# 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 09, 2011** (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 9, 2011, Corcept Therapeutics Incorporated (the "Company"), issued a press release announcing its financial results for the quarter ended December 31, 2010. 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 9, 2011, the Company issued a press release announcing its financial results for the quarter ended December 31, 2010. 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

(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 March 09, 2011

#### **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 09, 2011

#### 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 09, 2011

#### Corcept Therapeutics Announces Fourth Quarter Results and Corporate and Development Update

MENLO PARK, CA -- (Marketwire - March 09, 2011) - Corcept Therapeutics Incorporated (NASDAQ: CORT), a pharmaceutical company engaged in the discovery, development and commercialization of drugs for the treatment of severe metabolic and psychiatric disorders, today reported financial results for the fourth quarter ended December 31, 2010, and updated its corporate progress.

"We are very proud of our accomplishments during the fourth quarter and throughout 2010, most significantly the completion of our Phase 3 study of CORLUX for the treatment of patients with Cushing's Syndrome and the positive results from that study," said Joseph Belanoff, M.D., Chief Executive Officer of Corcept. "With the Phase 3 study complete, we look forward to submitting our NDA for CORLUX to the FDA by the end of March 2011, and, if approved by the FDA, providing an important treatment option to patients suffering from Cushing's Syndrome."

#### **Corporate and Development Highlights**

- Announced positive top-line results from the primary endpoints in our Phase 3 study of CORLUX for the treatment of Cushing's Syndrome in December 2010. In the trial, 60% of the patients with glucose intolerance and 38% of the patients with hypertension met the categorical response hurdle. Although only one endpoint needed to be positive for the study to be deemed positive, both of the endpoints were met with statistical significance.
- Announced positive top-line results from the key secondary endpoint in our Phase 3 study of CORLUX for the treatment of Cushing's Syndrome in January 2011. In the trial, 87% of the patients had a clinically significant improvement in the signs and symptoms of Cushing's Syndrome over the course of the study, as measured by the assessment of a panel of three independent Cushing's Syndrome experts. These results were statistically significant.
- Enrolled 88% of the patients who completed the six-month Phase 3 study of CORLUX for Cushing's Syndrome in the long-term extension study of the treatment. We now have patients treated with CORLUX through our Phase 3 and extension studies for over two years.
- Initiated a Phase 1b/2a multi-dose safety and proof of concept study of CORT 108297 in December 2010. The study is evaluating the compound in models of antipsychotic induced weight gain and changes in biomarkers induced by prednisone, a steroid.
- Raised approximately \$45 million in gross proceeds in an underwritten public offering of common stock in January 2011, which we believe is sufficient to operate the company into the third quarter of 2012.

In addition, we continued to make progress on:

- Preparing for an end of first quarter 2011 submission of our NDA for CORLUX in Cushing's Syndrome.
- Planning 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.
- Advancing our second selective GR-II antagonist, CORT 113083, towards an IND submission in 2011.
- Identifying additional compounds from among our three proprietary series of selective GR-II antagonists to advance toward an IND submission.

# **Fourth Quarter Financial Results**

For the fourth quarter of 2010, Corcept reported a net loss of \$7.1 million, or \$0.10 per share, compared to a net loss of \$5.2 million, or \$0.09 per share, for the fourth quarter of 2009.

Total operating expenses increased to \$7.8 million for the fourth quarter of 2010, from \$5.2 million for the same period in 2009. In the fourth quarter of 2010 research and development expenses increased to \$4.7 million from \$3.8 million in the fourth quarter of 2009. This increase in research and development expenses was due primarily to 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 other NDA supportive activities, and our selective GR-II antagonist program, including a Phase 1 study of CORT 108297 and the initiation of a Phase 1b / 2a study with this compound. General and administrative expenses increased to \$3.2 million for the fourth quarter of 2010 from \$1.4 million for the same period in 2009 due to the payment of cash bonuses in connection with corporate achievements during 2010 and additional resources focused on commercial planning for the potential launch of CORLUX in Cushing's Syndrome.

