# 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 05, 2014

(Date of earliest event reported)

**Corcept Therapeutics** 

(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, Menlo Park CA** (Address of principal executive offices)

**94025** (Zip Code)

(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

#### Item 7.01. Regulation FD Disclosure

On August 5, 2014, Corcept Therapeutics Incorporated (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2014 and reaffirming its revenue guidance for the year ending December 31, 2014. The press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 2.02 and 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 2.02 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 99.1 <u>Press Release of Corcept Therapeutics dated August 05, 2014</u> 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 05, 2014

## **CORCEPT THERAPEUTICS**

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

## Exhibit Index

<u>Exhibit No.</u> 99.1 **Description** 

Press Release of Corcept Therapeutics dated August 05, 2014

#### Corcept Therapeutics Announces Second Quarter 2014 Financial Results and Provides Corporate Update

MENLO PARK, CA -- (Marketwired - August 05, 2014) - Corcept Therapeutics Incorporated (NASDAQ: CORT)

- Revenue increases 33 percent from prior quarter on continued uptake of Korlym® for the treatment of Cushing's syndrome
- GAAP net loss narrows to \$0.07 per share; non-GAAP net loss narrows to \$0.05 per share
- Company reiterates 2014 revenue guidance of \$25-29 million
- Trial for treatment of triple-negative breast cancer to generate results in 2015
- Phase 1 clinical trial of next-generation selective GR antagonist starts this month

Corcept Therapeutics Incorporated (NASDAQ: CORT), a pharmaceutical company engaged in the discovery, development and commercialization of drugs for the treatment of severe metabolic, psychiatric and oncologic disorders, today reported its financial results for the quarter ended June 30, 2014. The company also provided an update on its clinical programs.

## Second Quarter Financial Results and Reaffirmation of 2014 Revenue Guidance

- Corcept recognized \$5.9 million in net revenue for the second quarter of 2014 compared to \$4.4 million in the first quarter, an increase of 33 percent. The company's net loss in the second quarter on a GAAP basis was \$7.6 million, or \$0.07 per share, compared to a net loss of \$13.9 million, or \$0.14 per share, in the first quarter.
- In 2014, Corcept's net loss on a GAAP basis included significant non-cash expenses of \$2.2 million in the second quarter and \$2.4 million in the first quarter. Excluding these non-cash expenses, the company's net loss on a non-GAAP basis was \$5.4 million, or \$0.05 per share, for the second quarter of 2014 and \$11.5 million, or \$0.11 per share, for the first quarter.
- As of June 30, 2014, the company held cash and cash equivalents of \$34.0 million.
- The company reaffirmed its 2014 full-year revenue guidance of \$25-29 million.

"Our Cushing's syndrome business grew broadly last quarter," said Joseph K. Belanoff, M.D., Corcept's Chief Executive Officer. "We continue to introduce new physicians to Korlym<sup>®</sup> and, as they see the marked difference it makes in the lives of the first patients for whom they prescribe the drug, these physicians become more likely to prescribe the medicine to additional patients."

"At this June's Endocrine Society meeting we offered tangible evidence that Korlym works well. Results from the long-term extension of our pivotal Phase 3 SEISMIC study showed maintenance of key Korlym benefits. Investigators also presented a number of case studies showing the remarkable degree to which Korlym has benefited commercial patients treated independently of that study."

## **Clinical Pipeline Progress**

"There is substantial evidence that glucocorticoid receptor (GR) antagonists, such as Korlym, may have utility in treating a variety of severe illnesses," said Dr. Belanoff. "This quarter we made significant progress in the development of both Korlym and our portfolio of proprietary next-generation GR antagonists: Our clinical trial of Korlym for the treatment of triple-negative breast cancer will generate results in 2015. We will begin a Phase 1 clinical trial of one new compound -- CORT 125134 -- in the next few weeks and will advance more compounds into clinical trials next year. We look forward to presenting the results of these studies."

## **Financial Results**

For the second quarter of 2014, Corcept recognized net product revenue of \$5.9 million. The company reported a net loss of \$7.6 million, or \$0.07 per share, for the second quarter of 2014 compared to a net loss of \$11.9 million, or \$0.12 per share, for the same period in 2013.

