

CORCEPT THERAPEUTICS INC

Form 424B3

January 12, 2010

**PROSPECTUS SUPPLEMENT NO. 5**

**(TO PROSPECTUS DATED APRIL 10, 2009)**

**This filing is made pursuant to Rule 424(b)(3)  
under the Securities Act of 1933  
in connection with Registration No. 333-150259**

## Common Stock

This Prospectus Supplement No. 5 supplements and amends the prospectus dated April 10, 2009, as supplemented to date, which we refer to as the Prospectus. The Prospectus relates to the resale by certain selling stockholders of up to 13,682,107 shares of our common stock.

On January 7, 2010, we filed with the Securities and Exchange Commission a Current Report on Form 8-K disclosing under Item 8.01 that we had announced four anticipated milestones for 2010. A copy of this Form 8-K is included in this Prospectus Supplement No. 5, however, the information in Item 7.01 thereof, including the exhibits attached thereto, shall not be deemed filed for any purpose, including for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that Section, and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act regardless of any general incorporation language in such filing.

On January 8, 2010, we filed with the Securities and Exchange Commission a Current Report on Form 8-K disclosing under Item 5.02 the resignation of Edward E. Penhoet, Ph.D., from the Corcept Board of Directors due to time pressures from his appointment as a member of President Obama's Council of Advisors on Science and Technology. A copy of this Form 8-K is included in this Prospectus Supplement No. 5.

This Prospectus Supplement No. 5 should be read in conjunction with, and delivered with, the Prospectus and is qualified by reference to the Prospectus except to the extent that the information in this Prospectus Supplement No. 5 supersedes the information contained in the Prospectus. All references in the Prospectus to this prospectus are hereby amended to read this prospectus (as supplemented and amended) .

This Prospectus Supplement No. 5 contains forward-looking statements, including, for example, statements relating to our clinical development and research programs, the timing of the introduction of CORLUX and future product candidates, including CORT 108297, estimates of the timing of enrollment or completion of our clinical trials and the anticipated results of those trials, the ability to create value from CORLUX or other future product candidates and our estimates regarding our capital requirements, spending plans and needs for additional financing. 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 with respect to the cost, rate of spending, completion or success of clinical trials; financial projections may not be accurate; there can be no assurances that we will pursue further activities with respect to the development of CORLUX, CORT 108297, or any of its other selective GR-II antagonists. These and other risk factors are set forth in our SEC filings. We disclaim any intention or duty to update any forward-looking statement made in this Prospectus Supplement No. 5.

Our common stock is traded on the Nasdaq Capital Market under the symbol CORT. On January 11, 2010, the closing price of our common stock was \$3.13.

**Investing in our common stock involves a high degree of risk. Please carefully consider the Risk Factors beginning on page 4 of the accompanying Prospectus, as well as the section entitled Risk Factors included in our recent quarterly and annual reports filed with the Securities and Exchange Commission.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying Prospectus to which this prospectus supplement relates are truthful or complete. Any representation to the contrary is a criminal offense.**

The date of this prospectus supplement is January 12, 2010.

**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 (Date of earliest event reported): January 5, 2010**

**Corcept Therapeutics Incorporated**

(Exact name of registrant as specified in its charter)

**000-50679**

(Commission File Number)

**Delaware**  
(State or other jurisdiction

of incorporation)

**77-0487658**  
(I.R.S. Employer

Identification No.)

**149 Commonwealth Drive**

Edgar Filing: CORCEPT THERAPEUTICS INC - Form 424B3

**Menlo Park, CA 94025**

**(Address of principal executive offices, with zip code)**

**(650) 327-3270**

**(Registrant's telephone number, including area code)**

**(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 (*see* General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 7.01. Regulation FD Disclosure**

On January 5, 2010, Corcept Therapeutic Incorporated (the Company) issued a press release announcing its anticipated milestones for 2010, which is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including the exhibits attached hereto, is being furnished pursuant to Item 7.01 and shall not be deemed filed for any purpose, including for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that Section. The information in this Item 7.01 of this Current Report on Form 8-K, including the exhibits attached hereto, shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended or the Exchange Act regardless of any general incorporation language in such filing.

**Item 8.01. Other Events**

On January 5, 2010, the Company announced four anticipated milestones for 2010:

Completion of Enrollment of CORLUX Pivotal Phase 3 Trial for Cushing's Syndrome in 1Q 2010

Announcement of Results from the CORLUX Phase 3 Trial for Cushing's Syndrome in 3Q 2010

Submission of CORLUX New Drug Application (NDA) for Cushing's Syndrome in 4Q 2010

Initiation of Phase 1 for Selective GR-II Antagonist CORT 108297 in 1Q 2010

The full text of the press release is included in the exhibit to this Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits. The following material is filed as an exhibit to this Current Report on Form 8-K:

99.1 Press Release of Corcept Therapeutics Incorporated dated January 5, 2010

**SIGNATURES**

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.

