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): October 14, 2013

CORONADO BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware (State or Other Jurisdiction of Incorporation)

24 New England Executive Park, Burlington, MA

(Address of Principal Executive Offices)

001-35366 (Commission File Number) 20-5157386 (IRS Employer Identification No.)

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))

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 October 14, 2013, Coronado Biosciences, Inc. issued a press release announcing top-line results from Trust-I, its Phase 2 clinical trial evaluating TSO (Trichuris suis ova or CNDO-201). A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit

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No.	Description

99.1 Press release dated October 14, 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.

Date: October 15, 2013

CORONADO BIOSCIENCES, INC.

/s/ Dale Ritter Dale Ritter, Senior Vice President, Finance

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BIOSCIENCES

CORONADO BIOSCIENCES ANNOUNCES TOP-LINE RESULTS FROM ITS TRUST-I PHASE 2 CLINICAL TRIAL OF TSO FOR THE TREATMENT OF CROHN'S DISEASE

-Company to Host Conference Call Today, October 14, 2013 at 9:00AM ET to Discuss Results

Burlington, MA – October 14, 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, today announced top-line results from TRUST-I, its Phase 2 clinical trial evaluating TSO (Trichuris suis ova or CNDO-201) in 250 patients with moderate-to-severe Crohn's disease.

The TRUST-I study did not meet its primary endpoint of improving response, defined as a 100-point decrease in the Crohn's Disease Activity Index (CDAI), nor the key secondary endpoint of remission, defined as achieving CDAI < 150 points. In the overall patient population, response rate of patients on TSO did not separate from that of placebo. The randomization was stratified by disease activity as measured by CDAI. In the corresponding pre-defined subset analysis, TSO showed a non-significant improved response in patients with CDAI>290. The lack of overall response was driven by higher-than-expected placebo response rate in patients with CDAI<290.

"While we are disappointed with the topline results, we are encouraged to see TSO's effect in patients with CDAI>290. These results support the potential of TSO to regulate the immune system in patients with Crohn's disease, particularly those with higher level of disease severity," said Dr. Harlan F. Weisman, Coronado's Chairman and CEO. "We look forward to further analyzing the data from TRUST-I, along with the anticipated data from Dr. Falk Pharma's TRUST-II study in Crohn's disease, to identify the most appropriate development path for TSO."

TSO was safe and well-tolerated, and adverse events were balanced between the TSO and the placebo group. The most common adverse event reported was abdominal pain and occurred in 11% of both TSO and placebo groups. Detailed trial results will be reported at upcoming medical and scientific meetings.

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 (n=125) or placebo (n=125) once every 2 weeks, for 12 weeks. The primary endpoint for the study is induction of response at 12 weeks, with induction of remission being a key secondary endpoint. Patients who completed the TRUST-I study had the option of enrolling in a 12-week open-label extension trial. All patients in the extension trial receive 7500 ova once every 2 weeks.

Coronado's development partner for TSO in Crohn's disease, Dr. Falk Pharma GmbH, is conducting TRUST-II, a phase 2, double-blind, 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 fourth quarter of 2013.

Conference Call and Webcast Information

Coronado management will discuss the results of this study via conference call and webcast today, October 14, 2013 at 9:00AM ET. To participate in the conference call, please dial 877-312-5413 or 253-237-1511. The conference ID is 86565121.

An audio replay will also be available shortly after the conclusion of the call and will be made available until October 21, 2013. The audio replay can be accessed by dialing 855-859-2056 or 404-537-3406 and entering Event ID 86565121.

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.

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, among others, statements we make regarding the potential of TSO to regulate the immune system in patients with Crohn's disease based on findings from the Phase 2 clinical trial, statements we make regarding clinical development plans for TSO, 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 successfully manufacture TSO in the United States; our dependence on third party suppliers; our ability to attract, integrate, and retain key personnel; 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.

Contact:

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