# 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): November 14, 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) 238-6621

15 New England Executive Park, Burlington, MA 01803 (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 2.02. Results of Operations and Financial Condition.

On November 14, 2012, we issued a press release containing certain financial results for our third quarter ended September 30, 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 November 14, 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: November 14, 2012

# No. Description

99.1 Press Release dated November 14, 2012



# BIOSCIENCES

#### Coronado Biosciences Reports Financial Results for the Third Quarter Ended September 30, 2012

Burlington, MA – November 14, 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 its financial results for the third quarter ended September 30, 2012.

Coronado reported net losses of \$5.9 million and \$18.9 million for the three and nine months ended September 30, 2012, respectively, compared to net losses of \$3.4 million and \$29.6 million for the three and nine months ended September 30, 2011, respectively. Included in the net loss for the nine months ended September 30, 2011 was a charge of \$20.7 million for in-process research and development expense related to the acquisition of TSO (*Trichuris suis* ova or CNDO-201).

Research and development expenses were \$3.8 million and \$12.9 million for the three and nine months ended September 30, 2012, respectively, compared to \$1.8 million and \$5.1 million for the three and nine months ended September 30, 2011, respectively. The increases in research and development expenses relate primarily to increased clinical activities in the TSO development program.

General and administrative expenses totaled \$2.1 million and \$6.0 million for the three and nine months ended September 30, 2012, respectively, compared to \$1.8 million and \$4.0 million for the three and nine months ended September 30, 2011, respectively. The increases in general and administrative expenses included expenses primarily related to the company's infrastructure growth and increased business activity. At September 30, 2012, Coronado's cash totaled \$47.5 million.

"During this quarter we initiated TRUST-I, a phase 2 clinical trial of TSO for Crohn's disease in the U.S., which we expect to complete in the second half of 2013. Our development partner, Dr. Falk Pharma, expects its phase 2 TRUST-II clinical trial of TSO for Crohn's disease will have an additional interim analysis in mid-2013. Additionally, we are on schedule to start screening patients for the phase 1/2 trial of CNDO-109 in acute myeloid leukemia before the end of this year," said Dr. Bobby W. Sandage, Jr., Coronado's President and CEO. "Importantly, we also secured a \$15 million loan from Hercules Technology Growth Capital to help support the development of TSO and CNDO-109, our two novel biologic product candidates. This capital strengthens our balance sheet and provides sufficient cash to fund operations into the first quarter of 2014."

Recent Corporate and Scientific Highlights:

- Initiated TRUST-I Phase 2 Clinical Trial of TSO for the Treatment of Crohn's Disease
- Secured \$15 Million Loan from Hercules Technology Growth Capital
- Initiation of Investigator-initiated Study Evaluating TSO in Ulcerative Colitis
- · Initiation of Investigator-initiated Study Evaluating TSO in Autism Spectrum Disorders
- Granted First U.S. Patent Covering CNDO-109
- · Elected Dr. Harlan Weisman to Board of Directors

#### Conference Call and Webcast Information

Coronado management will review its third 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 <u>www.coronadobiosciences.com</u> 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 November 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 34470774.

#### **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:

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# CORONADO BIOSCIENCES, INC. AND SUBSIDIARY

# (A development stage enterprise)

# **Consolidated Balance Sheets**

# (\$ in thousands)

# (Unaudited)

	September 30, 2012	December 31, 2011	
ASSETS			
Cash and cash equivalents	\$ 47,478	\$ 23,160	
Prepaid and other current assets	517	215	
Other	90		
Total Assets	\$ 48,085	\$ 23,375	
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities	\$ 4,465	\$ 3,493	
Debt	14,094	750	
Other	398		
Total Liabilities	18,957	4,243	
Stockholders' Equity	29,128	19,132	
Total Liabilities and Stockholders' Equity	\$ 48,085	\$ 23,375	

# CORONADO BIOSCIENCES, INC. AND SUBSIDIARY

# (A development stage enterprise)

# **Consolidated Statements of Operations**

# (\$ in thousands except for share amounts)

# (Unaudited)

	For the three months ended September 30,				For the nine months ended September 30,			
		2012		2011		2012		2011
Operating expenses:								
Research and development	\$	3,777	\$	1,753	\$	12,893	\$	5,141
General and administrative		2,054		1,778		5,984		3,965
In-process research and development						_		20,706
Loss from operations		(5,831)		(3,531)		(18,877)		(29,812)
Interest income		79		70		152		111
Interest expense		(183)		(19)		(220)		(55)
Warrant expense				115				115
Net loss		(5,935)		(3,365)		(18,945)		(29,641)
Common Stock dividend to Series A Convertible Preferred								
Stock						_		(5,861)
Net loss attributed to Common Stockholders	(\$	5,935)	(\$	3,365)	(\$	18,945)	(\$	35,502)
Basic and diluted net loss per common share	(\$	0.24)	(\$	0.48)	(\$	0.91)	(\$	6.02)
Weighted average common shares outstanding—basic and diluted	_24	1,375,749	7,	028,059	20	),738,007	_5	,897,462