# 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: June 30, 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 June 30, 2011, we issued a press release announcing that the U.S. Food and Drug Administration (FDA) has accepted for filing our New Drug Application (NDA) for CORLUX, a glucocorticoid receptor type II (GR-II) antagonist, for the treatment of the manifestations of Cushing's Syndrome. The FDA has indicated that this application will receive a standard review and that the Prescription Drug User Fee Act (PDUFA) goal date for completion of its review is February 17, 2012.

The full text of 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, including the press release incorporated herein by reference, other than statements of historical fact, are forward-looking statements, including, for example, statements relating to the potential benefit of CORLUX for patients diagnosed with Cushing's Syndrome, commercialization plans for CORLUX for the treatment of Cushing's Syndrome, the timing of completion and outcome of FDA review of our NDA, our clinical development and research programs, the timing of introduction of CORLUX and future product candidates, including CORT 108297 and CORT 113083 and the ability to create value from CORLUX 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, we cannot assure you with respect to the cost, rate of spending, completion or success of our clinical trials, of the timing of completion of the FDA's review of our NDA for CORLUX in Cushing's Syndrome, that the results of FDA's review will be favorable or that we will pursue further activities with respect to the development of CORLUX, CORT 108297, CORT 113083 or any of our other selective GR-II antagonists. 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, including the press release incorporated herein by reference.

# 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 June 30, 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: June 30, 2011

## CORCEPT THERAPEUTICS INCORPORATED

By: <u>/s/ Anne M. LeDoux</u>
Anne M. LeDoux
VP & Controller

# **Exhibit Index**

Exhibit No.

**Description** 

99.1

Press Release of Corcept Therapeutics Incorporated dated June 30, 2011

# FDA Accepts Submission of New Drug Application for CORLUX for Cushing's Syndrome

MENLO PARK, CA -- (Marketwire - June 30, 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 the U.S. Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA), which was submitted on April 15, 2011, for CORLUX, a glucocorticoid receptor type II (GR-II) antagonist, for the treatment of the manifestations of Cushing's Syndrome.

The FDA has indicated that this application will receive a standard review and that the Prescription Drug User Fee Act (PDUFA) goal date for completion of its review is February 17, 2012.

We are executing our commercial plans related to CORLUX for the treatment of Cushing's Syndrome based on the projected timeline for the FDA review of our NDA. This includes conducting market research and engaging third-party vendors to support distribution and other logistical needs for product launch, if CORLUX is approved by the FDA.

"Many patients with Cushing's Syndrome suffer debilitating manifestations of their disease, despite receiving the best available treatment," said Joseph K. Belanoff, M.D., Chief Executive Officer at Corcept. "In our Phase 3 study, CORLUX demonstrated its potential to significantly improve the clinical condition of these patients in a wide variety of important ways. We believe that CORLUX has the potential to provide a meaningful advance over the current standard of care for patients with Cushing's Syndrome and are gratified to receive the formal notice of the FDA's acceptance of the NDA for filing."

## **About Cushing's Syndrome**

Endogenous Cushing's Syndrome results from prolonged exposure of the body's tissues to high levels of the hormone cortisol generated by tumors. Cushing's Syndrome is an orphan indication which most commonly affects adults aged 20 to 50. An estimated 20,000 people in the United States have Cushing's Syndrome, with more than 3,000 newly diagnosed patients each year. Symptoms vary, but most patients have one or more of the following: diabetes mellitus, high blood pressure, weight gain, a rounded face, increased fat around the neck, severe fatigue, weak muscles, osteoporosis, skin changes, infections, poor quality of life irritability, anxiety and depression.

#### **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 the potential benefit of CORLUX for patients diagnosed with Cushing's Syndrome, commercialization plans for CORLUX for the treatment of Cushing's Syndrome, the timing of completion and outcome of FDA review of the NDA, Corcept's clinical development and research programs, the timing of introduction of CORLUX and future product candidates, including CORT 108297 and CORT 113083 and the ability to create value from CORLUX 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 cost, rate of spending, completion or success of clinical trials, of the timing of completion of the FDA's review of the NDA for CORLUX in Cushing's Syndrome, that the results of FDA's review will be favorable or 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 annual report on Form 10-K for the fiscal year ended December 31, 2010 and subsequent 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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