# 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: February 02, 2009** (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 7.01. Regulation FD Disclosure

On February 2, 2009, Corcept Therapeutic Incorporated (the "Company") issued a press release announcing positive results from a clinical study that tested whether CORLUX mitigates the weight gain associated with Risperdal, which is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including the exhibits attached hereto, is 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 (the "Exchange Act"), or otherwise subject to the liabilities of that Section. The information in this Item 7.01 of this Current Report on Form 8-K, including the exhibits attached hereto, shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended or the Exchange Act regardless of any general incorporation language in such filing.

### **Item 8.01. Other Events**

On February 2, 2009, the Company announced positive results from a clinical study that tested whether CORLUX mitigates the weight gain associated with Risperdal. The data demonstrated that adding CORLUX to Risperdal treatment in healthy subjects resulted in a statistically significant reduction in weight gain compared to that seen in subjects receiving Risperdal alone. Risperdal, a leading antipsychotic for the treatment of schizophrenia and bipolar disorder, is marketed by Johnson & Johnson. CORLUX is Corcept's late-stage GRII receptor antagonist, which the company is also evaluating in ongoing Phase 3 trials for psychotic depression and Cushing's Syndrome.

The data announced on February 2, 2009 confirmed results previously reported from similar clinical studies of CORLUX which demonstrated statistically significant mitigation of Zyprexa associated weight gain.

- -- Study Design: The study was a four-week randomized double-blind controlled study in 75 lean, healthy men (body mass index of 23 or less). Subjects were randomized to receive either Risperdal plus placebo (n=30), Risperdal plus CORLUX (n=30) or CORLUX plus placebo (n=15). Daily weights were recorded and a range of metabolic parameters were measured.
- -- Results: Subjects in the Risperdal alone group gained an average of 9.2 pounds, compared to a gain of 5.1 pounds in the Risperdal plus CORLUX group. This difference was highly statistically significant (p < 0.0001). Additional metabolic parameters, including fasting insulin, triglycerides and abdominal fat, are being analyzed. Consistent with prior studies, CORLUX appeared to be well tolerated.

#### Item 9.01. Financial Statements and Exhibits

(a) Financial statements:

None

(b) Pro forma financial information:

None

(c) Shell company transactions:

None

- (d) Exhibits. The following material is furnished as an exhibit to this Current Report on Form 8-K:
  - 99.1 Press Release of Corcept Therapeutics Incorporated dated February 2, 2009

#### **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: February 02, 2009 CORCEPT THERAPEUTICS INCORPORATED

By: <u>/s/ Caroline M. Loewy</u>
Caroline M. Loewy
Chief Financial Officer

## **Exhibit Index**

Exhibit No.

**Description** 

99.1

Press Release of Corcept Therapeutics Incorporated dated February 02, 2009

## CORLUX(R) Mitigates Weight Gain Associated With Risperdal(R), Expands on Proof of Concept Established in Earlier Trials

MENLO PARK, CA -- (Marketwire - February 02, 2009) - Corcept Therapeutics (NASDAQ: CORT) today announced positive results from a clinical study that tested whether CORLUX mitigates the weight gain associated with Risperdal. The data demonstrated that adding CORLUX to Risperdal treatment in healthy subjects resulted in a statistically significant reduction in weight gain compared to that seen in subjects receiving Risperdal alone. Risperdal, a leading antipsychotic for the treatment of schizophrenia and bipolar disorder, is marketed by Johnson & Johnson. CORLUX is Corcept's late-stage GRII receptor antagonist, which the company is also evaluating in ongoing Phase 3 trials for psychotic depression and Cushing's Syndrome.

The data announced today confirmed results previously reported from similar clinical studies of CORLUX which demonstrated statistically significant mitigation of Zyprexa associated weight gain.

"We are pleased to have demonstrated that CORLUX appears to mitigate the weight gain associated with Risperdal as it mitigated the weight gain associated with Zyprexa. This study provides evidence that the benefits of GRII antagonism are not limited to concurrent use with Zyprexa and may, in fact, be applicable to the broad class of antipsychotics," said Dr. Robert L. Roe, M.D., President of Corcept. "The use of GRII antagonists to prevent weight gain commonly associated with the use of many antipsychotic drugs could provide a significant health and quality of life benefit to the millions of people currently taking these medications."

Study Design: The study was a four-week randomized double-blind controlled study in 75 lean, healthy men (body mass index of 23 or less). Subjects were randomized to receive either Risperdal plus placebo (n=30), Risperdal plus CORLUX (n=30) or CORLUX plus placebo (n=15). Daily weights were recorded and a range of metabolic parameters were measured.

Results: Subjects in the Risperdal alone group gained an average of 9.2 pounds, compared to a gain of 5.1 pounds in the Risperdal plus CORLUX group. This difference was highly statistically significant (p < 0.0001). Additional metabolic parameters, including fasting insulin, triglycerides and abdominal fat, are being analyzed. Consistent with prior studies, CORLUX appeared to be well tolerated.

Atypical Antipsychotics Are All Known to Cause Weight Gain

The labels of the class of medications known as atypical antipsychotics contain a warning for hyperglycemia and diabetes mellitus, both associated with the weight gain seen in many patients. These medications are:

Abilify® (aripiprazole, Bristol Myers Squibb and Otsuka American Pharmaceutical)

Clozaril® (clozapine, Novartis)

Geodon® (ziprasidone, Pfizer)

Risperdal® (risperidone, Janssen, a unit of Johnson & Johnson)

Seroquel® (quetiapine, AstraZeneca)

Zyprexa® (olanzapine, Eli Lilly).

Despite their side effect profile, atypical antipsychotic medications are widely prescribed throughout the world because of their efficacy.

Next-Generation GRII Antagonists Demonstrated Weight Gain Mitigation in Preclinical Studies

Corcept has also discovered and filed patents for three additional series of compounds which, similar to CORLUX, block cortisol's activity at the GRII receptor, but unlike CORLUX, do not block the progesterone receptor. The company recently announced that CORT 108297, a potential lead compound from these series, demonstrated prevention and reversal of Zyprexa® (olanzapine) associated weight gain in two preclinical studies. In a human microdosing study the compound was extremely well absorbed, demonstrated good bioavailability and had a half-life that appears compatible with once-a-day oral dosing. Corcept retains worldwide commercial rights to CORT 108297 as well as all additional compounds within the three series.

About Corcept Therapeutics Incorporated

Corcept is a pharmaceutical company engaged in the development of drugs for the treatment of severe psychiatric and metabolic disorders. The company has two Phase 3 programs ongoing; CORLUX for the treatment of the psychotic depression and for Cushing's Syndrome.

Corcept has also developed an extensive intellectual property portfolio that covers the use of GRII 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.

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. 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, 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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