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): August 30, 2004

Corcept Therapeutics Incorporated
(Exact name of registrant as specified in its charter)

000-50679		
(Commission File Number)		
Delaware		**77-0487658**
(State or other jurisdiction of incorporation)		**(I.R.S. Employer Identification No.)**

275 Middlefield Road, Suite A
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))

Item 8.01 Other Events

On August 30, 2004, Corcept Therapeutics Incorporated ("Corcept") issued a press release announcing that it had reached a Special Protocol Assessment ("SPA") agreement with the U.S. Food and Drug Administration for the design of two pivotal Phase III clinical trials evaluating CORLUX™ (mifepristone) for the treatment of the psychotic features of psychotic major depression.

A copy of the Corcept's press release dated August 30, 2004 relating to the SPA is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits. The following material is filed as an exhibit to this Current Report on Form 8-K:

Exhibit Number	
99.1	Press Release issued August 30, 2004

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: **August 30, 2004**

By: /s/ Fred Kurland

Fred Kurland
Chief Financial Officer

Exhibit 99.1

CONTACT:
Fred Kurland
Chief Financial Officer
Corcept Therapeutics
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CORCEPT THERAPEUTICS RECEIVES SPECIAL PROTOCOL ASSESSMENT FROM FDA FOR TWO PIVOTAL PHASE III TRIALS OF CORLUX™

MENLO PARK, Calif. (Aug. 30, 2004) — Corcept Therapeutics Incorporated (NASDAQ: CORT) today announced that it has reached a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) for the design of two pivotal Phase III clinical trials evaluating CORLUX™ (mifepristone) for the treatment of the psychotic features of psychotic major depression (PMD). The Company plans on initiating the first of these trials immediately and expects the second to commence in the fourth quarter of 2004. Corcept anticipates having initial results from these studies available in the first half of 2006. CORLUX has been granted Fast Track designation for this indication.

“We are pleased to have reached agreement with the FDA on the design of these two pivotal trials and are excited to begin,” said Dr. Joseph K. Belanoff, Corcept’s chief executive officer. “PMD is a disorder that affects approximately three million people in the United States each year and for which there are no FDA-approved treatments. We look forward to determining the efficacy and safety of CORLUX. Through these studies, we will investigate whether CORLUX will provide rapid and sustained relief from the psychotic symptoms of this crippling illness.”

Clinical Trial Design

The primary endpoint for the two randomized, double-blind, placebo-controlled Phase III clinical trials of CORLUX is the proportion of patients with at least a 50% improvement in the Brief Psychiatric Rating Scale Positive Symptom Subscale (BPRS PSS) at both Day 7 and Day 56, otherwise known as a categorical improvement. The BPRS is an 18-item rating instrument used to assess psychopathology and the PSS includes the four

items in the BPRS that specifically measure psychosis. Patients must have at least mild psychotic symptoms (BPRS PSS ^{3} 12) to enter the studies and will be hospitalized if clinically necessary. BPRS PSS assessments will also be made at Days 14, 28 and 42.

“In our interactions with the FDA, we have discussed various potential primary endpoints to demonstrate that CORLUX provides a rapid and sustained response. In our previously completed Corcept 03 trial, we measured responses at Day 7 sustained to Day 28 and continued to measure symptom scores for about one-third of the patients through Day 56. There was a statistically significant difference between the CORLUX and placebo groups on the BPRS PSS at Day 56. Therefore, we reached agreement with the FDA to have the primary endpoint for these pivotal trials be a substantial reduction in psychotic symptoms at both Day 7 and Day 56, which will demonstrate rapid and sustained relief,” commented Dr. Belanoff.

The first of these trials, Corcept 07, which will begin immediately, is similar in design to the Corcept 03 trial, and will enroll up to 280 patients at approximately 20 sites in the U.S. with a randomized one-to-one distribution into either a treatment or a placebo arm. Patients in the treatment arm will receive 600 mg of CORLUX once daily for a period of seven days. All patients are to be off any antidepressant and antipsychotic medication for at least one week before beginning the seven day treatment period. After the seven days of CORLUX treatment, all patients will receive antidepressant therapy through Day 56. Treatment with antipsychotic medications or electroconvulsive therapy will not be allowed at any time during the study.

