# 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: August 08, 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 August 8, 2011, Corcept Therapeutics Incorporated (the "Company"), issued a press release announcing its financial results for the quarter ended June 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 August 8, 2011, the Company issued a press release announcing its financial results for the quarter ended June 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 August 08, 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: August 08, 2011

#### CORCEPT THERAPEUTICS INCORPORATED

By: <u>/s/ Anne M. LeDoux</u>
Anne M. LeDoux
Vice President and Controller

# **Exhibit Index**

Exhibit No.

**Description** 

99.1

Press Release of Corcept Therapeutics Incorporated dated August 08, 2011

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

MENLO PARK, CA -- (Marketwire - August 08, 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 June 30, 2011, and updated its corporate progress.

"We have achieved many important milestones over the past several months, including the announcement of positive Phase 3 data and the acceptance by the U.S. Food and Drug Administration (FDA) of our New Drug Application (NDA) for the use of CORLUX 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 a CORLUX launch, if CORLUX 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 from the FDA of the acceptance for filing of our NDA for CORLUX, a glucocorticoid receptor type II
  (GR-II) antagonist, for the treatment of the manifestations of Cushing's Syndrome. The FDA has indicated that the
  Prescription Drug User Fee Act (PDUFA) goal date for completion of its review is February 17, 2012.
- Presented detailed clinical data from our Phase 3 study of CORLUX for the treatment of Cushing's Syndrome to the endocrinologists who treat the disorder at the Endocrine Society's 93rd Annual Meeting on June 4, 2011.
- 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. Eleven of these patients have now been treated with CORLUX for over two years.
- 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.

In addition, we continued to make progress on:

- Advancing our commercial preparations related to CORLUX for the treatment of Cushing's Syndrome, including conducting
  market research and engaging third-party vendors to support distribution and other logistical needs for product launch, if
  CORLUX is approved by the FDA.
- Enrolling patients in our double-blind placebo controlled Phase 3 trial of CORLUX for the treatment of the psychotic features of psychotic depression.
- Identifying additional compounds from among our proprietary series of selective GR-II antagonists to advance toward an Investigational New Drug (IND) submission.

#### **Second Quarter Financial Results**

For the second quarter of 2011, Corcept reported a net loss of \$8.9 million, or \$0.11 per share, compared to a net loss of \$5.7 million, or \$0.09 per share, for the second quarter of 2010.

Total operating expenses increased to \$8.9 million for the second quarter of 2011, from \$6.4 million for the same period in 2010. In the second quarter of 2011, research and development expenses increased to \$6.2 million from \$4.6 million in the second quarter of 2010. This increase in research and development expenses was due primarily to increased costs associated with the prosecution of our NDA for CORLUX for the treatment of Cushing's Syndrome, costs associated with the purchase of additional supplies of the active pharmaceutical ingredient in CORLUX and other manufacturing development activities and costs associated with our selective GR-II antagonist program, including the progression of our Phase 1b/2a studies with CORT 108297. These increases were partially offset by decreases in clinical trial costs related to drug-drug interaction and other NDA-supportive studies with CORLUX. General and administrative expenses increased to \$2.7 million for the second quarter of 2011 from \$1.9 million for the same period in 2010 due to additional resources focused on pre-commercial activities for the potential launch of CORLUX in Cushing's Syndrome.

Our cash balance as of June 30, 2011 was \$52.2 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 Dr. Belanoff.

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

We continue to focus our efforts on advancing CORLUX toward approval and commercialization for the treatment of Cushing's Syndrome. We 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 developing plans and engaging third-party vendors to support a commercial launch of CORLUX in the United States, if approved by the FDA.

"With the acceptance by the FDA of our NDA we have moved another step closer to making CORLUX available to patients suffering from Cushing's Syndrome," added Dr. Belanoff. "CORLUX 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. We believe our expanding library of selective cortisol antagonists puts us in the position to approach large unmet medical needs through a novel but increasingly validated mechanism."

### **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**

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 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, 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 CORLUX for patients diagnosed with Cushing's Syndrome, Corcept's clinical development and research programs, the timing of completion and outcome of the FDA's review of our NDA filing, our estimates for our capital requirements and needs for additional financing, 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 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 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.

(in thousands)

e) 24,578 418
24,996
108
25,104 =====
817 3,043
3,860
21,244
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 June 30,			
	2011	2010	2011	2010
Operating expenses: Research and development* General and administrative*	6,203 2,666	4,574 1,871	11,127 4,840	3,446
Total operating expenses		6,445		12,509
Loss from operations	(8,869)	(6,445)	(15,967)	(12,509)
Interest and other income, net Other expense	(1) (12)	753 (3)	1 (17)	755 (14)
Net loss		\$ (5,695) ======		
Basic and diluted net loss per share		\$ (0.09) ======		
Shares used in computing basic and diluted net loss per share		66,142 ======		
*Includes non-cash stock-based compensation of the following: Research and development General and administrative	\$ 267 602	\$ 62 440	1,126	\$ 125 861
Total non-cash stock-based compensation	\$ 869 ======	\$ 502	\$ 1,449 ======	

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