The net loss on a GAAP basis for the second quarter of 2014 and for the second quarter of 2013 included non-cash stock-based compensation expenses of \$1.2 million and \$1.3 million, respectively. In addition, the company recognized non-cash interest expense related to its capped royalty financing transaction of \$935,000 in the second quarter of 2014 and \$1.1 million in the same period in 2013. After adjusting for these non-cash expenses, the company's net loss on a non-GAAP basis was \$5.4 million, or \$0.05 per share, for the second quarter of 2014, compared to \$9.5 million, or \$0.10 per share, for the second quarter of 2013. A reconciliation of GAAP net loss to non-GAAP net loss is included below.

Operating expenses for the second quarter of 2014 were \$12.4 million, compared to \$12.7 million for the corresponding period in 2013.

- Selling, general and administrative expenses in the second quarter declined to \$8.0 million, compared to \$8.2 million for the comparable period in 2013.
- Research and development expenses in the second quarter were \$4.3 million, compared to \$4.5 million for the second quarter of 2013.

Corcept's cash balance as of June 30, 2014 was \$34.0 million, compared to \$54.9 million at December 31, 2013.

## **Conference Call**

Corcept will hold a conference call on August 5, 2014, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time) to discuss this announcement. To participate, dial 1-888-771-4371 from the United States or +1-847-585-4405 internationally approximately ten minutes before the start of the call. The passcode is 37738631.

A replay will be available through August 19, 2014 at 1-888-843-7419 from the United States and +1-630-652-3042 internationally. The passcode is 37738631.

## About Korlym®

Korlym competitively blocks the glucocorticoid receptor type II (GR) to which cortisol normally binds, thereby inhibiting the effects of excess cortisol in Cushing's syndrome patients. In April 2012, Corcept made Korlym available as a once-daily oral treatment of hyperglycemia secondary to endogenous Cushing's syndrome in adult patients with glucose intolerance or diabetes mellitus type 2 who have failed surgery or are not candidates for surgery. Korlym was the first FDA-approved treatment for that illness and the FDA has designated it as an Orphan Drug for that indication. Orphan Drug designation is a special status designed to encourage the development of medicines for rare diseases and conditions. Because Korlym is an Orphan Drug, Corcept will have marketing exclusivity for the approved indication in the United States until February 2019.

## **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 that most commonly affects adults aged 20-50. An estimated 10-15 of every one million people are newly diagnosed with this syndrome each year, resulting in over 3,000 new patients annually 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 Triple-Negative Breast Cancer**

Triple-negative breast cancer is a form of the disease in which the three receptors that fuel most breast cancer growth -- estrogen, progesterone and the HER-2/neu gene -- are not present. Because the tumor cells lack the necessary receptors, common treatments, such as hormone therapy and drugs that target estrogen, progesterone and HER-2, are ineffective. In 2013, approximately 40,000 women were diagnosed with triple-negative breast cancer. There is no FDA-approved treatment and neither a targeted treatment nor a preferred standard chemotherapy regimen for relapsed triple-negative breast cancer patients exists.

## **About Corcept Therapeutics Incorporated**

Corcept is a pharmaceutical company engaged in the discovery, development and commercialization of drugs for the treatment of severe metabolic, psychiatric and oncologic disorders. Korlym, a first generation competitive GR antagonist, is the company's first FDA-approved medication. The company has a Phase 1 trial of mifepristone for the treatment of triple-negative breast cancer and a portfolio of selective GR antagonists that competitively block the effects of cortisol but not progesterone. It owns extensive intellectual property covering the use of GR antagonists, including mifepristone, in the treatment of a wide variety of metabolic, psychiatric and oncologic disorders. It also holds composition of matter patents for its selective GR antagonists.

## **Non-GAAP Measures of Net Loss**

To supplement Corcept's financial results presented on a GAAP basis, we use non-GAAP measures of net loss that exclude significant non-cash expenses related to stock-based compensation expense and the recognition of interest expense under our capped royalty financing transaction. We believe that this non-GAAP measure of net loss helps investors better evaluate the company's past financial performance and potential future results. Non-GAAP measures should not be considered in isolation or as a substitute for comparable GAAP accounting and investors should read them in conjunction with the company's financial statements prepared in accordance with GAAP. The non-GAAP measure of net loss we use may be different from, and not directly comparable to, similarly titled measures used by other companies.

