# 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: November 07, 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 November 7, 2011, Corcept Therapeutics Incorporated (the "Company"), issued a press release announcing its financial results for the quarter ended September 30, 2011. The press release is attached hereto as Exhibit 99.1.

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 November 7, 2011, the Company issued a press release announcing its financial results for the quarter ended September 30, 2011. The press release is attached hereto as Exhibit 99.1.

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 November 07, 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: November 07, 2011

## CORCEPT THERAPEUTICS INCORPORATED

By: <u>/s/ G. Charles Robb</u>
G. Charles Robb
Chief Financial Officer

# **Exhibit Index**

Exhibit No.

**Description** 

99.1

Press Release of Corcept Therapeutics Incorporated dated November 07, 2011

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

MENLO PARK, CA -- (Marketwire - November 07, 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 quarter ended September 30, 2011, and updated its corporate progress.

"Following the acceptance by the U.S. Food and Drug Administration (FDA) of our New Drug Application (NDA) for the use of our lead product candidate, Korlym™, in Cushing's Syndrome," said Joseph Belanoff, M.D., Chief Executive Officer of Corcept, "we continue to focus our efforts on building our commercial capabilities to support the launch of Korlym, if Korlym is approved by the FDA, in order to allow us to provide an important treatment option to patients suffering from Cushing's Syndrome."

## **Corporate and Development Highlights**

- Received notification in October 2011 that the FDA had accepted our proposed brand name, Korlym (formerly referred to as CORLUX®), for our lead product candidate in the treatment of endogenous Cushing's Syndrome.
- Advanced our commercial launch preparations related to Korlym for the treatment of Cushing's Syndrome, including
  developing our internal infrastructure and engaging third-party vendors to provide market analytics and to support
  distribution and other logistical needs in the event Korlym is approved by the FDA.
- Received notification in October 2011 that the European Commission had granted Korlym Orphan Designation for the treatment of endogenous Cushing's Syndrome (hypercortisolism) in the European Union (EU). Benefits of Orphan Drug Designation in the EU are similar to those in the U.S., but include ten years of marketing exclusivity in all 27 member states, free scientific advice during drug development, access to a centralized review process and a reduction or complete waiver of fees levied by the European Medicines Agency.
- Enrolled additional patients in our double-blind placebo controlled Phase 3 trial of Korlym for the treatment of the psychotic features of psychotic depression.
- Continued the clinical portion of our Phase 1b/2a multi-dose safety and proof of concept studies of CORT 108297, one of our selective GR-II antagonists.
- Identified additional compounds from among our proprietary series of selective GR-II antagonists to advance toward an Investigational New Drug submission.

## **Third Quarter Financial Results**

For the third quarter of 2011, Corcept reported a net loss of \$6.4 million, or \$0.08 per share, compared to a net loss of \$7.1 million, or \$0.10 per share, for the third quarter of 2010.

In the third quarter of 2011, research and development expenses decreased to \$3.2 million from \$5.2 million in the third quarter of 2010. This decrease in research and development expenses was due primarily to decreases in clinical trial costs related to drug-drug interaction and other NDA-supportive studies with Korlym, which were substantially completed in late 2010, and decreases in the clinical trial costs related to the Phase 1b/2a studies with CORT 108297. These decreases were partially offset by increased costs associated with the prosecution of our NDA for Korlym for the treatment of Cushing's Syndrome. General and administrative expenses increased to \$3.2 million for the third quarter of 2011 from \$1.9 million for the same period in 2010 due primarily to additional expenditures on commercialization activities for the potential launch of Korlym for Cushing's Syndrome.

Our cash balance as of September 30, 2011 was \$45.9 million, up from \$24.6 million at December 31, 2010. "We anticipate that our current cash balance is sufficient to fund the company through the end of 2012," said Charles Robb, the company's Chief Financial Officer.

#### **Anticipated Activities for the Remainder of 2011**

We continue to concentrate our efforts on advancing Korlym toward approval and commercialization for the treatment of Cushing's Syndrome. We also continue our efforts to be prepared to respond in a timely fashion to any questions posed by the FDA during the course of their review of our NDA.

"We are focused intently on developing the commercial and logistical capabilities we will need to make Korlym available to patients suffering from Cushing's Syndrome, should the FDA approve our drug for this indication," added Dr. Belanoff. "Korlym is the first step in unlocking the value of our scientific platform. The regulation of cortisol is a critical biological function; its dysregulation is equally critical in many important disease states. Our own research and research from increasing numbers of academic investigators point to the potential importance of cortisol antagonism in a wide variety of diseases. We believe our expanding library of selective cortisol antagonists may help address these unmet medical needs."

#### **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 Korlym**

Corcept's first-generation compound, Korlym, 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 Korlym. Corcept retains worldwide rights to its intellectual property related to Korlym.

#### **About CORT 108297**

CORT 108297 is a potent, selective antagonist 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 this compound has no 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 Korlym for the treatment of Cushing's Syndrome, and has an ongoing Phase 3 study of Korlym for the treatment of the psychotic features of psychotic depression. Corcept also has a Phase 2 program for CORT 108297, a selective GR-II antagonist that blocks the effects of cortisol but not progesterone. 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 the potential benefit of Korlym for patients diagnosed with Cushing's Syndrome, Corcept's clinical development and research programs, the outcome of the FDA's review of our NDA filing, our estimates for our capital requirements and needs for additional financing, the introduction of Korlym and future product candidates, including CORT 108297, the ability to create value from Korlym or other future product candidates or our scientific platform and our commercialization plans. 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 Korlym, 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)

September 30, December 31, 2011 2010 (Unaudited) (Note)

Cash and cash equivalents Other current assets	\$ 45,909 427	. ,
Total current assets	46,336	24,996
Other assets	43	108
Total assets	\$ 46,379 =======	\$ 25,104 =======
LIABILITIES AND STOCKHOLDERS' EQUITY: Current liabilities: Accounts payable Other current liabilities	\$ 1,066 1,647	\$ 817 3,043
Total current liabilities	2,713	3,860
Total stockholders' equity	43,666	21,244
Total liabilities and stockholders' equity	\$ 46,379 ========	\$ 25,104 ========

Note: Derived from audited financial statements at that date.

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

(Unaudited)

For the Three Months Ended For the Nine Months Ended

		September 30,			September 30,			
						2011		
Operating expenses: Research and development* General and administrative*						14,355 8,049		
Total operating expenses						22,404		
Loss from operations		(6,437)		(7,105)		(22,404)		(19,613)
Interest and other income, net Other expense		3 (1)		4 (3)		3 (17)		758 (18)
Net loss		(6,435)	\$	(7,104)	\$	(22,418)	\$	(18,873)
Basic and diluted net loss per share  Shares used in computing basic and diluted net loss		======	===	=======	==:	(0.27)	===	======
per share	===:	84,188 ======	===	72,045 =====	==:	83,000 =====	===	66,982 ======
*Includes non-cash stock-based compensation of the following: Research and	ď	110	¢	45	ď	422	¢	170
development General and administrative		844				432 1 971		
Total non-cash stock-based compensation						1,971  2,403		
						=======		

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