# 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: September 11, 2007** (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 September 11, 2007 Corcept Therapeutics Incorporated issued a press release announcing that it has received notification from the Food and Drug Administration (FDA) that the FDA has opened the Investigational New Drug Application (IND) for CORLUX for the treatment of Cushing's Syndrome.

# 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 September 11, 2007

#### **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: September 12, 2007 CORCEPT THERAPEUTICS INCORPORATED

By: <u>/s/ Anne LeDoux</u> Anne LeDoux

Vice President & Controller

# **Exhibit Index**

Exhibit No.

**Description** 

99.1

Press Release of Corcept Therapeutics Incorporated dated September 11, 2007

## Corcept Therapeutics Receives FDA Notification Opening IND for CORLUX(R) for the Treatment of Cushing's Syndrome

MENLO PARK, CA -- 09/11/2007 -- Corcept Therapeutics Incorporated (NASDAQ: CORT) today announced that it has received notification from the Food and Drug Administration (FDA) that the FDA has opened the Investigational New Drug application (IND) for CORLUX for the treatment of Cushing's Syndrome. CORLUX is a cortisol receptor (GR-II) antagonist.

In July 2007, the Company announced the receipt of Orphan Drug Designation for CORLUX for the treatment of Cushing's Syndrome. Drugs that receive Orphan Drug Designation obtain seven years of marketing exclusivity from the date of drug approval as well as tax credits for clinical trial costs, marketing application filing fee waivers and assistance from the FDA in the drug development process.

In the communication regarding the opening of the IND, the FDA indicated that a single study may provide a reasonable basis for the submission of a New Drug Application (NDA) for Corlux for the treatment of Cushing's Syndrome, which allows us to initiate the 50-patient open label study defined by the protocol submitted with the application for the IND. Corcept has begun qualifying potential sites for this study and expects to open the trial for enrollment late in the fourth quarter of 2007.

Joseph K. Belanoff, M.D., Corcept's Chief Executive Officer, commented, "We are pleased that the FDA has allowed us to open our IND for CORLUX for the treatment of Cushing's Syndrome and to initiate the Phase 3 protocol included in the IND submission. We look forward to advancing a potential treatment for this rare illness."

# About Cushing's Syndrome

Cushing's Syndrome is a disorder caused by prolonged exposure of the body's tissues to high levels of the hormone cortisol. Sometimes called "hypercortisolism," it is relatively rare and most commonly affects adults aged 20 to 50. An estimated 10 to 15 of every one million people are affected each year. Symptoms vary, but most people have high blood sugar, high blood pressure, upper body obesity, rounded face, increased fat around the neck, thinning arms and legs, severe fatigue and weak muscles. Irritability, anxiety and depression are common. Cushing's Syndrome can affect every organ system in the body and be lethal if not treated effectively.

## About Corcept Therapeutics Incorporated

Corcept Therapeutics Incorporated is a pharmaceutical company engaged in the development of drugs for the treatment of severe psychiatric and metabolic diseases. Corcept's lead product, CORLUX, is currently in Phase 3 clinical trials for the treatment of the psychotic features of psychotic depression. The drug is administered orally to psychotic depression patients once per day for seven days. CORLUX, a potent GR-II antagonist, appears to mitigate the effects of the elevated and abnormal release patterns of cortisol seen in psychotic depression. In June 2007, Corcept Therapeutics announced positive results from its proof of concept study evaluating the ability of CORLUX to mitigate weight gain associated with olanzapine, a commonly used antipsychotic medication. The Company is in the process of fully evaluating all of the data from the study and considering its next steps. For additional information about the company, please visit www.corcept.com.

Statements made in this news release, other than statements of historical fact, are forward-looking statements, including, for example, statements relating to the timing and results of the clinical trial for CORLUX for the treatment of Cushing's Syndrome, Corcept's other clinical development programs, and its spending 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 commencement, cost, rate of spending, completion or success of clinical trials; financial projections may not be accurate; there can be no assurances that the investigations for future clinical trials will be completed, or that Corcept will pursue further activities with respect to clinical development of CORLUX.

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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