Our cash balance as of December 31, 2010 was \$24.6 million, up from \$23.9 million at December 31, 2009. "We anticipate that our current cash balance is sufficient to fund the company into the third quarter of 2012," said Caroline Loewy, Chief Financial Officer of Corcept.

#### **Anticipated Milestones for 2011**

We are focusing our efforts on advancing CORLUX toward approval and commercialization for the treatment of Cushing's Syndrome. In that vein, we are working to submit our NDA to the FDA by the end of the first quarter of 2011. We plan to request a priority (six-month) review of our application at that time. Concurrently, we are developing plans and engaging third-party vendors to support a commercial launch of CORLUX in the United States, if approved by the FDA. We also expect to make detailed data from our Phase 3 trial of CORLUX in Cushing's Syndrome available to the endocrinologists who treat the disorder at the Endocrine Society Annual Meeting (ENDO), June 4-7 in Boston.

"The past year has been transformational for Corcept, driven by the achievement of several important milestones, particularly in our Cushing's Syndrome program. We are well underway preparing for our next steps: working toward the NDA submission and potential approval of CORLUX and its commercial launch. The FDA has 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. We look forward to having the chance to help patients with this life-threatening disease," concluded Dr. Belanoff.

#### **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 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. 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 and CORT 113083**

CORT 108297 and CORT 113083 are two of the 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 neither of these compounds 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, development and commercialization of drugs for the treatment of severe metabolic and psychiatric disorders. The company has completed its Phase 3 study of CORLUX for the treatment of Cushing's Syndrome, and has an ongoing Phase 3 study of CORLUX for the treatment of the psychotic features of psychotic depression. Corcept also has a Phase 2 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.

# CORCEPT THERAPEUTICS INCORPORATED CONDENSED BALANCE SHEETS (in thousands)

(III tilousalius)	December 31, 2010	December 31, 2009	
ASSETS:	(Unaudited)	(Note)	
Current assets: Cash and cash equivalents Other current assets	\$ 24,578 418	\$ 23,867 553	
Total current assets	24,996	24,420	
Other assets	108	91	
Total assets	\$ 25,104 =======	\$ 24,511 =======	
LIABILITIES AND STOCKHOLDERS' EQUITY: Current liabilities:			
Accounts payable Other current liabilities		\$ 1,270 1,149	
Total current liabilities	3,860	2,419	
Total stockholders' equity	21,244	22,092	
Total liabilities and stockholders' equity	\$ 25,104 ======	\$ 24,511 =======	

Note: Derived from audited financial statements at that date.

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

(Unaudited)

	Mont	the Three ns Ended nber 31,		Year Ended December 31,			
	2010	2009	2010	2009			
Collaboration revenue	\$ -	- \$ -	\$	\$ 29			
Operating expenses: Research and development* General and administrative* Total operating expenses	3,16	0 1,41 	18,949 14 8,488 	5,877			
Loss from operations	(7,82	3) (5,16	(27, 437)	(20,250)			
Interest and other income, net Other expense Net loss	(	3) (1	5 1,496 (1) (25) (70) \$ (25,966)	) (17)			

Basic and diluted net loss per share	\$ ( =====	0.10) ====	\$	(0.09)	\$	(0.38)	\$	(0.38)
Shares used in computing basic and diluted net loss per share	72	, 354 ====	====	60,390 =====	===	68,336 =====	==:	52,443 ======
*Includes non-cash stock- based compensation of the following:								
Research and development General and	\$	49	\$	65	\$	220	\$	263
administrative		536		394		1,896		1,552
Total non-cash stock- based compensation	\$	585 ====	\$	459 =====	\$	2,116	\$	1,815 ======

CONTACT: Caroline Loewy Chief Financial Officer Corcept Therapeutics 650-688-8783 cloewy@corcept.com www.corcept.com