

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): May 14, 2014

CORONADO BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in Charter)

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**

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))
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Item 8.01. Other Events.

On May 14, 2014, Coronado Biosciences, Inc. issued a press release announcing its initiation of a Phase 2A clinical study of TSO (*Trichuris suis* ova or CNDO-201) in pediatric patients with autism spectrum disorder. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|------------------------------------|
| 99.1 | Press release issued May 14, 2014. |

SIGNATURES

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.

CORONADO BIOSCIENCES, INC.

Date: May 14, 2014

/s/ Lucy Lu, M.D.

Lucy, Lu, M.D.

Executive Vice President and Chief Financial
Officer



CORONADO BIOSCIENCES INITIATES PHASE 2A CLINICAL STUDY OF TSO IN PEDIATRIC PATIENTS WITH AUTISM SPECTRUM DISORDER

Burlington, MA – May 14, 2014 – Coronado Biosciences, Inc. (NASDAQ: CNDO) today announced that it has initiated a Phase 2a clinical trial of TSO (*Trichuris suis* ova or CNDO-201) for the treatment of pediatric patients with autism spectrum disorder (ASD) at multiple centers in the United States.

“We are excited to begin this study,” said Dr. Lindsay A. Rosenwald, Chairman, President and CEO of Coronado. “Data from this study will greatly expand our understanding of TSO’s clinical usefulness in pediatric patients with ASD, an indication with a great unmet need in medicine today.”

The study is a randomized, double-blind, placebo-controlled crossover study designed to evaluate the safety and efficacy of TSO in pediatric patients with ASD. Approximately 20 ASD patients in the age range of 5 to 17 will be enrolled and randomized to receive either TSO or placebo once every 2 weeks, for 16 weeks, followed with a 4 week washout and the opposite treatment for 16 weeks. The primary endpoint for the study is Aberrant Behavior Checklist – Irritability subscale (ABC-I) and the key secondary endpoint is Children’s Yale-Brown Obsessive Compulsive Scale Modified for Pervasive Developmental Disorders (CYBOCS-PDD). Additional study details can be found at www.clinicaltrials.gov.

About Autism Spectrum Disorder

Autism spectrum disorder and autism are both general terms for a group of complex disorders of brain development. These disorders are characterized by three core symptoms: difficulties in social interaction, verbal and nonverbal communication and repetitive behaviors. Autism statistics from the U.S. Centers for Disease Control and Prevention identify approximately 1 in 68 American children as on the autism spectrum. Autism Speaks, the world’s leading autism science and advocacy organization, announced in March 2012 preliminary results of new research that estimates autism costs society \$126 billion per year in the U.S.

About Coronado Biosciences

Since inception, Coronado Biosciences has been a biopharmaceutical company involved in the development of novel immunotherapy agents for the treatment of autoimmune diseases and cancer, namely CNDO-201 or *Trichuris suis* ova (TSO) and CNDO-109. As part of its growth strategy, the Company plans to identify, evaluate and potentially in-license, acquire or invest in pharmaceutical and biotechnology products, technologies and/or companies. Coronado may also from time to time consider financing existing or later-acquired products, technologies or companies through partnerships, joint ventures, direct financings and/or public or private spin-outs.

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 our growth strategy and 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; uncertainties relating to preclinical and clinical testing; risks related to our growth strategy; our dependence on third party suppliers; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; our ability to attract, integrate, and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; 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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