

**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): January 7, 2013**

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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.)**

**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**

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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 January 2013.

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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: January 7, 2013

/s/ Dale Ritter

Name: Dale Ritter

Title: Senior Vice President, Finance

# coronado

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B I O S C I E N C E S

***Developing Unique Products for Autoimmune  
Diseases and Cancer (NASDAQ: CNDO)***

**Harlan F. Weisman, MD**  
*Chairman & Chief Executive Officer*

January 2013

# 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 risks include those set forth in our SEC filings including, in particular, risks relating to: our ability to attract, integrate and retain key personnel; 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 ability to successfully manufacture TSO in the US; dependence on third party manufacturers; and competition. 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

- » Two **biologic product candidates** in clinical stage development
  - Focused on autoimmune diseases and cancer immunotherapy
  - Strong proprietary position
- » Novel treatments with **broad therapeutic applications** addressing multi-billion dollar markets
- » Four efficacy clinical trials completed and multiple additional trials ongoing
  - **TSO**: *Trichuris suis ova* (CNDO-201) in Crohn's Disease, Ulcerative Colitis (UC) and Multiple Sclerosis (MS)
  - **CNDO-109**: Tumor Activated NK Cells in relapsed Acute Myeloid Leukemia (AML)
- » Experienced management team and board of directors

# Coronado Pipeline Overview

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

Indication	Pre-Clinical	Phase 1	Phase 2a*	Phase 2	Phase 3
Crohn's Disease	→			→	
Ulcerative Colitis	→			→ 1Q2013	
Multiple Sclerosis	→				
Autism	→				
Psoriasis	→	→ 1Q2013	→		
Type-1 Diabetes	→	→ 1H2013	→		
Psoriatic Arthritis	→	→ 1H2013	→		
Rheumatoid Arthritis	→	→ 1H2013	→		

## CNDO-109 (Tumor-Activated Natural Killer Cells)

Acute Myeloid Leukemia	→				
Multiple Myeloma	→	→ 2H2013	→		

\* TSO Phase 2a studies being conducted as Investigator-Initiated Studies; CNDO-109 Phase 2a AML study is a Phase 1/2 study

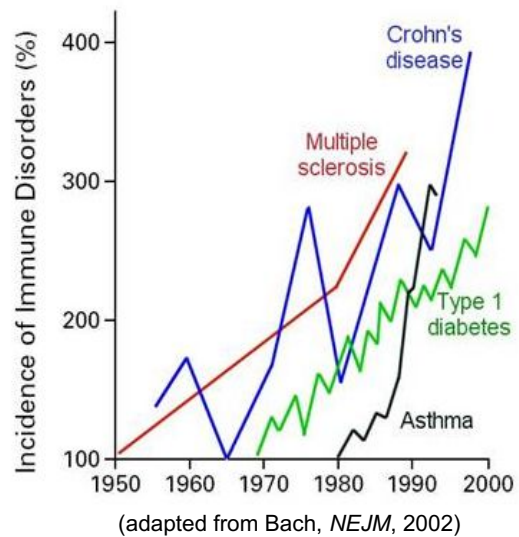
## TSO: *Trichuris suis* ova (CNDO-201)

- » Porcine whipworm ova
  - Represents a novel approach to treating autoimmune diseases – the “Hygiene Hypothesis”
  - Natural immunomodulator - regulates T-Reg cells and inflammatory cytokines
- » Clinical proof of principle established in Inflammatory Bowel Disease and Multiple Sclerosis
- » Phase 2 studies ongoing in Crohn’s disease
- » Planned studies in multiple additional autoimmune indications
- » Natural properties suggest strong potential for a safe profile
- » North and South America and Japanese rights for all indications



# Rapid Emergence of Autoimmune and Immune Mediated Diseases

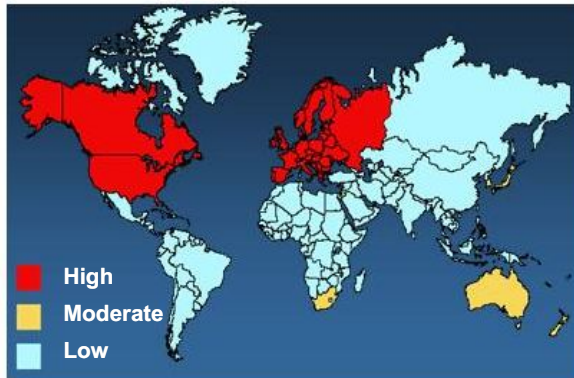
- » There are >100 immune-mediated diseases affecting 50 million Americans
- » Second highest cause of chronic disease in United States and number one cause of morbidity in women
- » In contrast, most of these diseases are rare in less developed countries



