# 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: January 28, 2016** (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 January 28, 2016, the Company issued a press release announcing its preliminary summary financial results for the quarter and year ended December 31, 2015. 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 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

#### (d) Exhibits

99.1 Press Release of Corcept Therapeutics dated January 28, 2016

#### 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: January 28, 2016

# **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 January 28, 2016

# Corcept Therapeutics Announces Preliminary Fourth Quarter and Full Year 2015 Summary Financial Results, Provides 2016 Revenue Guidance and Corporate Update

MENLO PARK, CA -- (Marketwired - January 28, 2016) - Corcept Therapeutics Incorporated (NASDAQ: CORT)

- Full year 2015 revenue of \$50.3 million, an 89 percent increase from 2014
- Fourth quarter 2015 revenue of \$15.0 million, a 66 percent increase from the fourth quarter of 2014
- 2016 revenue guidance is \$76-81 million
- Preliminary GAAP net income for the fourth quarter is \$0.01 per share, compared to a GAAP net loss of \$0.04 in the fourth quarter of 2014
- Phase 1/2 trial of mifepristone in combination with eribulin to treat triple-negative breast cancer (TNBC) expected to generate efficacy and safety results by mid-year
- Patient recruitment planned to begin by the end of the first quarter for two Phase 2 studies of next-generation, selective cortisol modulator CORT125134 -- one in Cushing's syndrome and another in solid-tumor cancers

Corcept Therapeutics Incorporated (NASDAQ: CORT), a pharmaceutical company engaged in the discovery, development and commercialization of drugs that treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of cortisol, today reported its preliminary financial results for the quarter and year ended December 31, 2015. The company also provided an update of its clinical development programs and issued 2016 revenue guidance.

#### Preliminary 2015 Financial Results; 2016 Revenue Guidance

Corcept reported preliminary revenue of \$15.0 million for the fourth quarter of 2015 and \$50.3 million for the full year. Preliminary GAAP net income for the fourth quarter of 2015 was \$0.01 per share, compared to a net loss of \$0.04 per share in the fourth quarter of 2014. For the full year, the company reported a preliminary GAAP net loss of \$0.06 per share for 2015, compared to a net loss of \$0.31 per share in 2014. The company's cash and cash equivalents were \$40.4 million at year-end, an increase of \$4.0 million from September 30, 2015.

The company estimates 2016 revenue will be \$76-81 million.

"Our Korlym® revenue grew 89 percent last year. We expect significant growth in 2016 and beyond, as there are still many patients who could benefit from the medication and have not received it," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "The continued growth in our Cushing's syndrome business, in conjunction with our lean business model, allowed us to generate our first GAAP profit last quarter and will be sufficient to fund our planned development activities."

#### 2016 Clinical and Pre-Clinical Development

"Our clinical and pre-clinical pipeline will expand significantly in 2016," said Robert S. Fishman, MD, Corcept's Chief Medical Officer. "Our Phase 1/2 trial of mifepristone with eribulin to treat triple-negative breast cancer will generate efficacy and safety results around mid-year."

"We also plan to begin two Phase 2 studies of our next-generation, selective cortisol modulator, CORT125134, by the end of the first quarter," Dr. Fishman said. "And we are advancing additional selective cortisol modulators towards Phase 1, including CORT118335, a compound that has shown promise in animal models of non-alcoholic fatty liver disease."

Dr. Fishman also noted the importance to Corcept's development program of its collaborations with independent researchers. "We have more than thirty pre-clinical and clinical studies underway with academic investigators around the world. Their work has deepened our understanding of cortisol modulation's therapeutic potential and is invaluable as we select new development targets. Our oncology program, for example, is based on pioneering work by University of Chicago researchers in the study of cortisol modulators, both mifepristone and our next-generation compounds, as potential treatments for TNBC, ovarian and prostate cancer."

#### Mifepristone for the Treatment of Triple-Negative Breast Cancer

Corcept is investigating whether mifepristone, the active ingredient in Korlym, will enhance the effect of eribulin in patients with TNBC. At the San Antonio Breast Cancer Symposium in December 2015, Corcept presented preliminary data from its Phase 1/2 trial's efficacy phase. Enrollment is ongoing.

# Two Phase 2 Trials of CORT125134

CORT125134 is a next-generation, selective cortisol modulator. It was well-tolerated in its Phase 1 trial, which showed that the compound shares Korlym's ability to modulate activity at the glucocorticoid receptor (the essential quality in treating Cushing's syndrome). Unlike Korlym, CORT125134 is not active at the progesterone receptor and so does not terminate pregnancy or cause other side effects associated with progesterone receptor antagonism. When administered with a chemotherapeutic agent, CORT125134 slows tumor growth significantly in mouse models of TNBC and castration-resistant prostate cancer. In vitro, it similarly slows the growth of ovarian cancer tumor cells. Corcept has submitted INDs to the FDA covering CORT125134's use in two Phase 2 trials -- one to treat patients with Cushing's syndrome and another for the treatment of patients with a range of solid tumors.

### **Conference Call**

Corcept will hold a conference call on January 28, 2016, 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 10 minutes before the start of the call. The passcode will be 4156 8920.

A replay will be available through February 12, 2016 at 1-888-843-7419 from the United States and 1-630-652-3042 internationally. The passcode will be 4156 8920.

# About Korlym®

Korlym modulates the effect of cortisol at the glucocorticoid receptor (GR), one of the two receptors to which cortisol binds, thereby inhibiting the effects of excess cortisol in patients with Cushing's syndrome. Since 2012, Corcept has 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.

# **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, treatments that target estrogen, progesterone and HER-2 receptors are ineffective. In 2013, approximately 40,000 women were diagnosed with TNBC. It is estimated that more than 75 percent of these women's tumor cells expressed the GR receptor to which cortisol binds. There is no FDA-approved treatment and neither a targeted treatment nor an approved standard chemotherapy regimen for relapsed TNBC patients exists.

#### **About Corcept Therapeutics Incorporated**

Corcept is a pharmaceutical company engaged in the discovery, development and commercialization of drugs that treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of cortisol. Korlym, a first-generation cortisol modulator, is the company's first FDA-approved medication. The company is conducting a Phase 1/2 trial of mifepristone for the treatment of TNBC and has a portfolio of other proprietary selective GR antagonists that modulate the effects of cortisol but not progesterone. Corcept owns extensive intellectual property covering the use of cortisol modulators, including mifepristone, in the treatment of a wide variety of metabolic, oncologic and psychiatric disorders. It also holds composition of matter patents for its portfolio of selective cortisol modulators.

#### **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, continued revenue growth, the advancement of clinical trials and expansion of the company's clinical and pre-clinical pipeline, 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 pace of enrollment in or the outcome of the company's Phase 1/2 study of mifepristone in the treatment of triple-negative breast cancer and the Phase 2 studies of its next-generation selective cortisol modulator, CORT125134, 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.

#### CONTACT:

Charles Robb Chief Financial Officer Corcept Therapeutics 650-688-8783 crobb@corcept.com www.corcept.com