

**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: December 22, 2010
(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))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01. Regulation FD Disclosure

On December 22, 2010 we issued a press release announcing positive top-line results from our Phase 3 study of CORLUX for the treatment of Cushing's Syndrome. The study evaluated the response of two patient groups to CORLUX treatment: one included patients who were glucose intolerant and one included patients who were hypertensive. Statistically significant improvement in the primary endpoint was achieved for both groups: with 60% responding in the glucose intolerant group and 43% in the hypertensive group. An initial review of safety data indicates that CORLUX was well tolerated by Cushing's Syndrome patients in this Phase 3 study.

The information in this Item 7.01 and the press release furnished as Exhibit 99.1 to this Current Report on Form 8-K are being "furnished" pursuant to Item 7.01 and shall not be deemed "filed" for any purpose, including for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that Section, or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information in this Item 7.01 and the press release furnished as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act made by us, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01. Other Events

On December 22, 2010 we issued a press release announcing positive top-line results from our Phase 3 study of CORLUX for the treatment of Cushing's Syndrome. The study evaluated the response of two patient groups to CORLUX treatment: one included patients who were glucose intolerant and one included patients who were hypertensive. Statistically significant improvement in the primary endpoint was achieved for both groups: with 60% responding in the glucose intolerant group and 43% in the hypertensive

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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 December 22, 2010](#)

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: December 27, 2010

CORCEPT THERAPEUTICS INCORPORATED

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

Exhibit Index

Exhibit No.

99.1

Description

Press Release of Corcept Therapeutics Incorporated dated
December 22, 2010

Corcept Therapeutics Announces Positive Phase 3 Study Results for CORLUX for the Treatment of Cushing's Syndrome

Treatment With CORLUX Resulted in a Statistically Significant Improvement in Glucose Tolerance and Hypertension -- Conference Call Scheduled for 8:30 a.m. Eastern Time Today

MENLO PARK, CA -- (Marketwire - December 22, 2010) - Corcept Therapeutics Incorporated (NASDAQ: CORT) today announced positive top-line results from its Phase 3 study of CORLUX for the treatment of Cushing's Syndrome. The study evaluated the response of two patient groups to CORLUX treatment: one included patients who were glucose intolerant and one included patients who were hypertensive. Statistically significant improvement in the primary endpoint was achieved for both groups: with 60% responding in the glucose intolerant group and 43% in the hypertensive group. An initial review of safety data indicates that CORLUX was well tolerated by Cushing's Syndrome patients in this Phase 3 study. "The results of the study demonstrate that CORLUX has the potential to become an important treatment option for patients suffering from Cushing's Syndrome," said Joseph Belanoff, M.D., Chief Executive Officer of Corcept. "We remain on track to submit a New Drug Application (NDA) to the FDA for CORLUX in Cushing's Syndrome by the end of the first quarter of 2011 and continue to work toward our goal of making CORLUX available to patients with this severe disease."

Primary Endpoints Met in Both Patient Groups

Each group in the study had its own primary endpoint. The primary analysis is a responder analysis. In the "glucose intolerant group" (patients with diabetes or carbohydrate intolerance) a responder was defined as a patient who achieved a 25% or greater improvement in glucose tolerance as measured by a standard 2-hour glucose tolerance test at 24 weeks (or at the early termination visit) compared to baseline. In the "hypertension group" (patients with a diagnosis of hypertension) a responder was defined as a patient who achieved a 5 millimeter or greater improvement in diastolic blood pressure at 24 weeks (or at the early termination visit) compared to baseline.

The protocol for the trial dictates that if a sufficient number of patients in either the glucose intolerant group or the hypertension group are responders, such that the lower limit of the exact one-sided 95% binomial confidence interval (CI) for the responder rate is greater than 20%, then the trial will have demonstrated efficacy for the treatment of Cushing's Syndrome. The calculation, which was predetermined in the study design, is based on analyzing the response rates in a modified intention to treat group (mITT) defined as those patients treated for at least 30 days (the mITT group).

- 15 of 25, or 60%, of patients in the glucose intolerant group responded to treatment with CORLUX, significantly higher than the 20% hurdle rate (lower bound of the 95% CI = 41.7 which equates to $p < 0.0001$).
- 9 of 21, or 43%, of patients in hypertension group responded to treatment with CORLUX, significantly higher than the 20% hurdle rate (lower bound of the 95% CI = 24.5 which equates to $p < 0.01$).

CORLUX Was Well Tolerated In The Trial

CORLUX was well tolerated in the trial population. Although the detailed analysis of the safety data from the study has not yet been completed, the tolerability of CORLUX in the treatment of Cushing's Syndrome in the Phase 3 study met our expectations. Adverse events related to treatment included symptoms of adrenal insufficiency, endometrial thickening, and hypokalemia, all of which were consistent with earlier published reports. The majority of the serious adverse events (SAEs) reported in the study were not related to CORLUX treatment, as determined by the clinical investigators. Of those that were related to treatment, all resolved with clinical management. We plan to present detailed safety data at scientific conferences during 2011.

Ninety percent of the patients who completed the Phase 3 study opted to enter the long-term extension study.

About the Phase 3 Trial 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 either not eligible for, had failed or had relapsed from surgery and were glucose intolerant or were diagnosed with hypertension at entry. Patients in the Phase 3 study were placed in one of two groups: those with glucose intolerance 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. The FDA indicated that this trial may provide a reasonable basis for the submission of an NDA for the treatment of endogenous Cushing's Syndrome.

In addition to the primary endpoints described above, the key secondary endpoint in the trial was global clinical improvement, designed to capture the broader clinical benefit CORLUX may confer in this patient population. This endpoint is based on the evaluation of broader clinical outcomes by a Data Review Board, an independent three-member panel of academic physicians with expertise in Cushing's Syndrome. Data on this key secondary endpoint is expected to be available in the first quarter of 2011.

Additional secondary measures of efficacy include changes from baseline to the end of the study in fasting plasma glucose, hemoglobin A1c (HgbA1c), change in glucose lowering medications, systolic blood pressure, change in antihypertensive medications, body composition, weight, bone turnover and bone density, cognitive/psychiatric assessments, metabolic functions, Quality of Life (SF-36 questionnaire), muscle strength and physical function. Detailed data, including data on these secondary endpoints is expected to be announced at scientific conferences during 2011.

CORLUX Regulatory Status Update

Corcept is planning to submit an NDA to the FDA late in the first quarter of 2011 based on the positive results of this Phase 3 study. The final Phase 3 trial design and our statistical analysis plan reflect the feedback Corcept received in discussions with the FDA.

CORLUX was granted Orphan Drug Designation by the FDA for the treatment of endogenous Cushing's Syndrome in 2007. 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.

Corcept Therapeutics Conference Call

Corcept will hold a conference call this morning, Wednesday, December 22, 2010 at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time) to discuss this announcement. To participate in the live call please dial 1 (866) 712-7678 from the United States or +1 (847) 413-2425 internationally. The pass code is 6158584. Please dial in approximately 10 minutes prior to the start of the call.

A replay of the conference call will be available for 7 days following the call at (877) 213-9653 from the United States and +1 (630) 652-3041 internationally. The pass code is 6158584.

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 and development of drugs for the treatment of severe metabolic and psychiatric disorders. The company has two Phase 3 programs: CORLUX for the treatment of Cushing's Syndrome, and CORLUX for the treatment of the psychotic features of psychotic depression. Corcept also has a Phase 1 program for CORT 108297 and an IND-enabling program for CORT 113083. 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) 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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