the disorder at the Endocrine Society Annual Meeting (ENDO), June 4-7 in Boston.

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 the FDA's review of our NDA submission, including our request for Priority Review, and timing of the release of detailed data from our Phase 3 trial of CORLUX in Cushing's Syndrome. 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

(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 April 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: April 18, 2011

CORCEPT THERAPEUTICS INCORPORATED

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

Exhibit Index

Exhibit No.

99.1

Description

Press Release of Corcept Therapeutics Incorporated dated April 15, 2011

Corcept Therapeutics Announces NDA Submitted to the FDA for the Use of CORLUX in Cushing's Syndrome

Submitted Request for Six-Month Priority Review

MENLO PARK, CA -- (Marketwire - April 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 submitted its New Drug Application (NDA) for the use of CORLUX in Cushing's Syndrome to the U.S. Food and Drug Administration (FDA).

"The submission of our NDA marks a significant milestone for Corcept and our efforts to make CORLUX available to patients suffering from Cushing's Syndrome," said Joseph Belanoff, M.D., Chief Executive Officer of Corcept. "We believe that Corcept is well positioned to develop important therapies to address unmet medical needs by focusing on the regulation of cortisol, and CORLUX for Cushing's Syndrome is the first step in executing on that strategy."

NDA Submission Includes Proposed REMS Guidelines and Request for Priority Review

We are committed to making CORLUX available to patients as rapidly as possible. In support of that goal, we included a proposal for our Risk Evaluation and Mitigation Strategies (REMS) along with our NDA submission for consideration as part of the NDA review process. We have also submitted a request to the FDA for Priority Review, which 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 and 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.

NDA Submission Supported by Positive Phase 3 Data

We announced positive results from our primary endpoints in our Phase 3 Cushing's Syndrome study in December 2010 and from our key secondary endpoint in January 2011. We expect to make detailed data available to the endocrinologists who treat the disorder at the Endocrine Society Annual Meeting (ENDO), June 4-7 in Boston.

The study evaluated the response of two patient groups to CORLUX treatment: one included patients who were glucose intolerant with or without a diagnosis of hypertension, and one included patients who had a diagnosis of hypertension but had a normal glucose tolerance. Statistically significant improvement in the primary endpoint was achieved for both groups: with 60% responding in the glucose intolerant group ($p < 0.0001$) and 38% in the hypertensive group ($p < 0.05$).

Whether included in the glucose intolerant group or the hypertension group for the purpose of evaluating the primary endpoints, patients were evaluated as a single group on the key secondary endpoint of "global clinical improvement" as determined by an independent Data Review Board (DRB). A statistically significant improvement was achieved in the key secondary endpoint with a response rate of 87% ($p < 0.000001$).

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 CORLUX

Corcept's first-generation compound, CORLUX, 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 CORLUX. Corcept retains worldwide rights to its intellectual property related to CORLUX.

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 CORLUX for the treatment of Cushing's Syndrome, and has an ongoing Phase 3 study of CORLUX for the treatment of the psychotic features of psychotic depression. Corcept also has a Phase 2 program for CORT 108297 and an IND-enabling program for CORT 113083. Both of these novel compounds are selective GR-II antagonists -- compounds which block the effects of cortisol but not progesterone. Corcept has developed an extensive intellectual property portfolio that covers 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 Corcept's clinical development and research programs, the timing of the FDA's review of our NDA submission, including our request for Priority Review, timing of the release of detailed data from our Phase 3 trial of CORLUX in Cushing's Syndrome, the introduction of CORLUX and future product candidates, including CORT 108297 and CORT 113083, estimates of the timing of enrollment or completion of our clinical trials and the anticipated results of those trials, the ability to create value from CORLUX or other future product candidates and our 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, there can be no assurances with respect to the cost, rate of spending, completion or success of clinical trials; financial projections may not be accurate; there can be no assurances that Corcept will pursue further activities with respect to the development of CORLUX, CORT 108297, CORT 113083 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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