**CORCEPT THERAPEUTICS INCORPORATED**

Date: January 7, 2010

By: /s/ CAROLINE M. LOEWY  
Caroline M. Loewy  
Chief Financial Officer

-3-

CONTACT:  
Caroline Loewy  
Chief Financial Officer  
Corcept Therapeutics  
650-688-8783  
[cloewy@corcept.com](mailto:cloewy@corcept.com)  
[www.corcept.com](http://www.corcept.com)

**CORCEPT THERAPEUTICS ANNOUNCES**  
**FOUR ANTICIPATED MILESTONES FOR 2010**

**Completion of Enrollment of CORLUX Pivotal Phase 3 Trial for Cushing's Syndrome in 1Q 2010**

**Announcement of Results from the CORLUX Phase 3 Trial for Cushing's Syndrome in 3Q 2010**

**Submission of CORLUX New Drug Application (NDA) for Cushing's Syndrome in 4Q 2010**

**Initiation of Phase 1 for Selective GR-II Antagonist CORT 108297 in 1Q 2010**

**MENLO PARK, Calif.**, (January 5, 2010) Corcept Therapeutics Incorporated (NASDAQ: CORT), a pharmaceutical company engaged in the discovery and development of drugs for the treatment of severe metabolic and psychiatric disorders, announces its anticipated milestones for 2010.

These four milestones should mark a transformational year for the company said Joseph K. Belanoff, M.D., Chief Executive Officer of Corcept. Most important, we expect to complete enrollment in our pivotal trial of CORLUX for the treatment of Cushing's Syndrome in the first quarter of this year. The results of this trial, if positive, should support an NDA submission by year-end and, if approved by the FDA, commercialization of CORLUX in 2011. We are focusing our efforts on preparing to make CORLUX commercially available to patients and address this significant unmet medical need.

**FOUR KEY MILESTONES FOR 2010**

We expect to reach major milestones related to our development of CORLUX and our selective GR-II antagonists during 2010:

**CORLUX for Cushing's Syndrome**

We are nearing completion of enrollment in our 50-patient open-label Phase 3 study of CORLUX for the treatment of endogenous Cushing's Syndrome, a serious metabolic disorder affecting approximately 20,000 patients in the US.

Based on the timing of enrollment and the 6-month glucose tolerance and blood pressure endpoints agreed to with the FDA, we anticipate completing patient treatment in the Phase 3 trial of CORLUX for Cushing's Syndrome and announcing efficacy results in 3Q 2010.

We expect to submit our NDA to the FDA in the fourth quarter of 2010. Additional studies and preparation of documentation in support of our NDA submission are ongoing, which should enable our submission soon after the Phase 3 efficacy results are available.

We are now preparing for the 2011 commercialization of CORLUX in the United States and pursuing partnerships for commercialization outside of the United States. Management is focused on making this potential treatment available to patients in an expeditious and efficient manner.

The FDA granted us Orphan Drug Designation for CORLUX for the treatment of endogenous Cushing's Syndrome, which provides seven years of marketing exclusivity in the U.S. from the date of approval, as well as potential tax credits related to product development expenses.

#### **Selective GR-II Antagonist    CORT 108297    for the Prevention of Weight Gain Caused by Antipsychotic Medication**

We plan to begin enrollment in the Phase 1 study of our lead selective GR-II antagonist, CORT 108297, in the first quarter of 2010, based on the Investigational New Drug (IND) application we submitted to the FDA in December 2009. The study is a single ascending dose safety and tolerability study in healthy volunteers, which should be completed by year-end 2010. If successful, this study should support advancing CORT 108297 into additional trials evaluating its safety and efficacy in the prevention of weight gain and other metabolic effects caused by antipsychotic medications, a major unmet medical need in a large market.

During 2010 we plan to continue our research and preclinical efforts to advance additional compounds within our three distinct series of selective GR-II antagonists. Based on the published literature, the regulation of cortisol could have applications in a wide array of serious diseases, including diabetes, obesity, hypertension, osteoporosis, Alzheimer's disease, and other neurodegenerative diseases.

#### **CORLUX for Psychotic Depression**

We plan to continue enrolling patients in our Phase 3 trial of CORLUX for the treatment of psychotic depression. As previously announced, we are conducting the trial at eight clinical sites to focus our resources on completion of our NDA and the near-term commercialization of CORLUX for the Cushing's Syndrome indication. With this reduced number of sites, we do not expect data from this trial to be available during 2010.

