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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**Form 8-K**

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**Current Report**

**Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): June 4, 2011**

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**Corcept Therapeutics Incorporated**

(Exact name of registrant as specified in its charter)

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**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):

- 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))
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**Item 8.01 Other Events.**

On June 4, 2011, we issued a press release announcing detailed findings from our Phase 3 study of CORLUX for the treatment of Cushing's Syndrome, which show that CORLUX significantly improves clinical and metabolic manifestations of Cushing's Syndrome, and that CORLUX was well tolerated and enabled almost 50% of patients taking anti-diabetic, insulin and hypertensive medications at enrollment to reduce the dosage by study's end. The Phase 3 study data were presented as part of a session titled "*Will Medical Management Replace Surgery for Cushing Syndrome*" on June 4th at the Endocrine Society's 93rd Annual Meeting held June 4 – 7, 2011 in Boston.

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, other than statements of historical fact, are forward-looking statements, including, for example, statements relating to the ability of CORLUX to significantly improve clinical and metabolic manifestations of Cushing's Syndrome in future patients or for an extended period of time and the potential benefit of CORLUX for patients diagnosed with 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 extension study will receive positive results or that CORLUX will be a beneficial treatment for future patients with Cushing's Syndrome, that the FDA's review of our New Drug Application for CORLUX in Cushing's Syndrome 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.

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**Item 9.01 Financial Statements and Exhibits.**

Exhibit 99.1 Press Release dated June 4, 2011

**SIGNATURES**

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.

**CORCEPT THERAPEUTICS INCORPORATED**

Date: June 6, 2011

By: \_\_\_\_\_ /s/ CAROLINE M. LOEWY  
Caroline M. Loewy  
Chief Financial Officer

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## Exhibit Index

Exhibit No.

Description

99.1

Press Release dated June 4, 2011



INVESTOR CONTACT: Caroline Loewy  
 Chief Financial Officer  
 Corcept Therapeutics  
 650-688-8783  
[cloewy@corcept.com](mailto:cloewy@corcept.com)

MEDIA CONTACT: Edie DeVine  
 415-365-8543  
[edie.devine@gcihealth.com](mailto:edie.devine@gcihealth.com)

**CORCEPT THERAPEUTICS ANNOUNCES DETAILED FINDINGS FROM PHASE 3 STUDY WHICH SHOW CORLUX SIGNIFICANTLY IMPROVES CLINICAL AND METABOLIC MANIFESTATIONS OF CUSHING'S SYNDROME**

- *CORLUX was well tolerated and enabled almost 50% of patients taking anti-diabetic, insulin and hypertensive medications at enrollment to reduce the dosage by study's end –*
- *Company to host conference call on Sunday, June 5, 2011 at 8 a.m. Eastern Daylight Time –*

**MENLO PARK, Calif.**, (June 4, 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 detailed data from the Phase 3 SEISMIC study of CORLUX (mifepristone) in Cushing's Syndrome. The data demonstrated that refractory Cushing's Syndrome patients receiving CORLUX experienced significant clinical and metabolic improvements over baseline measurements. CORLUX is a glucocorticoid receptor type II (GR-II) antagonist that has been granted Orphan Drug Designation for the treatment of endogenous Cushing's Syndrome by the U.S. Food and Drug Administration (FDA). The Phase 3 study data were presented as part of a session titled "*Will Medical Management Replace Surgery for Cushing Syndrome?*" today at the Endocrine Society's 93rd Annual Meeting held June 4 – 7, 2011 in Boston.

"In the SEISMIC study, CORLUX was shown to significantly improve blood glucose levels, blood pressure and to decrease body weight and waist circumference – all key manifestations of Cushing's Syndrome," said Maria Fleseriu, M.D., F.A.C.E., Director Northwest Pituitary Center, Oregon Health & Science University, Department of Medicine, Endocrinology & Neurological Surgery. She is a principal investigator in the study and presenter at the Endocrine Society's 93rd Annual Meeting. "Cushing's Syndrome is a severe debilitating disease if not properly treated. A very high percentage of patients receiving CORLUX experienced improvement in their individual clinical manifestations of this rare hormonal disorder, including quality of life. Glucocorticoid receptor antagonism with CORLUX offers a new approach for the treatment of Cushing's syndrome that failed other therapies with a manageable side effect profile in our study."

**Presentation Highlights**

Fifty Cushing's Syndrome patients were enrolled in the study. Forty-three had Cushing's disease (pituitary tumor), of which 42 had prior surgery, four patients had ectopic ACTH-producing tumors and three had adrenal cancer. All patients were included in the analysis for safety. Forty-six of the patients completed at least 30 days of treatment and were included in the modified intent to treat group (mITT) for the efficacy analysis. Thirty-four patients completed the study.

Statistically significant improvement in the primary endpoint was achieved for the glucose intolerant group and the hypertensive group. 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’s (DRB) evaluation of eight clinical areas (glucose, blood pressure, lipids, weight and body composition, appearance, strength, bone, psychiatric and quality of life measures). A statistically significant improvement was achieved in the key secondary endpoint with a response rate of 87% ( $p < 0.000001$ ).

There were 29 patients enrolled in the glucose intolerant group, of which 60% ( $p < 0.0001$ ) were responders, defined as a 25% or greater reduction in blood sugar level on a standard oral glucose tolerance test from baseline to 24 weeks. There was a continued improvement in glucose tolerance measured at each of the evaluations at week 6, 10, and 16, as well as at week 24. Of the 12 patients taking insulin at baseline, seven cut their daily dose by at least 50%. There was also a statistically significant reduction in mean HbA1c over the course of the study, from 7.43% at baseline to 6.29% at study conclusion ( $p < 0.001$ ).

