# 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**

(State or other jurisdiction of incorporation)

**77-0487658** (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	l on its behalf by the undersigned
hereunto duly authorized.	

Date: April 8, 2011

CORCEPT THERAPEUTICS INCORPORATED

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

### **Exhibit Index**

Exhibit No. Description

99.1 Press Release dated March 31, 2011



### Corcept Therapeutics Announces NDA Submission to Be Completed the Week of April 11, 2011

MENLO PARK, CA--(Marketwire - March 31, 2011) - Corcept Therapeutics Incorporated (NASDAQ: <u>CORT</u>), 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 will submit its New Drug Application (NDA) for the use of CORLUX in Cushing's Syndrome to the FDA the week of April 11, 2011.

"We are in the final stages of preparing our NDA submission and are on track to submit our application to the FDA within the next two weeks," said Joseph Belanoff, M.D., Chief Executive Officer of Corcept. "We look forward to submitting our NDA for CORLUX to the FDA, and, if approved by the FDA, providing an important treatment option to patients suffering from Cushing's Syndrome."

### CORLUX in Cushing's Syndrome Regulatory and Commercialization Update

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 (ENDO), 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.

### **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 NDA submission and 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 estimates regarding our capital requirements, spending plans and needs for additional financing. 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 (<a href="https://www.corcept.com">www.corcept.com</a>) or from the SEC's website (<a href="https://www.sec.gov">www.sec.gov</a>). We disclaim any intention or duty to update any forward-looking statement made in this news release.

CONTACT: Caroline Loewy Chief Financial Officer Corcept Therapeutics 650-688-8783 cloewy@corcept.com www.corcept.com