

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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FORM 8-K

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CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 14, 2014

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**CORONADO BIOSCIENCES, INC.**

(Exact Name of Registrant as Specified in Charter)

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**Delaware**

(State or Other Jurisdiction  
of Incorporation)

**001-35366**

(Commission File Number)

**20-5157386**

(IRS Employer  
Identification No.)

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**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.**

Attached hereto as Exhibit 99.1 and incorporated herein by reference is a presentation that Coronado Biosciences, Inc. plans to use with various investors and analysts.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Presentation of April 2014.

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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: April 14, 2014

/s/ Lucy, Lu, M.D.

Lucy, Lu, M.D.

Executive Vice President and Chief Financial Officer

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# coronado

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BIOSCIENCES

NASDAQ: CNDO

**Lindsay A. Rosenwald, MD**  
*Chairman, President and CEO*

April 2014

# Forward-Looking Statements

Statements in this presentation that are not descriptions of historical facts are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. We have attempted to identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," or "will" or the negative of these terms or other comparable terminology. 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: our growth strategy; results of research and development activities; uncertainties relating to preclinical and clinical testing; 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 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 update or revise any statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances after the date of this presentation.

# Value Proposition

- » Experienced management team and board of directors
  - In both drug development and business development
  - Dedicated to maximizing **shareholder** value
- » Business development expertise
  - Products and technologies acquisitions and licensing
  - Investment and spin-out opportunities
  - Creative financing solutions
- » Two **biologic product candidates** in clinical stage development
  - Focused on autoimmune diseases and cancer immunotherapy
  - Strong proprietary position

# Key Board Members and Management

**Lindsay A. Rosenwald, MD**  
**Chairman, President and CEO**

- » Prolific and successful investor in the life sciences industry for over 20 years previously as Chairman of Paramount BioCapital
- » Co-Portfolio Manager and Partner of Opus Point Partners

**Michael S. Weiss**  
**Executive Vice-Chairman, Strategic Development**

- » Co-Portfolio Manager and Partner of Opus Point Partners, LLC (since 2009)
- » Executive Chairman, Interim CEO and President of TG Therapeutics
- » Previously Chairman and CEO of Keryx Biopharmaceuticals

**Eric K. Rowinsky, MD**  
**Co-Vice Chairman**

- » World renown oncologist, former CMO at ImClone, board of Biogen/Idex
- » Chief Medical Officer and Head of Research and Development; Executive Vice President at Stemline Therapeutics

**Lucy Lu, MD**  
**EVP & Chief Financial Officer**

- » Former Senior Analyst at Citi Investment Research
- » Over 10 years of biotech equity research experience

**George C. Avgerinos, PhD**  
**Sr. VP, Biologics Operations**

- » Former Divisional VP, Global Process and Manufacturing Sciences, Abbvie
- » Over 30 years experience in biopharmaceutical process development including Humira™ process and manufacturing

# Business Development Strategies

- » Products and technologies
  - We intend to pursue product and technology acquisitions and licenses.
- » Investment opportunities
  - We may make controlling and non-controlling investments in companies with proprietary products and/or technologies where we believe shareholder value will be enhanced, while preserving capital and strength of our balance sheet.
- » Spin-out opportunities
  - From time to time we may spin out new companies based on current and new technologies and products that we develop, license or acquire.



## TSO: *Trichuris suis ova* (CNDO-201)

- » A biologic comprising the microscopic eggs of the porcine whipworm
- » A novel approach to treat immune-mediated diseases based on the science of the “Hygiene Hypothesis”
- » Favorable tolerability and safety profile
  - Non-human parasite
  - Transient exposure in humans
  - Does not multiply in human host
  - No systemic phase
  - No direct transmission
  - Oral; taken once every 2 weeks
  - Clear liquid, odorless, tasteless



# TSO Phase 2 Crohn's Disease Studies- Negative Topline Announced 4Q13

## TRUST - I

- » 12 week study
  - TSO 7500 or placebo
  - N=250
    - CDAI = 220-450
    - The randomization was stratified by disease activity as measured by CDAI
- » Outcome – Did NOT meet overall primary endpoint of response

## TRUST - II

- » 12 week, dose ranging study
  - TSO 250, 2500, 7500 or placebo
  - N=240
    - CDAI = 220-350
- » Outcome – Discontinued post 2<sup>nd</sup> Interim analysis

***What did we learn and where do we go from here?***

***Is there a case for continued investment in TSO? If yes, what is the best path?***

## Is there any reason for optimism?

- » Signal of biological activity and efficacy in TRUST-I subset analysis
  - TSO demonstrated a non-significant improvement in approximately half of the patients with higher disease activity (CDAI>290), a pre-specified subset
    - 56% response rate in TSO arm versus 42% in placebo arm = 14% treatment effect, the magnitude is comparable to approved biologics
    - ***Importantly, this treatment effect is not due to low placebo response rate.*** (The 42% placebo rate is as high as published Crohn's trial)
    - This also demonstrated a systemic effect as all Crohn's drugs work via systemic pathways

## Other TSO Positives

- » Qualified supply of OVA
- » Reference IND with growing safety database
- » Compelling epidemiological “story”
- » Continual anecdotal reports of efficacy in autism
- » Broad academic and “grass roots” interest
  - Reagents developed suitable for clinical development monitoring
- » Increased awareness of difficulty to demonstrate TSO efficacy in established immune-mediated diseases versus potential to alter outcomes during immune development
  - Pediatric patients have malleable immune systems