There were 21 patients enrolled in the hypertension group, of which 38% ( $p < 0.05$ ) achieved a 5 millimeter or greater reduction in diastolic blood pressure without increasing the patient’s prescribed hypertensive medication. There were a total of 40 patients in the study with a diagnosis of hypertension (including those in the glucose intolerant group). Among that group, 17 patients (42.5%) had a  $\geq 5$ mm decrease in diastolic blood pressure, and 21 patients (52.5%) had either a  $\geq 5$ mm decrease in diastolic blood pressure or a reduction in medications at week 24.

The study examined patients weight gain/loss during the 24-week study, with over half of study participants experiencing weight loss of at least 5%, compared to baseline ( $p < 0.001$ ). Patients demonstrated a mean reduction in waist circumference compared to baseline; 6.8 cm in females and 8.4 cm for males ( $p < 0.0001$  for both groups).

“We believe these additional analyses further demonstrate the potential benefit of CORLUX for patients diagnosed with Cushing’s Syndrome,” said Joseph Belanoff, M.D., chief executive officer of Corcept. “Our management team and staff are committed to advancing CORLUX as a potential treatment for patients with this serious unmet medical need. In April, we submitted a new drug application for CORLUX in Cushing’s Syndrome and requested Priority Review status from the FDA.”

### **Safety Findings**

CORLUX was well tolerated in the Phase 3 study and consistent with the safety profile of CORLUX’s active ingredient, mifepristone. As expected, both salivary and urinary free cortisol levels were elevated with CORLUX treatment. Fatigue and nausea were the most commonly reported adverse events attributed to CORLUX in the Phase 3 study. Sixteen patients had serious adverse events, of which six were considered to be probably related to CORLUX treatment. Of the 16 patients who withdrew from the study, seven discontinued due to adverse events and seven withdrew consent or discontinued for other reasons, in addition to two who died from underlying metastatic disease. No deaths were attributed to treatment with CORLUX.

## Common Adverse Events Attributed to CORLUX

<u>Adverse Event</u>	<u>% of Patients</u>	<u>Adverse Event</u>	<u>% of Patients</u>
Fatigue	36%	Myalgia	14%
Nausea	30%	Vomiting	12%
Decreased Potassium	30%	Hypertension	10%
Headache	22%	Abnormal Thyroid Function	10%
Endometrial Thickening	20%	Back Pain	8%
Decreased Appetite	18%	Pain	8%
Arthralgia	16%	Dyspnea	4%
Peripheral Edema	14%	Pain in Extremity	4%
Dizziness	14%	Diarrhea	2%
Dry Mouth	14%		

Notable adverse events which were related to treatment included low potassium levels (hypokalemia), adrenal insufficiency, and endometrial thickening, all of which were consistent with earlier published reports and all of which were resolved with clinical management. Incidents of hypokalemia were common, though generally mild to moderate (three severe), and all responded to potassium supplementation or spironolactone. Adrenal insufficiency was uncommon (two patients incurring adverse events) and resolved with brief treatment with dexamethasone or reduction in CORLUX dose allowing the patients to be able to remain in the study. Five additional patients had adverse events potentially consistent with adrenal insufficiency. There was an increase in endometrial thickness in half of the women in the study, with five cases of vaginal bleeding. Three women underwent dilation and curettage (D&C) for unresolved endometrial thickening.

### Study Design

The Phase 3 trial was a 50-patient open-label study in endogenous Cushing's Syndrome patients conducted at 17 clinical sites in the United States. Patients met the trial enrollment criteria if they were not eligible for, had failed or had relapsed after surgery and, in addition, were either glucose intolerant or diagnosed with hypertension at entry. Patients in the Phase 3 study were placed in one of two groups: those with glucose intolerance with or without a diagnosis of hypertension, and those who were diagnosed with hypertension but were not glucose intolerant. In the trial, each patient's CORLUX dose was titrated by their study investigator to the level necessary to achieve clinical benefit. Patients received CORLUX for up to 24 weeks, with dose escalation, from 300 mg a day up to 1200 mg a day, titrated at the investigator's discretion. Patients were evaluated for efficacy and safety at weeks 6, 10, 16 and 24. The 24-week treatment period was followed by a 6-week follow-up period.

### Extension Study

Approximately 90% of the patients who completed the Phase 3 SEISMIC study chose to continue as part of the Company's ongoing extension study. Patients in the extension study are still receiving CORLUX, some for over two years. The study collects supportive efficacy data and long term safety data that is submitted to the FDA. There are no specific endpoints in the study.



## **Corcept Therapeutics Conference Call**

Corcept will hold a conference call tomorrow morning, Sunday, June 5, 2011 at 8:00 a.m. Eastern Daylight Time (5:00 a.m. Pacific Daylight Time) to discuss this announcement. To participate in the live call please dial 1 800-264-7882 from the United States or +1 847-413-3708 internationally. The pass code is 29928210. Please dial in approximately 10 minutes prior to the start of the call.

A replay of the conference call will be available through June 18, 2011 at 1-888-843-7419 from the United States and +1-630-652-3042 internationally. The pass code is 29928210.

## **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 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 ([www.corcept.com](http://www.corcept.com)) or from the SEC's website ([www.sec.gov](http://www.sec.gov)). We disclaim any intention or duty to update any forward-looking statement made in this news release.

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