# 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: May 03, 2012** (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

On May 3, 2012, Corcept Therapeutics Incorporated (the "Company"), issued a press release announcing its financial results for the quarter ended March 31, 2012. 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 May 3, 2012, the Company issued a press release announcing its financial results for the quarter ended March 31, 2012. 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 dated May 03, 2012

#### **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: May 09, 2012

#### **CORCEPT THERAPEUTICS**

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 dated May 03, 2012

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

MENLO PARK, CA -- (Marketwire - May 03, 2012) - 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 updated its corporate progress and reported financial results for the quarter ended March 31, 2012.

On April 10, 2012, Corcept began offering its first medicine, Korlym<sup>TM</sup> (mifepristone), less than eight weeks after the United States Food and Drug Administration (FDA) approved it 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 is the first and only FDA-approved treatment for that illness.

"We are proud to have made Korlym available so quickly following its approval," said Joseph K. Belanoff, M.D., Corcept's Chief Executive Officer. "Cushing's is a debilitating, life-threatening illness. We wanted patients who might benefit from the medicine to receive it without delay."

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

So far in 2012, Corcept has:

- Received approval from the FDA to market Korlym.
- Made Korlym available to patients on April 10, 2012, three weeks earlier than anticipated.
- Launched its "Support Program for Access and Reimbursement for Korlym ("SPARK"). SPARK connects patients and physicians with patient advocates and reimbursement specialists to make sure they can receive Korlym quickly and easily. SPARK can be reached by calling **855-4KORLYM** or by going to **www.korlymspark.com**.
- Established a program to support uninsured and underinsured patients with the National Organization for Rare Disorders (NORD). The program provides financial assistance for the expenses of diagnosis, treatment and care that are not covered by insurance. Patients seeking information may contact NORD by calling **800-999-6673**, **Ext. 326** or by emailing **cushings@rarediseases.org**.
- Published the results of its phase 3 SEISMIC trial of Korlym in The Journal of Clinical Endocrinology and Metabolism, which demonstrated that refractory Cushing's syndrome patients receiving Korlym experienced significant clinical improvement.
- Enrolled patients in its ongoing double-blind placebo controlled Phase 3 trial of mifepristone for treatment of the psychotic features of psychotic depression.
- Continued development of its proprietary families of next generation selective GR-II antagonists.

# **Anticipated Activities for the Remainder of 2012**

"While the successful launch of Korlym is our primary focus," said Dr. Belanoff, "we continue to investigate mifepristone as a potential treatment for psychotic depression and to advance our next-generation of selective GR-II antagonists."

# **First Quarter Financial Results**

Corcept reported a net loss of \$11.0 million, or \$0.13 per share, for the first quarter of 2012, compared to a net loss of \$7.1 million, or \$0.09 per share, for the first quarter of 2011.

Research and development expenses decreased to \$3.5 million for the first quarter of 2012 as compared to \$4.9 million for first quarter of 2011, primarily due to higher costs during the first quarter of 2011 associated with preparations for the submission of the company's NDA for Korlym, purchase of Korlym's active pharmaceutical ingredient, manufacture of Korlym tablets and manufacturing development activities at a potential second tableting facility. There were also decreases between these periods in costs related to clinical trials of Korlym for the treatment of Cushing's syndrome, for drug-drug interaction and other NDA-supportive studies with Korlym and studies related to the Phase 1b/2a studies of CORT 108297, one of our next-generation compounds. These decreases from 2011 expenses were only partially offset by increases in staffing costs that included bonuses in an aggregate amount of approximately \$441,000 awarded on FDA approval in 2012 to employees working in these functions.

Selling, general and administrative expenses increased to \$7.5 million for the first quarter of 2012 as compared to \$2.2 million for first quarter of 2011, reflecting increased costs associated with our preparations for commercialization of Korlym. Selling, general and administrative expenses in the first quarter of 2012 included bonuses in an aggregate amount of approximately \$1.6 million awarded on FDA approval to officers and employees working in these functions and \$1.3 million of stock-based compensation expense related to option awards to officers with performance-based criteria that vested upon the FDA approval.

Our cash balance as of March 31, 2012 was \$42.6 million, as compared to \$39.6 million at December 31, 2011, and reflects net proceeds of approximately \$12.9 million from our March 2012 financing transaction, less approximately \$10.2 million spent on operations during the first quarter of 2012. "We anticipate that our current cash balance is sufficient to fund the company through the first quarter of 2013," said Charles Robb, the company's Chief Financial Officer.

#### **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 Korlym™ (mifepristone) 300 mg Tablets

Korlym blocks the glucocorticoid receptor type II (GR-II) to which cortisol normally binds, thereby inhibiting the effects of excess cortisol in Cushing's syndrome patients. On April 10, 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 is the first and only 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 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.

