

CORCEPT THERAPEUTICS INC

Form 8-K

February 27, 2009

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 23, 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:

- ☐ 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))

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 23, 2009, Corcept Therapeutics Incorporated (the "Company") issued a press release announcing additional positive results from a clinical study that tested whether CORLUX mitigates the weight gain and other metabolic effects 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 exhibit 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 exhibit 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 23, 2009, the Company announced additional positive results from a clinical study that tested whether CORLUX mitigates the weight gain and other metabolic effects associated with Risperdal. The Company previously announced top-line data demonstrating 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. Analysis of key secondary endpoints demonstrates that the addition of CORLUX to Risperdal also results in less abdominal fat, lower fasting insulin levels and lower triglyceride levels - all of which were statistically significant compared to treatment with Risperdal alone.

The data announced on February 23, 2009, demonstrated benefits of adding CORLUX to treatment with Risperdal, beyond the mitigation of weight gain. The results from this study confirmed results previously reported from a similar clinical study of CORLUX when added to treatment with Zyprexa, which demonstrated statistically significant mitigation of Zyprexa-associated weight gain, as well as a favorable impact on metabolic markers

-- 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, as well as abdominal fat (as measured by waist circumference), fasting insulin, and triglycerides.

-- Results: As previously reported, 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 ($p < 0.0001$). In the press release on February 23, 2009, we announced that the increase in abdominal fat (as measured by waist circumference) was 3.57 cm in the Risperdal alone group, compared to 2.03 cm in the Risperdal plus CORLUX group ($p < 0.05$). Fasting insulin increased by 10.97 mU/L in the Risperdal alone group, compared to 1.80 mU/L in the Risperdal plus CORLUX group ($p < 0.05$). In addition, triglycerides increased by 30.57 mg/dL in the Risperdal alone group, compared to an increase of only 3.13 mg/dL in the Risperdal plus CORLUX group ($p < 0.01$)

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 February 23, 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 27, 2009

CORCEPT THERAPEUTICS INCORPORATED

By: /s/ Caroline M. Loewy

Caroline M. Loewy

Chief Financial Officer

Exhibit Index **Exhibit No.** **Description** 99.1 Press Release of Corcept Therapeutics Incorporated dated February 23, 2009