# 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: March 25, 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:

- 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 2.02. Results of Operations and Financial Condition

On March 25, 2010, Corcept Therapeutics Incorporated (the "Company"), issued a press release announcing its financial results for the quarter and year ended December 31, 2009. The press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

The information in this Item 2.02 and the information contained in the press release attached as Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act of 1934, as amended, 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 2.02 and the information contained in the press release attached as Exhibit 99.1 shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in the filing unless specifically stated so therein.

#### Item 7.01. Regulation FD Disclosure

On March 25, 2010, the Company issued a press release announcing its financial results for the quarter and year ended December 31, 2009. The press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

The information in this Item 7.01 and the information contained in the press release attached as Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act of 1934, as amended, 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 information contained in the press release attached as Exhibit 99.1 is not incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in the filing unless specifically stated so therein.

# Item 9.01. Financial Statements and Exhibits

# (d) Exhibits

The following exhibit is furnished with this Current Report on Form 8-K:

99.1 Press Release of Corcept Therapeutics Incorporated dated March 25, 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: March 25, 2010

# 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 March 25, 2010

# Corcept Therapeutics Announces Fourth Quarter and Full Year 2009 Results and Update on Development Programs

MENLO PARK, CA -- (Marketwire - March 25, 2010) - Corcept Therapeutics Incorporated (NASDAQ: CORT), a pharmaceutical company engaged in the discovery and development of drugs for the treatment of severe metabolic and psychiatric disorders, today reported financial results for the fourth quarter and the full year ended December 31, 2009, and updated its corporate progress and anticipated milestones for 2010.

"The past year was one of significant progress and set the stage for the achievement of four important milestones in 2010. We are pleased to have already achieved the first of these last month with the initiation of the initial Phase 1 study of our lead selective cortisol receptor (GR-II) antagonist, CORT 108297," said Joseph Belanoff, M.D., Chief Executive Officer of Corcept. "We are continuing to make progress toward our other three goals, all of which relate to developing CORLUX for the treatment of Cushing's Syndrome, a disease with a significant unmet medical need. We now expect to complete enrollment in the Phase 3 study in April, as the requisite 50 patients have now been dosed or identified. We expect to announce results of this study in the fourth quarter of this year and we remain on track to submit our New Drug Application (NDA) for the use of CORLUX in Cushing's Syndrome by year end."

#### Fourth Quarter and Recent Development Highlights

- -- Raised gross proceeds of \$18 million in a private placement of our stock and warrants, sufficient capital to support our operations through early 2011. Participants in this financing included existing investors Longitude Capital, Sutter Hill Ventures, Alta Partners, and members of our Board of Directors, as well as new investors including Federated Kauffman Funds.
- -- Submitted our Investigational New Drug application to the FDA for our lead selective cortisol receptor (GR-II) antagonist, CORT 108297, in December 2009 and began a Phase 1 trial of the compound in February 2010.
- -- Identified and began testing two additional cortisol receptor (GR-II) antagonists. Initial preclinical studies of CORT 112716 and CORT 113083 generated positive results in animal models of olanzapine induced weight gain and modulation of insulin sensitivity. These compounds are from one of the three separately patented series of selective GR-II antagonists that we have discovered.

#### In addition, we continued to make progress on:

- -- Enrolling patients in our 50-patient open-label Phase 3 trial of CORLUX in patients with Cushing's Syndrome, which is being conducted at 20 leading institutions throughout the United States.
- --- Preparing for the submission of our NDA for CORLUX in Cushing's Syndrome, including the design of a Risk Evaluation and Mitigation Strategy (REMS), to enable submission by the end of 2010.
- -- Developing detailed plans for the commercialization of CORLUX in the United States.
- -- Enrolling patients in our double-blind placebo controlled Phase 3 trial of CORLUX in patients with psychotic depression at eight clinical

#### Fourth Quarter and 2009 Financial Results

For the fourth quarter of 2009, Corcept reported a net loss of \$5.2 million, or \$0.09 per share, compared to a net loss of \$6.2 million, or \$0.13 per share, for the fourth quarter of 2008. For the full year 2009, the company reported a net loss of \$20.2 million, or \$0.38 per share. Corcept reported a net loss of \$20.1 million, or \$0.43 per share, for the full year 2008.

As of December 31, 2009, Corcept had cash and cash equivalents of \$23.9 million. We used \$18 million of cash to fund the company's operating activities for the full year 2009.

Total operating expenses decreased to \$5.2 million for the fourth quarter of 2009, from \$6.2 million for the same period in 2008. In the fourth quarter of 2009, research and development expenses decreased to \$3.8 million from \$4.7 million in the fourth quarter of 2008. This decrease in research and development expenses was due primarily to scaling back the number of sites in the Phase 3 study of CORLUX for the treatment of psychotic depression, which was announced in March 2009. The decreased costs for this study were partially offset by increased costs associated with clinical trials for CORLUX for the treatment of Cushing's Syndrome, the conduct of drug-drug interaction studies for CORLUX, and our selective GR-II antagonist program, including work necessary to enable the filing of the IND for CORT 108297 with the FDA in December 2009. General and administrative expenses were \$1.4 million for the fourth quarter of 2009 and for the same period in 2008.