#### IMPORTANT SAFETY INFORMATION

#### WARNING: TERMINATION OF PREGNANCY

See full prescribing information for complete boxed warning.

Mifepristone has potent antiprogestational effects and will result in the termination of pregnancy. Pregnancy must therefore be excluded before the initiation of treatment with Korlym, or if treatment is interrupted for more than 14 days in females of reproductive potential

#### **Contraindications**

- Pregnancy
- Use of simvastatin or lovastatin and CYP 3A substrates with narrow therapeutic range
- Concurrent long-term corticosteroid use
- Women with history of unexplained vaginal bleeding
- Women with endometrial hyperplasia with atypia or endometrial carcinoma

#### **Warnings and Precautions**

- Adrenal insufficiency: Patients should be closely monitored for signs and symptoms of adrenal insufficiency.
- Hypokalemia: Hypokalemia should be corrected prior to treatment and monitored for during treatment.
- Vaginal bleeding and endometrial changes: Women may experience endometrial thickening or unexpected vaginal bleeding. Use with caution if patient also has a hemorrhagic disorder or is on anti-coagulant therapy.
- QT interval prolongation: Avoid use with QT interval-prolonging drugs or in patients with potassium channel variants resulting in a long QT interval.
- Use of Strong CYP3A Inhibitors: Concomitant use can increase mifepristone plasma levels significantly. Use only when necessary and limit mifepristone dose to 300 mg.

# **Adverse Reactions**

Most common adverse reactions in Cushing's syndrome ( $\geq 20\%$ ): nausea, fatigue, headache, decreased blood potassium, arthralgia, vomiting, peripheral edema, hypertension, dizziness, decreased appetite, endometrial hypertrophy.

To report suspected adverse reactions, contact Corcept Therapeutics at 1-855-844-3270 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

#### **Drug Interactions**

- Drugs metabolized by CYP3A: Administer drugs that are metabolized by CYP3A at the lowest dose when used with Korlym.
- CYP3A inhibitors: Caution should be used when Korlym is used with strong CYP3A inhibitors. Limit mifepristone dose to 300 mg per day when used with strong CYP3A inhibitors.
- CYP3A inducers: Do not use Korlym with CYP3A inducers.
- Drugs metabolized by CYP2C8/2C9: Use the lowest dose of CYP2C8/2C9 substrates when used with Korlym.
- Drugs metabolized by CYP2B6: Use of Korlym should be done with caution with bupropion and efavirenz.

• Hormonal contraceptives: Do not use with Korlym.

#### **Use in Specific Populations**

• Nursing mothers: Discontinue drug or discontinue nursing.

# Please see the full Prescribing Information including boxed warning at www.corcept.com/prescribinginfo.pdf

#### Please see the Medication Guide at www.corcept.com/medicationguide.pdf

# **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. Korlym, a first generation GR-II antagonist, is the company's first FDA-approved medication. The company has a portfolio of new selective GR-II antagonists that block the effects of cortisol but not progesterone. It owns extensive intellectual property covering the use of GR-II antagonists, including mifepristone, in the treatment of a wide variety of metabolic and psychiatric disorders. It also holds composition of matter patents for its selective GR-II antagonists.

Statements made in this news release, other than statements of historical fact, are forward-looking statements. 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 that clinical results will be predictive of real-world use, or regarding the pace of Korlym's acceptance by physicians and patients, the reimbursement decisions of government or private insurance payers, 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, and the cost, pace and success of Korlym commercialization and its 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)

			December 31, 2011	
ASSETS:	(Unaudited)		(Note)	
Current assets: Cash and cash equivalents Other current assets	\$			39,635 140
Total current assets		42,785		39,775
Other assets		102		58
Total assets	\$ ====	42,887	\$ ==	39,833 =====
LIABILITIES AND STOCKHOLDERS' EQUITY: Current liabilities: Accounts payable Other current liabilities	\$			3,611 1,415
Total current liabilities		1,486 3,570		5,026
Total stockholders' equity		39,317		34,807
Total liabilities and stockholders' equity	\$ ====	42,887 ======	\$ ==	39,833 ======

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 March 31,

	2012		2011	
Operating expenses: Research and development* Selling, general and administrative*	\$	3,542 7,487	\$	4,924 2,174
Total operating expenses				7,098
Interest and other income, net Other expense		_ (5)		2 (5)
Net loss		(11,034) ======		
Basic and diluted net loss per share		(0.13) ======		
Shares used in computing basic and diluted net loss per share	===:	84,420		80,764
*Includes non-cash stock-based compensation of the following:				
Research and development Selling, general and administrative		118 2,270		
Total non-cash stock-based compensation		2,388		580 ======

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