# 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 1934**

**Date of Report (Date of earliest event reported): April 24, 2012**

# Coronado Biosciences, Inc.

**(Exact name of registrant as specified in charter)**

**Delaware**
**(State or other jurisdiction of incorporation)**

| **Delaware** | **001-35366** | **20-5157386** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| **15 New England Executive Park, Burlington, MA** | **01803** |
|---|---|
| **(Address of Principal Executive Offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: (781) 238-6621**

**(Former Name or Former Address, is Changed Since Last Report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of 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(b) under the Exchange Act (17 CFR 240.14a-12(b))

☐ 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 April 24, 2012, Coronado Biosciences, Inc. announced that it received from Dr. Falk Pharma GmbH ("Falk"), its development partner, a recommendation from the independent data monitoring committee that conducted an interim analysis (blinded to Falk) of clinical data from the initial 120 patients to continue Falk's Phase 2 clinical trial in Europe evaluating *Trichuris Suis* ova (TSO) in Crohn's disease. The committee noted no safety concerns and a positive efficacy trend in its recommendation that the study continue. The press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

99.1 Press Release dated April 24, 2012

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CORONADO BIOSCIENCES, INC.

By: /s/ Bobby W. Sandage
Name: Bobby W. Sandage, Jr.
Title: President and Chief Executive Officer

Dated: April 24, 2012

**Exhibit 99.1**

**Coronado Biosciences Announces Independent Data Monitoring Committee Recommendation to Continue Falk Phase 2 Trial of TSO in Crohn's Disease**

No Safety Issues Noted

Burlington, MA – April 24, 2012 – 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 received from Dr. Falk Pharma GmbH (Falk), its development partner, a recommendation from the independent data monitoring committee that conducted an interim analysis (blinded to Falk) of clinical data from the initial 120 patients to continue Falk's Phase 2 clinical trial in Europe evaluating *Trichuris suis* ova (TSO) in Crohn's disease. The committee noted no safety concerns and a positive efficacy trend in its recommendation that the study continue.

Falk has advised they are adopting the committee's recommendations to increase the sample size and to conduct a subsequent interim analysis at the time the trial reaches approximately 250 patients.

"We are pleased that the committee recommended continuation of the Falk study and noted a positive efficacy trend and no safety concerns associated with TSO," said Dr. Bobby W. Sandage, Jr., Coronado's President and Chief Executive Officer. "We support and concur with Falk's decisions and look forward to the further results of their trial. We currently expect the additional analysis to occur in mid-2013. In the meantime, pending final discussions with the FDA, we are on track to commence our Phase 2 clinical trial in the United States this quarter, evaluating two doses of TSO versus placebo in approximately 200 patients with Crohn's disease."

The Falk trial, entitled *Double-blind, randomised, placebo-controlled, multi-centre phase II study to evaluate the efficacy and safety of three different dosages of oral Trichuris suis ova (TSO) suspension in active Crohn's disease*, is being conducted in Europe and was initially expected to enroll approximately 212 patients and to evaluate three different dosages of TSO versus placebo. The interim analysis aimed to verify the assumptions of the sample size calculation or to recalculate sample size based on the effect size estimations of the interim analysis, as well as evaluating whether to discontinue one or two of the active treatment arms. For more information, please visit www.clinicaltrials.gov.

**About TSO**

TSO, 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.

The Company recently 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% 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) and solid tumors. For more information, please visit www.coronadobiosciences.com.

**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 risks relating to the results of research and development activities, uncertainties relating to preclinical and clinical testing, 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 Information:**

Investor Relations
Lucy Lu, MD, Executive Vice President & Chief Financial Officer
Coronado Biosciences, Inc.
781-238-6619; ir@coronadobio.com

Marcy Nanus, Vice President
The Trout Group, LLC.
646-378-2927; mnanus@troutgroup.com

Media Relations
Dennis S. Dobson Jr., CEO
Dobson Media Group
203-258-0159; dobsonpr@erols.com