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): November 7, 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))

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 November 7, 2013, Coronado Biosciences, Inc. issued a press release announcing that it has been informed by Dr. Falk Pharma GmbH ("Falk") that Falk is discontinuing TRUST-II, a Phase 2 study of TSO (*Trichuris suis* ova or CNDO-201) in patients with active Crohn's disease. 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

No. Description

99.1 Press release dated November 7, 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: November 7, 2013

CORONADO BIOSCIENCES, INC.

/s/ Harlan F. Weisman, M.D. Harlan F. Weisman, M.D., Chairman and Chief Executive Officer

coronado

BIOSCIENCES

CORONADO BIOSCIENCES ANNOUNCES INDEPENDENT DATA MONITORING COMMITTEE RECOMMENDATION TO DISCONTINUE FALK PHASE 2 Trial of TSO in CROHN'S DISEASE

Burlington, MA – November 6, 2013 – Coronado Biosciences, Inc. (NASDAQ: CNDO), a biopharmaceutical company focused on the development of novel immunotherapy agents for the treatment of autoimmune diseases and cancer, today announced that it has been informed by Dr. Falk Pharma GmbH (Falk), its development partner, that an Independent Data Monitoring Committee (IDMC) has conducted a second interim analysis of clinical data from approximately 240 patients who have completed 12 weeks of treatment in Falk's Phase 2 clinical trial in Europe evaluating *Trichuris suis* ova (TSO) in Crohn's disease. The committee recommended that the trial be stopped due to lack of efficacy and noted no safety concerns. Falk has advised Coronado that it is adopting the committee's recommendations and discontinuing the study.

"We are not surprised by these results, given the disappointing data from our TRUST-I study," said Dr. Harlan F. Weisman, Coronado's Chairman and CEO. "We believe TSO has therapeutic potential in other diseases and will continue to work diligently to advance its development for the treatment of autoimmune diseases and to develop CNDO-109 for the treatment of cancer."

The Falk trial, also known as the TRUST-II study, is a double-blind, randomized, placebo-controlled, multi-center Phase 2 study to evaluate the efficacy and safety of three different dosages of oral TSO in patients with active Crohn's disease. The purpose of the interim analysis was to verify the assumptions of the sample size calculation or to recalculate sample size based on the effect size estimations of the interim analysis and determine whether to discontinue the study due to futility.

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 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; our ability to attract, integrate and retain key personnel; 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 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.

Contact:

Lucy Lu, MD, Executive Vice President & Chief Financial Officer Coronado Biosciences, Inc. 781-652-4525; ir@coronadobio.com