# 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 30, 2017** (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 30, 2017, Corcept Therapeutics Incorporated (the Company) issued a press release announcing its preliminary summary financial results for the quarter ended December 31, 2016. 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 30, 2017

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 30, 2017

# **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 January 30, 2017

Corcept Therapeutics Announces Preliminary Fourth Quarter and Full-Year 2016 Financial Results and Corporate Update; Provides 2017 Revenue Guidance

MENLO PARK, CA -- (Marketwired - January 30, 2017) - Corcept Therapeutics Incorporated (NASDAQ: CORT)

- 2016 revenue of \$81.3 million, a 62 percent increase from 2015
- Fourth quarter 2016 revenue of \$23.8 million, a 59 percent increase from fourth quarter 2015
- Preliminary fourth quarter GAAP net income of \$0.04 per share, compared to GAAP net income of \$0.01 in fourth quarter 2015
- 2017 revenue guidance of \$115 125 million
- Results expected by year-end in Phase 2 trial of proprietary, selective cortisol modulator CORT125134 to treat Cushing's syndrome
- CLIA-validation of FKBP5 gene expression assay for diagnosing and optimally treating patients with Cushing's syndrome expected in third quarter 2017
- Expansion portion of Phase 1/2 trial of CORT125134 in combination with Abraxane® to treat patients with solid-tumor cancers expected in fourth quarter
- Phase 1 trials of selective cortisol modulators CORT125281 and CORT118335 on track to start in second quarter 2017

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 preliminary financial results for the quarter- and year-ended December 31, 2016. The company also provided an update of its development programs and issued 2017 revenue guidance.

Corcept reported preliminary revenue of \$23.8 million for the fourth quarter of 2016 and \$81.3 million for the full year. Preliminary GAAP net income for the fourth quarter of 2016 was \$0.04 per share, compared to net income of \$0.01 per share in the fourth quarter of 2015. For the full year, the company reported preliminary GAAP net income of \$0.07 per share, compared to a net loss of \$0.06 per share in 2015. The company's cash and cash equivalents were \$51.5 million at December 31, 2016, an increase of \$11.1 million from December 31, 2015.

The company estimates that 2017 revenue will be \$115 - 125 million.

"We are very pleased with our commercial performance in 2016," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "Korlym® revenue grew 62 percent and we expect significant growth in 2017 and beyond. Our Cushing's syndrome clinical program also made important advances. By year-end, we expect to have results of the Phase 2 trial of our proprietary selective cortisol modulator, CORT125134, which promises to provide Korlym's benefits, but without the side effects associated with Korlym's affinity for the progesterone receptor. For many patients, CORT125134 would be a superior medication. It has the potential to greatly expand and extend our Cushing syndrome franchise."

"This will be a pivotal year for our Cushing's syndrome program," said Robert S. Fishman, MD, Corcept's Chief Medical Officer. "In addition to completing CORT125134's Phase 2 trial, we also expect to complete development of a CLIA-validated assay measuring expression of the gene FKBP5, which is stimulated by cortisol. By allowing physicians to measure the degree to which their patients suffer from excess cortisol activity -- the cause of Cushing's syndrome -- our assay will help them identify patients with the disease and treat those already in their care more effectively.

"We are also looking forward to important advances in our other clinical programs," he added. "We continue to enroll patients in the dose-finding portion of our Phase 1/2 trial of CORT125134 in combination with Abraxane® to treat patients with solid-tumor cancers and expect to begin testing the combination's efficacy before year-end in patients with ovarian and triple-negative breast cancer. Two new selective cortisol modulators will enter the clinic -- CORT125281 as a potential treatment for castration-resistant prostate cancer and CORT118335, which has shown promise in animal models of non-alcoholic fatty-liver disease and other metabolic disorders."

### **Conference Call**

Corcept will hold a conference call on January 30, 2017, 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 44112876. A replay will be available through February 13, 2017 at 1-888-843-7419 from the United States and 1-630-652-3042 internationally. The passcode will be 44112876.

# **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 Korlym®**

Korlym modulates the effect of cortisol at the glucocorticoid receptor, 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. The FDA has designated it as an Orphan Drug for that indication.

# **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 has a portfolio of proprietary compounds 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 covering its 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 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. Such risks and uncertainties include the pace of Korlym's acceptance by physicians and patients, the cost, pace of enrollment in and the outcome of the planned Phase 1 trials of CORT118335 and CORT125281, the trials of CORT125134 in patients with Cushing's syndrome and certain solid-tumor cancers, development of a CLIA-validated assay of FKBP5 gene expression, the protections afforded by Korlym's Orphan Drug designation and Corcept's other intellectual property rights. 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.

Abraxane® is a registered trademark of Celgene Corporation.

#### **CONTACT:**

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