## 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): July 1, 2013

# **CORONADO BIOSCIENCES, INC.**

(Exact Name of Registrant as Specified in Charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-35366 (Commission File Number) 20-5157386 (IRS Employer Identification No.)

24 New England Executive Park, Burlington, MA (Address of Principal Executive Offices) 01803 (Zip Code)

Registrant's Telephone Number, Including Area Code: (781) 652-4500

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:

□ 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))

D Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 8.01. Other Events.

On July 1, 2013, Coronado Biosciences, Inc. issued a press release announcing that it has completed the enrollment of TRUST-I, its phase 2 clinical trial with TSO (Trichuris suis ova or CNDO-201) in 250 Crohn's disease patients. A copy of this press release is attached as Exhibit 99.1.

## Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 Press release issued July 1, 2013.

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.

## CORONADO BIOSCIENCES, INC.

Date: July 1, 2013

/s/ Dale Ritter

Name: Dale Ritter Title: Senior Vice President, Finance

# coronado

## BIOSCIENCES

## CORONADO BIOSCIENCES ANNOUNCES COMPLETION OF ENROLLMENT IN TRUST-I PHASE 2 CLINICAL TRIAL OF TSO FOR CROHN'S DISEASE

Burlington, MA – July 1, 2013 – Coronado Biosciences, Inc. (NASDAQ: CNDO), a biopharmaceutical company focused on the development of novel immunotherapy biologic agents for the treatment of autoimmune diseases and cancer, announced today that it has completed the enrollment of TRUST-I, its phase 2 clinical trial with TSO (*Trichuris suis* ova or CNDO-201) in 250 Crohn's disease patients.

"We are excited to have completed enrollment in our phase 2 TRUST-I trial and we expect to report top-line data in the fourth quarter of 2013," said Dr. Harlan F. Weisman, Coronado's Chairman and CEO. "This is a significant milestone for our TSO program as a potential game changer in the treatment paradigm of Crohn's disease and other autoimmune diseases. This accomplishment continues to demonstrate the strength of our clinical development program as we move closer to completing the first company-sponsored phase 2 trial and meeting our timeline projection for the results of the study."

TRUST-I is a randomized, double-blind, placebo-controlled, U.S. multicenter study designed to evaluate the safety and efficacy of TSO in Crohn's disease. The trial enrolled and randomized 250 patients with moderate-to-severe Crohn's disease to receive either 7500 ova or placebo once every 2 weeks, for 12 weeks. The final number of patients in the trial surpassed the target enrollment of 220 patients to accommodate individuals in the screening process when the trial's enrollment goal was achieved. The primary endpoint for the study is induction of response at 12 weeks, with induction of remission being a key secondary endpoint. Additional study details can be found at www.clinicaltrials.gov.

Coronado's development partner for TSO in Crohn's disease, Dr. Falk Pharma GmbH, is also conducting TRUST-II, a phase 2, doubleblind, randomized, placebo-controlled, multi-center study in Europe to evaluate the efficacy and safety of three different dosages of TSO in active Crohn's disease. The results from a second interim analysis are expected in the second half of 2013.

## About TSO

TSO (*Trichuris suis* ova or CNDO-201), the microscopic eggs of the porcine whipworm, is a novel, orally administered, natural immunomodulator that regulates T-Cells and pro-inflammatory cytokines. The use of TSO as a therapeutic is based on the "hygiene hypothesis" and numerous animal and human studies. TSO was chosen as the biological agent of choice because it is not a human pathogen, and is spontaneously eliminated from the body within several weeks after dosing.

In February 2012, the company reported positive results from a phase 1 clinical study of TSO in patients with Crohn's disease, where TSO was shown to be safe and well tolerated. The phase 1 trial was a multi- center, sequential dose, dose-escalation, double-blind, placebo-controlled study of 36 patients with Crohn's disease.

Multiple investigator-sponsored clinical trials of TSO for the treatment of Crohn's disease, ulcerative colitis and multiple sclerosis have been completed, in which TSO demonstrated benefit with regard to

accepted outcome measurements of remission of disease, and was shown to be well tolerated. In an open-label clinical trial with 29 patients reported in GUT in January 2005, TSO was shown to induce clinical remission in over 72 percent of patients with Crohn's disease after 24 weeks of treatment using the Crohn's Disease Activity Index as the primary outcome variable. As reported in the American Journal of Gastroenterology in April 2005, in a double-blind, randomized placebo-controlled trial in 54 patients with ulcerative colitis, TSO was shown to produce statistically significantly more responders than those treated with placebo (43.3% vs. 16.7%, p=.04).

### **About Coronado Biosciences**

Coronado Biosciences is engaged in the development of novel immunotherapy biologic agents. The company's two principal pharmaceutical product candidates in clinical development are: TSO (*Trichuris suis* ova or CNDO-201), a biologic for the treatment of autoimmune diseases, such as Crohn's disease, ulcerative colitis and multiple sclerosis; and CNDO-109, a biologic that activates natural killer (NK) cells, for the treatment of acute myeloid leukemia (AML), multiple myeloma and solid tumors. For more information, please visit <u>www.coronadobiosciences.com</u>.

#### Forward-Looking Statements

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to the company's product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated are: risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; our ability to attract, integrate and retain key personnel; our dependence on third party suppliers; and competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

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