

CORCEPT THERAPEUTICS INC

Form 8-K

April 18, 2011

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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**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))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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### **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

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### **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*

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