# 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): May 15, 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.)

15 New England Executive Park, Burlington, MA (Address of Principal Executive Offices)

01803 (Zip Code)

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

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

ck the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of 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 2.02. Results of Operations and Financial Condition.

On May 15, 2012, we issued a press release containing certain financial results for our first quarter ended March 31, 2012. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

As provided in General Instruction B.2 of SEC Form 8-K, such information shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

#### No. Description

99.1 Press Release dated May 15, 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/ Dale Ritter

Name: Dale Ritter

Title: Senior Vice President, Finance

Dated: May 15, 2012

## Exhibit Index

No. Description

99.1 Press Release dated May 15, 2012

#### Coronado Biosciences Reports Financial Results for the First Quarter Ended March 31, 2012

Burlington, MA – May 15, 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 its financial results for the first quarter ended March 31, 2012.

Coronado reported a net loss of \$6.6 million, or \$0.35 per share, for the first quarter of 2012 compared to a net loss of \$22.5 million, or \$4.71 per share, for the first quarter of 2011. Included in the net loss for the first quarter of 2011 was an in-process research and development (R&D) expense of \$20.7 million in connection with the acquisition of the TSO (*Trichuris suis* ova or CNDO-201) related assets.

Research and development expenses were \$4.6 million for the three months ended March 31, 2012 compared to \$1.2 million for the three months ended March 31, 2011. General and administrative (G&A) expenses totaled \$2.0 million for the three months ended March 31, 2012 compared to \$0.6 million for the three months ended March 31, 2011. In the three months ended March 31, 2012, R&D included expenses related to the TSO and CNDO-109 clinical programs, and G&A included expenses related to the company's infrastructure growth, increased business activity and becoming a publicly-traded entity. At March 31, 2012, Coronado's cash and cash equivalents totaled \$17.7 million.

In April 2012, Coronado 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 in Falk's Phase 2 trial evaluating TSO in Crohn's disease. "The Company is pleased with this development and we are using the information and recommendations derived from the interim analysis to finalize the design of our planned Phase 2 trial of TSO in Crohn's disease," said Dr. Bobby W. Sandage, Jr., Coronado's President and CEO. "Because the committee noted a positive efficacy trend and no safety concerns in addition to its sample size recommendations, we are planning dosage and sample size adjustments to maximize the probability of observing a TSO-treatment effect. We have been focused on moving our drug candidates into large-scale clinical trials. Pending final discussions with the FDA, we currently plan to commence the trial in the third quarter of 2012 and to have top-line study results in the second half of 2013."

#### Recent Corporate Highlights:

- Signed a Collaboration Agreement with Falk and OvaMed GmbH (OvaMed) for the development of TSO for Crohn's disease and obtained exclusive rights and licenses under certain Falk patent rights, pre-clinical data and clinical data from Falk's clinical trials of TSO in Crohn's disease, including an ongoing Phase 2 clinical trial, for use in North America, South America and Japan
- Hosted an Analyst & Investor Event in New York City with key opinion leaders in the fields of immunology, gastroenterology and oncology
- Strengthened senior management team through appointment of Lucy Lu, M.D., as Executive Vice President and Chief Financial Officer and the promotion of Karin Hehenberger, M.D., Ph.D., to Executive Vice President and Chief Medical Officer

#### Recent Scientific Highlights:

- Announced Phase 1 clinical trial results for TSO in Crohn's disease that demonstrated TSO is safe and well tolerated; oral
  presentation, entitled "Evaluation of Safety and Tolerability of *Trichuris suis* ova in Patients with Crohn's Disease," presented at
  the 8th International Congress on Autoimmunity
- Reported an Independent Data Monitoring Committee recommendation to continue the Falk Phase 2 Trial of TSO being
  conducted in Europe, noting no safety concerns and a positive efficacy trend; Falk adopted 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
- Filed IND with the FDA for CNDO-109 to treat acute myeloid leukemia (AML); on track to initiate a Phase 1/2 allogeneic clinical trial for the treatment of patients with high risk AML in first complete remission in the second half of 2012

#### Conference Call and Webcast Information

Coronado management will review its first quarter financial results and development programs via conference call and webcast today at 8:30 AM ET. To participate in the conference call, please dial (877) 312-5413 (toll free from the US and Canada), or (253) 237-1511 (for international callers). Investors may also access a live audio webcast of the call at <a href="https://www.coronadobiosciences.com">www.coronadobiosciences.com</a> on the Events & Webcasts page.

A replay of the webcast will be available shortly after the conclusion of the call. The webcast archive will remain available for one year. An audio replay will also be available shortly after the conclusion of the call and will be made available until May 23, 2012. The audio replay can be accessed by dialing (855) 859-2056 (toll free from the US and Canada), or (404) 537-3406 (for international callers) and entering Event ID 80148097.

#### **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 <a href="https://www.coronadobiosciences.com">www.coronadobiosciences.com</a>.

#### 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

## CORONADO BIOSCIENCES, INC. AND SUBSIDIARY

(A development stage enterprise)

## **Consolidated Balance Sheets**

## (\$ in thousands)

(Unaudited)

	March 31, 2012	December 31, 2011
ASSETS		
Cash and cash equivalents	\$17,735	\$ 23,160
Prepaid and other current assets	308	215
Total Assets	\$18,043	\$ 23,375
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	\$ 3,843	\$ 3,493
Debt	750	750
Total Liabilities	4,593	4,243
Stockholders' Equity	13,450	19,132
Total Liabilities and Stockholders' Equity	\$18,043	\$ 23,375

## CORONADO BIOSCIENCES, INC. AND SUBSIDIARY

(A development stage enterprise)

## **Consolidated Statements of Operations**

## (\$ in thousands except for share and per share amounts)

(Unaudited)

		For the three months ended March 31,		
		2012	2011	
Operating expenses:				
Research and development	\$	4,581	\$ 1,24	6
General and administrative		2,000	59	3
In-process research and development			20,70	6
Loss from operations		(6,581)	(22,54	5)
Interest income		44	1	9
Interest expense		(19)	(1	<u>7</u> )
Net loss	\$	(6,556)	\$ (22,54	3)
Basic and diluted net loss per common share	\$	(0.35)	\$ (4.7	1)
Weighted average common shares outstanding—basic and diluted	13	3,604,245	4,791,10	2