# 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 22, 2012** (Date of earliest event reported)

**Corcept Therapeutics Incorporated** (Exact name of registrant as specified in its charter)

DE

000-50679

(State or other jurisdiction of incorporation)

(Commission File Number) 77-0487658 (IRS Employer Identification Number)

94025

(Zip Code)

149 Commonwealth Drive, Menlo Park, CA

(Address of principal executive offices)

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 8.01. Other Events

In a press release issued on March 22, 2012, we announced that we would be ready to ship Korlym(TM) (mifepristone) 300 mg Tablets to patients by April 11th, three weeks ahead of the our previously announced launch date. We also stated that the wholesale acquisition price would be \$0.62 per milligram and that we would offer financial assistance and other support to patients who are prescribed the medicine.

The press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

#### Item 9.01. Financial Statements and Exhibits

(a) Financial s	tatements:
None	
(b) Pro forma	financial information:
None	
(c) Shell comp	any transactions:
None	
(d) Exhibits	
99.1	Press Release of Corcept Therapeutics Incorporated dated March 22, 2012

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 22, 2012

#### CORCEPT THERAPEUTICS INCORPORATED

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 Incorporated dated March 22, 2012

## Korlym(TM) (mifepristone), the First Approved Medication for Patients With Endogenous Cushing's Syndrome, to Be Available by April 11

MENLO PARK, CA -- (Marketwire - March 22, 2012) - Corcept Therapeutics Incorporated (NASDAQ: CORT) announced today that it would be ready to ship Korlym to patients by April 11th, three weeks ahead of the company's previously announced launch date. "Cushing's syndrome is a life altering and life threatening disease," said Joseph K. Belanoff, M.D., the company's Chief Executive Officer. "We have worked hard to bring this first-in-class treatment to patients as quickly as possible."

On February 17, 2012, the U.S. Food and Drug Administration (FDA) approved Korlym<sup>™</sup> (mifepristone) 300 mg Tablets as a once-daily oral medicine to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Physicians and patients seeking more information can visit http://www.korlym.com.

Korlym is distributed in 300 milligram tablets to be taken once each day. The wholesale acquisition price of Korlym is \$0.62 per milligram. The FDA-approved labeling instructs physicians to titrate each patient's Korlym dose to clinical efficacy by assessing tolerability and degree of improvement in Cushing's syndrome manifestations. In the first six weeks, these manifestations may include changes in glucose control, anti-diabetic medication requirements, insulin levels and psychiatric symptoms. After two months, assessment may also be based on improvements in cushingoid appearance, acne, hirsutism, striae or decreased body weight, along with further changes in glucose control.

#### **Patient Assistance Programs**

"Our highest priority is that every patient who is prescribed Korlym will receive it," said Dr. Belanoff. To that end, the company has launched a comprehensive financial assistance and patient support program. A dedicated team of Corcept case managers will help patients understand their insurance benefits and the financial and medical support programs available to them.

"Patients face tremendous challenges managing their illness -- from finding physicians familiar with the disease to navigating the complexities of insurance reimbursement to paying for the cost of care," said Dr. Belanoff. "We are determined that none of these barriers will keep patients from receiving the benefits of Korlym."

## **About Cushing's Syndrome**

Endogenous Cushing's syndrome is a rare and life-threatening endocrine disorder that results from long-term exposure to excess levels of the hormone cortisol. This excess is caused by tumors that usually occur in the pituitary or adrenal glands that over-produce, or prompt the over-production of, cortisol.

Although cortisol at normal levels is essential to health, in excess it causes a variety of problems, including hyperglycemia, upper body obesity, a rounded face, stretch marks on the skin, an accumulation of fat on the back, thin and easily bruised skin, muscle weakness, bone weakness, persistent infections, high blood pressure, fatigue, irritability, anxiety, psychosis and depression. Women may have menstrual irregularities and facial hair growth, while men may have decreased fertility or erectile dysfunction. More than 70 percent of Cushing's syndrome patients suffer from glucose intolerance or diabetes.

The treatment of an endogenous Cushing's syndrome patient depends on the cause. The first-line approach is surgery to remove the tumor. If surgery is not successful or is not an option, radiation may be used, but that therapy can take up to ten years to achieve full effect. Surgery and radiation are successful in only approximately one-half of all cases.

If left untreated, Cushing's syndrome has a five-year mortality rate of 50 percent.

An orphan disease, Cushing's syndrome occurs in about 20,000 people in the United States, mostly women between the ages of 20 and 50.

#### About Korlym<sup>™</sup> (mifepristone) 300 mg Tablets

Korlym is a once-daily oral medication that blocks the glucocorticoid receptor type II (GR-II) to which cortisol normally binds. By blocking this receptor, Korlym inhibits the effects of excess cortisol in Cushing's syndrome patients.

The FDA has designated Korlym as an Orphan Drug, 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 FDA-approved indication until February 2019.

## 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 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 accompanying full Prescribing Information including boxed warning at www.corcept.com/prescribinginfo.pdf

## Please see the accompanying 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. Corcept also owns an extensive intellectual property portfolio covering the use of GR-II antagonists, including mifepristone, in the treatment of a wide variety of psychiatric and metabolic disorders. The company 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 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 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.

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