# TSO Rehabilitation

- » Multiple step plan to re-gain, restore and reward investor confidence
- » Re-focus on pediatric indication with high unmet medical need that will drive investor value
  - Autism
- » Other indications we may be interested in
  - Food allergy
  - Eosinophilic esophagitis (EE)
  - Celiac disease
- » Will focus on PK/PD, dose, and surrogate markers of biological efficacy in indications with objective outcomes

# Scientific Rationale for TSO for Autism

- » Numerous threads of evidence suggest that Autism is an immune mediated disorder linked to the hygiene hypothesis (HH)
  - Gene – environment mismatch is likely responsible for the dramatic increase in incidence
  - Increase parallels that of asthma and other HH conditions
- » Strong evidence for GI issues and immune dysregulation in Autism patients
  - Up to 70% of the patients have current or past GI issues, and endoscopy often shows low level inflammation in these patients
  - Abnormal cytokines, B cell and T cell subsets, and low levels of regulatory cytokines
  - Evidence of activation of the innate immune system in the CNS
  - Maternal autoimmune diagnosis is a recognized risk factor
- » Anecdotal evidence and the interim data from Dr. Hollander's study point to potential efficacy

## Pilot Investigator-Initiated Trials of TSO in Autism

- » Montefiore Medical Center/Albert Einstein College of Medicine: double-blind, placebo-controlled, randomized cross-over study in 10 adult, high functioning autism patients
  - In the first 5 patients that completed the study, a separation from placebo in favor of TSO on three measures of disease that reflect a core feature of autism (the restrictive interests and repetitive behavior domain) was observed in an exploratory analysis
    - Montefiore-Einstein Rigidity Scale (MERS)
    - Repetitive Behavior Scale-Revised (RBS-R) Sameness Scale
    - Social Responsiveness Scale (SRS)-Repetitive Behaviors Scale
  - TSO is well tolerated
  - Consistent with anecdotal data that some patients will benefit from TSO
  - Final results are expected in mid-2014
- » Hadassah-Hebrew University Medical Center: randomized, double-blind, placebo-controlled, 16-week study in 60 pediatric patients
  - Started in April 2014

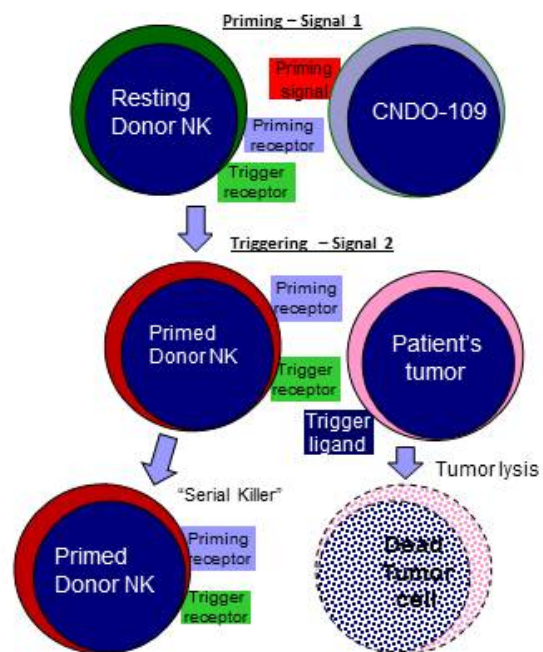
# CNDO-109: Activated Natural Killer Cells

- » NK cells represent the key component of the body's innate immune surveillance system
  - Activation with CNDO-109 does not require toxic cytokines or long-term culture/expansion, and does not change NK cell phenotypes
  - Preclinical activity demonstrated in multiple myeloma, breast cancer, prostate cancer and ovarian cancer
- » Proof of principle established in patients with high-risk refractory or relapsed acute myeloid leukemia (AML)
- » Clinical Development: Initiated Phase 1/2 allogeneic clinical trial for the treatment of relapsed AML
  - Future autologous studies in other tumor types are possible (e.g. multiple myeloma, breast, ovarian and prostate)



# CNDO-109 Mechanism of Action

- » Activated *ex vivo* by tumor cell lysate (CNDO-109)
- » Effective from autologous or allogeneic NK cell source
- » Uniquely positioned in patients with “minimal residual disease”
- » Remains active after freeze/thaw



# CNDO-109 Phase 1 Study in AML

- » Phase 1 investigator sponsored open-label trial
- » To determine the safety of infusion of allogeneic Tumor-activated NK (TaNK) cells after low dose radiotherapy plus chemotherapy in high-risk relapse or refractory AML patients
- » Enrolled 8 AML patients
  - 5 in Complete Remission at time of study entry
  - 1 patient in partial relapse (PR) at time of study entry
- » 3/5 experienced a longer CR than their previous CR, in addition PR patient achieved CR

Kottaridis, *et al.*, ASH 2011

# Financials

Listed on NASDAQ: CNDO

Market Cap *as of 4/7/2014* ~\$78M

Shares Outstanding 44.2M

Additional 2.9 M options and warrants

Cash Position *as of 12/31/2013* \$99.5M

Total Restricted Cash/Debt (03-31-2014) \$14.0M