For the full year 2009, total operating expenses increased to \$20.3 million from \$19.9 million for 2008. Research and development expenses for the full year 2009 increased to \$14.4 million from \$14.2 million in 2008. This increase was primarily due to activities

related to the IND for CORT 108297 and the continuation of the Phase 3 trial and long-term extension study for CORLUX for the treatment of Cushing's Syndrome that were only partially offset by cost reductions from scaling back the Phase 3 study of CORLUX for psychotic depression. General and administrative expenses increased to \$5.9 million for the full year 2009 from \$5.7 million in 2008 due primarily to increases in non-cash stock-based compensation.

## Four Key Anticipated Milestones for 2010

In January 2010, we announced four key anticipated milestones for 2010. We have initiated the Phase 1 study of CORT 108297 as planned and expect continued progress in achieving our three remaining milestones this year.

- --- We are continuing to aggressively pursue completion of enrollment in our Phase 3 pivotal trial of CORLUX in Cushing's Syndrome. While the timing of enrollment of patients with this orphan disease has been difficult to forecast, we expect the final patients to be enrolled in April.
- -- Based on the anticipated completion of enrollment into the Phase 3 study and the 6-month duration of treatment to address the endpoints agreed to with the FDA, we expect to complete the trial of CORLUX for Cushing's Syndrome and announce efficacy results in 4Q 2010.
- -- We continue to expect to submit our NDA to the FDA in the fourth quarter of 2010. Additional studies and preparation of documentation in support of our NDA submission are ongoing, which should enable our submission soon after the Phase 3 efficacy results are available.

"We believe that the Cushing's Syndrome program provides near-term value creation for our shareholders. The FDA granted us Orphan Drug Designation for CORLUX for the treatment of endogenous Cushing's Syndrome, which provides seven years of marketing exclusivity from the date of approval, which could be as early as 2011. Orphan Drug Designation also provides tax credits for clinical trial costs, marketing application filing fee waivers and assistance from the FDA in the drug development process," added Dr. Belanoff.

"We anticipate that our current cash balance is sufficient to fund the company into early 2011," said Caroline Loewy, Chief Financial Officer of Corcept.

# 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 due to a variety of pathologic conditions. 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 Psychotic Depression**

Psychotic depression is a serious psychiatric disorder that affects approximately three million people annually in the United States. It is more prevalent than either schizophrenia or bipolar I disorder. The disorder is characterized by severe depression accompanied by delusions, hallucinations or both. People with psychotic depression 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 psychotic depression.

# About Weight Gain Caused by Antipsychotic Medications

The group of medications known as second-generation antipsychotics, including olanzapine (Zyprexa), risperidone (Risperdal), quetiapine (Seroquel) and clozapine (Clozaril), are widely used to treat schizophrenia and bipolar disorder. All medications in this group are associated with treatment emergent weight gain of varying degrees and also carry warning labels relating to treatment emergent hyperglycemia and diabetes mellitus. Weight gain and alterations in metabolic efficiency have been observed for many years in patients with abnormally high circulating cortisol. There is no FDA-approved treatment for the weight gain associated with the use of antipsychotic medications.

#### 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 CORT 108297

CORT 108297 is one of several potent, selective antagonists of the cortisol (GR-II) receptor that we have discovered and for which Corcept owns worldwide intellectual property rights. In in vitro binding affinity and functional assays it does not have affinity for the progesterone (PR), estrogen (ER), androgen (AR) or mineralocorticoid (GR-I) receptors.

# 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 ongoing 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. 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 introduction of CORLUX and future product candidates, including CORT 108297, 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, 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.

# CORCEPT THERAPEUTICS INCORPORATED CONDENSED BALANCE SHEETS (in thousands)

			December 31, 2008		
ASSETS: Current assets:		(Unaudited)		(Note)	
Cash, cash equivalents and short-term investments Other current assets		23,867 553			
Total current assets		24,420		19,579	
Other assets		91		196	
Total assets		24,511			
LIABILITIES AND STOCKHOLDERS' EQUITY: Current liabilities: Accounts payable Other current liabilities	\$	1,270 1,149	\$	1,304 1,558	
Total current liabilities					
Capital lease obligation, long-term portion				6	
Total stockholders' equity		22,092		16,907	
Total liabilities and stockholders' equity	\$ =====	24,511	\$	19,775	

Note: Derived from audited financial statements at that date.

CORCEPT THERAPEUTICS INCORPORATED
STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

(Unaudited)

For the Three Months Ended December 31,

Year Ended December 31,

	2009	2008	2009	2008	
Collaboration revenue	\$	\$ 143 	\$ 29	\$ 209	
Operating expenses: Research and development* General and administrative*		4,726 1,434		5,746	
Total operating expenses		6,160	20,279	19,898	
Loss from operations	(5,164)	(6,017)	(20,250)		
Interest and other income, net Other expense		197 (351)		(1,316)	
Net loss	\$ (5,170)	\$ (6,171) =======	\$ (20,166)	\$ (20,061)	
Basic and diluted net loss per share		\$ (0.13) ======			
Shares used in computing basic and diluted net loss per share	60,390		52,443	46,721	
*Includes non-cash stock-based compensation of the following: Research and development General and administrative	\$ 65 394	337	1,552	1,360	
Total non-cash stock-based compensation		\$ 404	\$ 1,815	•	

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