#### **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 due to a variety of pathologic conditions. 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 US. An estimated 20,000 patients in the US 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 common. Cushing's Syndrome can affect every organ system in the body and can be lethal if not treated effectively. There is no FDA-approved treatment for Cushing's Syndrome.

### **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.

### **About Weight Gain Caused by Antipsychotics**

The group of medications known as atypical antipsychotics, including olanzapine, risperidone, clozapine and quetiapine, are widely used to treat schizophrenia and bipolar disorder. All medications in this group are associated with treatment emergent weight gain of varying degrees and carry warning labels relating to treatment emergent hyperglycemia and diabetes mellitus. Weight gain and alterations in metabolic efficiency have been observed for many years in patients with abnormally high circulating cortisol. There is no FDA-approved treatment for the weight gain associated with the use of antipsychotic medications.

### **About CORLUX**

Corcept's first-generation compound, CORLUX, also known as mifepristone, directly blocks the GR-II (cortisol) receptor and the progesterone receptor. Intellectual property protection is in place to protect important methods of use for CORLUX. Corcept retains worldwide rights to its intellectual property related to CORLUX.

### **About CORT 108297**

CORT 108297 is one of several potent, selective antagonists of the GR-II receptor that we have discovered and for which Corcept owns worldwide intellectual property rights. In *in vitro* binding affinity and functional assays it does not have affinity for the PR (progesterone), ER (estrogen), AR (androgen) or GR-I (mineralocorticoid) receptors.

### **About Corcept Therapeutics Incorporated**

Corcept is a pharmaceutical company engaged in the discovery and development of drugs for the treatment of severe metabolic and psychiatric disorders. The company has two Phase 3 programs ongoing; CORLUX for the treatment of Cushing's Syndrome and CORLUX for the treatment of the psychotic features of psychotic depression. Corcept has also developed an extensive intellectual property portfolio that covers the use of GR-II antagonists in the treatment of a wide variety of psychiatric and metabolic disorders, including the prevention of weight gain caused by the use of antipsychotic medication.

Statements made in this news release, other than statements of historical fact, are forward-looking statements, including, for example, statements relating to Corcept's clinical development and research programs, the timing of the introduction of CORLUX and future product candidates, including CORT 108297, estimates of the timing of enrollment or completion of our clinical trials and the anticipated results of those trials, the ability to create value from CORLUX or other future product candidates and our estimates regarding our capital requirements, spending plans and needs for additional financing. 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 with respect to the cost, rate of spending, completion or success of clinical trials; financial projections may not be accurate; there can be no assurances that Corcept will pursue further activities with respect to the development of CORLUX, CORT 108297, or any of its other selective GR-II antagonists. These and other risk factors are set forth in the Company's SEC filings, all of which are available from our website ([www.corcept.com](http://www.corcept.com)) or from the SEC's website ([www.sec.gov](http://www.sec.gov)). We disclaim any intention or duty to update any forward-looking statement made in this news release.

**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 (Date of earliest event reported): January 5, 2010**

**Corcept Therapeutics Incorporated**

(Exact name of registrant as specified in its charter)

**000-50679**

(Commission File Number)

**Delaware**  
(State or other jurisdiction

of incorporation)

**77-0487658**  
(I.R.S. Employer

Identification No.)

**149 Commonwealth Drive**

Edgar Filing: CORCEPT THERAPEUTICS INC - Form 424B3

**Menlo Park, CA 94025**

**(Address of principal executive offices, with zip code)**

**(650) 327-3270**

**(Registrant's telephone number, including area code)**

**(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 (*see* General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensation Arrangements of Certain Officers**

(b) On January 5, 2010, Corcept Therapeutics Incorporated (the Company) was advised by Edward E. Penhoet, Ph.D., of his decision to resign from the Corcept Board of Directors due to time constraints associated with his appointment as a member of President Obama's Council of Advisors on Science and Technology (PCAST). PCAST is an advisory group comprised of 20 of the nation's leading scientists and engineers who directly advise the President and the Executive Office of the President. PCAST makes policy recommendations in the many areas where understanding of science, technology, and innovation is key to strengthening our economy and forming policy that works for the American people.

Dr. Penhoet has served as a member of the Corcept Board since June 2008. He has served as a Director of Alta Partners, LLP, a venture capital firm, since 2000.

**SIGNATURES**

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.

**CORCEPT THERAPEUTICS INCORPORATED**

Date: January 8, 2010

By: */s/* CAROLINE M. LOEWY  
Caroline M. Loewy  
Chief Financial Officer

-3-