## **Forward-Looking Statements**

Statements made in this news release, other than statements of historical fact, are forward-looking statements. These forward-looking statements, including statements regarding anticipated future revenues, the timing of clinical trials and clinical trial results and the advancement of additional compounds, are subject to known and unknown risks and uncertainties that might cause actual results to differ materially from those expressed or implied by such statements, including the pace of Korlym's acceptance by physicians and patients, the reimbursement decisions of government or private insurers, the pace of enrollment in or the outcome of the company's phase 1 study of mifepristone in the treatment of triple-negative breast cancer and the phase 1 study of its next-generation selective GR antagonist, CORT 125134, the effects of rapid technological change and competition, the protections afforded by Korlym's Orphan Drug designation or by Corcept's other intellectual property rights, or the cost, pace and success of

Corcept's other product development efforts. These and other risks are set forth in the company's SEC filings, all of which are available from the company's website (http://www.corcept.com) or from the SEC's website (http://www.sec.gov). Corcept disclaims any intention or duty to update any forward-looking statement made in this news release.

#### CORCEPT THERAPEUTICS INCORPORATED CONDENSED BALANCE SHEETS (in thousands)

	June 30, 2014		December 31, 2013	
	(Unaudited)		(Note)	
ASSETS:				
Cash and cash equivalents Trade receivables, net Inventory Other assets	\$	33,974 2,225 5,642 2,549		54,877 1,428 5,546 1,226
Total assets	\$ 	44,390	\$ 	63,077
LIABILITIES AND STOCKHOLDERS' EQUITY:				
Accounts payable Deferred revenue Long-term obligation Other liabilities Stockholders' equity	\$	2,595 44 35,032 3,267 3,452		2,381 25 35,065 4,589 21,017
Total liabilities and stockholders' equity	\$ 	44,390	\$ 	63,077

Note: Derived from audited financial statements at that date.

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

#### (Unaudited)

		30,	Six Months Ended June 30,		
		2013	2014		
Revenues: Product sales, net	\$ 5,851	\$ 1,891	\$ 10,255	\$ 3,608	
Operating expenses: Cost of sales Research and development Selling, general and	4,252	4,491	389 11,537	8,748	
administrative	7,965	8,160	17,769	16,544	
Total operating expenses	12,432	12,674		25,335	
Loss from operations	(6,581)				
Interest and other expense	(971)	(1,114)	(2,041)	(2,254)	
Net loss and comprehensive loss	\$ (7,552)	\$(11,897)	\$(21,481)	\$(23,981)	
Basic and diluted net loss per share			\$ (0.21)		
Shares used in computing basic and diluted net loss per share	100,980	99,814	100,751	99,814	

#### CORCEPT THERAPEUTICS INCORPORATED RECONCILIATION OF GAAP TO NON-GAAP NET LOSS (in thousands, except per share amounts)

#### (Unaudited)

	Three Mon June	ths Ended 30,	Six Months Ended June 30,		
		2013			
GAAP net loss	\$ (7,552)	\$(11,897)	\$(21,481)	\$(23,981)	
Significant non-cash expenses: Stock-based compensation Research and development	169	157	331	305	
Selling, general and administrative	1,057	1,108	2,272	2,270	
Total stock-based compensation	1,226		2,603		
Accretion of interest expense related to long-term obligation	935		1,979	2,207	
Non-GAAP net loss	\$ (5,391)	\$ (9,540)	\$(16,899)	\$(19,199)	
GAAP basic and diluted net loss per share		\$ (0.12)		\$ (0.24)	
Non-GAAP basic and diluted net loss per share as adjusted for significant non-cash expenses		\$ (0.10)			
Shares used in computing basic and diluted net loss per share	100,980	99,814	100,751	99,814	
<b>CONTACT:</b> Charles Robb Chief Financial Officer					

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