# 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): December 21, 2012

# Coronado Biosciences, Inc.

(Exact name of registrant as specified in charter)

Delaware

(State or other jurisdiction of incorporation)

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

(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 1.01 Entry into a Material Definitive Agreement.

On December 21, 2012, we and Ovamed GmbH ("Ovamed") entered into a Second Amendment and Agreement (the "Second Amendment") amending certain provisions of the Exclusive Sublicense Agreement (the "Ovamed License") and the Manufacturing and Supply Agreement, each as previously amended, between us and Ovamed, and providing for certain additional agreements between the parties. Pursuant to the Second Amendment, our exclusive license from Ovamed in North America, South America, and Japan (the "Territory") was amended to include an exclusive license to make and have made product containing TSO (Trichuris suis ova or CNDO-201) (the "Product") for the Territory (the "Manufacturing License") and Ovamed's exclusive supply rights in the Territory will terminate once we establish an operational manufacturing facility in the United States. The Ovamed License now terminates 15 years from first commercial sale in the United States, subject to earlier termination under certain circumstances.

In exchange, we agreed to pay Ovamed a total of \$1,500,000 in three equal installments of \$500,000 each in December 2014, 2015, and 2016. Additionally, in lieu of product supply payments that would have been payable to Ovamed as the exclusive supplier, we will pay Ovamed a "Manufacturing Fee" for product manufactured and sold by us. The Manufacturing Fee will consist of the greater of (i) a royalty on net sales of Product manufactured by us or (ii) a specified amount per unit (the "Transfer Fee Component"). The Manufacturing Fee is subject to certain adjustments and credits and we have a right to reduce the Transfer Fee Component by paying Ovamed an agreed amount within ten business days following FDA approval of a Biologics License Application approving the manufacturing, marketing and commercial sale of Product in the United States and an additional amount within ninety days after the end of the first calendar year in which net sales in the Territory exceed an agreed amount.

Simultaneously with the execution of the Second Amendment, Ovamed assigned to us a five-year property lease in Woburn, MA for space in which we intend to establish a TSO manufacturing facility. Build out and site preparation of the manufacturing facility are planned to commence in early 2013 and continue throughout the year to enable production of phase 3 supplies of TSO. Ovamed agreed to assist us in establishing this facility and the Second Amendment contemplates that we and Ovamed would act as second source suppliers to each other at agreed transfer prices pursuant to a Second Source Agreement to be negotiated between the parties.

On December 27, 2012, we issued a press release announcing the acquisition of the manufacturing rights to TSO for the territory from Ovamed. A copy of the press release is included as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

## Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press Release dated December 27, 2012.

# **SIGNATURES**

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

CORONADO BIOSCIENCES, INC.

By: /s/ Dale Ritter

Name: Dale Ritter

Title: Chief Accounting Officer

Dated: December 27, 2012



# CORONADO BIOSCIENCES ACQUIRES TSO MANUFACTURING RIGHTS FROM OVAMED

Burlington, MA – December 27, 2012 – 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 the acquisition of manufacturing rights to its lead product TSO (*Trichuris suis* ova or CNDO-201) from Ovamed GmbH, for North America, South America, and Japan, Coronado's licensed territory. As part of the transaction, Coronado entered into a lease agreement to establish a manufacturing facility in Woburn, MA to produce TSO.

Coronado entered into amendments to its existing license and supply agreements with Ovamed expanding Coronado's exclusive license to include TSO manufacturing rights in Coronado's territory and terminating Ovamed's exclusive supply rights once Coronado's planned manufacturing facility is operational. Build out and site preparation of the manufacturing facility are planned to commence in early 2013 and continue throughout the year to enable production of phase 3 supplies of TSO. Ovamed agreed to provide assistance in establishing the manufacturing facility and to continue to supply Coronado with clinical supplies until the facility is operational. Ovamed retains TSO manufacturing rights outside Coronado's territory, and the amendments contemplate that Coronado and Ovamed would act as second source suppliers to each other at agreed transfer prices.

Under the amendments, Coronado will pay Ovamed a total of \$1.5M in three equal installments in 2014-2016, and, in lieu of product supply payments that would have been payable to Ovamed as the exclusive supplier, certain fees for product manufactured and sold by Coronado.

"The acquisition of exclusive manufacturing rights for TSO in our territories is an integral piece of our strategy for our lead product in development, and enables us to control the development and commercialization of the product," said Dr. Bobby W. Sandage, Jr., President and CEO of Coronado. "The amended agreement is not only cost effective, but also reduces product risk by having two qualified suppliers of TSO. We continue to move forward with our TRUST-I trial, the company's phase 2 Crohn's study, as well as our support for the recently initiated and planned investigator-initiated clinical trials evaluating TSO in a broad range of autoimmune diseases."

# **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. In August 2012, Coronado initiated TRUST- I (TRichUris Suis ova Trial), a phase 2 clinical trial of TSO in patients with Crohn's disease in the United States, which is expected to be completed in the second half of 2013.

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 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:**

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

Marcy Nanus, Vice President The Trout Group, LLC.

646-378-2927; <u>mnanus@troutgroup.com</u>

Susan Forman
Dian Griesel Inc.
212-825-3210; susan@dgicomm.com