The second clinical trial, Corcept 06, will enroll approximately 440 patients at about 30 sites in the U.S. These patients will be evenly distributed among three active dose groups (300 mg, 600 mg and 1200 mg) or a placebo group with patients receiving once daily dosing for a period of seven days. The three dosing levels fulfill the FDA’s request to supplement data on a range of potential doses beyond that provided by our 33 patient dose ranging study completed in 2001. All patients in the study must be off any antidepressant and antipsychotic medication for at least one week before the seven day treatment period and will receive antidepressant therapy starting on Day 1 through Day 56. As with Corcept 07, treatment with antipsychotic medications or electroconvulsive therapy will not be allowed at any time during this study.

Previously Completed Trials

The Company has completed four studies of CORLUX for the treatment of psychotic features of PMD. In January 2001, a dose finding clinical trial evaluating the efficacy, tolerability and dose response of CORLUX showed that after one week of treatment, approximately two-thirds of the patients in the two higher dosage groups (600 mg and 1200 mg) experienced clinically meaningful reductions in psychosis, as measured by the BPRS. Based on these encouraging results, the Company conducted two clinical trials, the 02 study and 03 study, which were double-blind, placebo-controlled safety and efficacy studies in which a total of 429 patients were enrolled.

The 02 study showed that CORLUX was well tolerated and that there were no discernible problems with drug interactions between CORLUX and commonly prescribed antipsychotic and antidepressant medications. The 03 study demonstrated with statistical significance that patients in the CORLUX group were more likely than patients in the placebo group to achieve a 50% reduction in the BPRS PSS at Day 7 sustained to Day 28. In a fourth trial, an open label study of the safety of retreatment in patients with a favorable response to treatment in the 02 and 03 studies, it was indicated that patients tolerated their retreatment well. Twenty-eight patients participated in this study.

About Psychotic Major Depression

PMD is a serious psychiatric disorder that affects approximately three million people annually in the United States. It is more prevalent than either schizophrenia or manic depressive illness. The disorder is characterized by severe depression accompanied by delusions, hallucinations or both. People with PMD are approximately 70 times more likely to commit suicide than the general population and often require lengthy and expensive hospital stays. There is no FDA-approved treatment for PMD.

Special Protocol Assessments (SPA)

The SPA is a process that provides for an official FDA evaluation of Phase III clinical study protocols. The SPA provides trial sponsors with binding written agreement that the design and analysis of the studies are adequate to support a license application submission if the study is performed according to the SPA and the results are

successful. The SPA agreement may only be changed by the sponsor company or the FDA by a written agreement, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety. There can be no assurance that the Company's efforts to obtain marketing approval for CORLUX will be successful.

About Corcept Therapeutics Incorporated

Corcept Therapeutics Incorporated is a pharmaceutical company engaged in the development of drugs for the treatment of severe psychiatric and neurological diseases. Corcept's lead product, CORLUX™, is currently in Phase III clinical trials for the treatment of the psychotic features of psychotic major depression. The drug is administered orally to PMD 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 PMD. Corcept is also conducting a clinical trial to evaluate the safety and efficacy of our product in improving cognition in patients with mild to moderate Alzheimer's disease. For additional information about the company, please visit www.corcept.com.

Forward Looking Statements

Statements made in this news release, other than statements of historical fact, are forward-looking statements, including, for example, statements relating to our PMD clinical development program, FDA agreements and the timing of the start and completion of pivotal Phase III trials. Forward-looking statements are subject to a number of known and unknown risks and uncertainties which 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, efficacy, safety, completion or success of clinical trials, there can be no assurances with respect to the regulatory process or regulatory approvals, there can be no assurances with respect to commercial success, and financial projections and trial timetables may not be accurate. 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.