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): December 9, 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

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

01803 (Zip Code)

(Address of Principal Executive Offices)

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 December 9, 2013, Coronado Biosciences, Inc. issued a press release announcing that it has submitted an Investigational New Drug application to the U.S. Food and Drug Administration to begin a Phase 2 clinical trial of TSO (*Trichuris suis* ova or CNDO-201) for the treatment of moderate to severe chronic plaque psoriasis. 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 December 9, 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: December 9, 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 IND SUBMISSION FOR TSO FOR THE TREATMENT OF MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS

Burlington, MA – December 9, 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 submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration to begin a Phase 2 clinical study of *Trichuris suis* ova (TSO) for the treatment of moderate to severe chronic plaque psoriasis.

"We believe psoriasis represents a medical need where a natural immune system regulator like TSO may provide considerable sustained relief to those with the condition," said Dr. Harlan F. Weisman, Coronado's Chairman and CEO. "Psoriasis is a logical human clinical model for immune-mediated diseases because clear, validated and objective endpoints can be established and there are low placebo rates. As such, we believe it is a good disease model in which to determine the potential immunomodulatory effect of TSO." Coronado is also pursuing the trial based upon encouraging preliminary results from open-label investigator-sponsored trials at two U.S. centers that are currently evaluating multiple doses of TSO in patients with psoriasis.

Coronado's proposed Phase 2 trial is a U.S. multi-center, dose-ranging study that will use the Psoriasis Area and Severity Index score from week 0 to week 12 to assess efficacy. Coronado intends to begin enrolling patients in the trial during the first quarter of 2014 if the IND application is approved.

About Psoriasis

Psoriasis (psoriasis vulgaris) is a chronic inflammatory skin disease characterized by red, scaly, raised plaques. The disease process is driven by T-cell infiltration and associated elevation in cytokine levels leading to increased cell division and aberrant differentiation, resulting in the psoriatic phenotype. Plaque psoriasis has a worldwide prevalence of 2-3%, and is a chronic, recurrent skin condition with varying degrees of severity. While many patients with mild disease are able to control psoriasis symptoms with topical medications alone, patients with moderate to severe disease usually require treatment with systemic agents to achieve good clearance. These systemic agents are usually well tolerated, but can have potentially significant side effects including organ toxicity, infection, malignancy, and teratogenicity that limit their usefulness in the long-term management of psoriasis. Despite all the available treatments, there is still a need for therapies that will provide high continuous efficacy, improved safety, and a more convenient route of administration to maximize compliance and satisfaction with treatment, leading to decreased burden of the disease.

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 immune-mediated diseases, such as psoriasis, Crohn's disease, ulcerative colitis and multiple sclerosis; and CNDO-109, a biologic that activates natural killer cells, for the treatment of acute myeloid leukemia, 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; <u>ir@coronadobio.com</u>