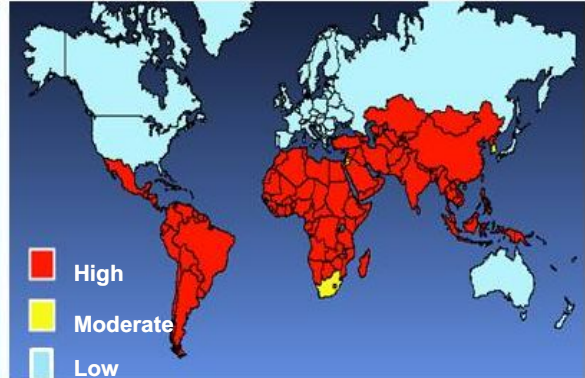
Walsh SJ, Rau LM. *Am J Public Health* 2000  
Faustman, D. Institute of Medicine Report, "Women's Health Research: Progress, Pitfalls, and Promise, 2010

# Distribution of Autoimmune Disorders and Helminths

Autoimmune disorders incidence



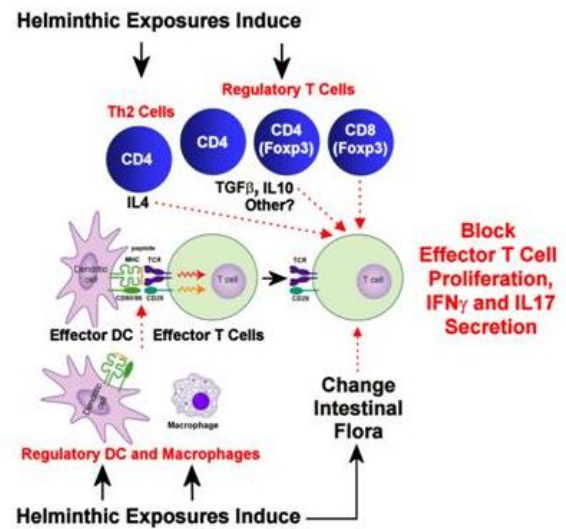
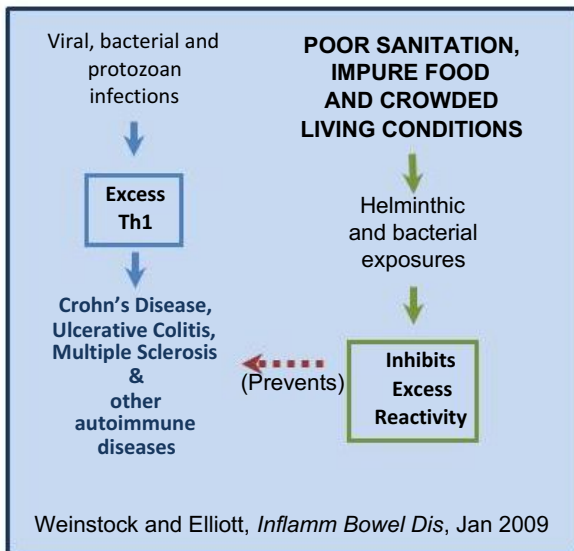
Helminths infestation incidence



Epidemiological data demonstrate:

- » Various immunological and autoimmune diseases are much less common in the developing world than the industrialized world
- » Immigrants to the industrialized world from the developing world increasingly develop immunological disorders in relation to the length of time since arrival in the industrialized world

# The Biology Supporting the Hygiene Hypothesis



Elliott & Weinstock, *Ann NY Acad Sci*, 2012

# Benefits of *Trichuris suis ova* (TSO)

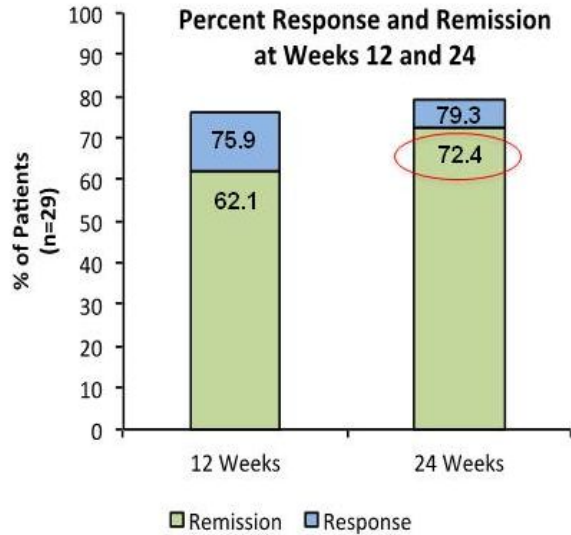
- » Does not multiply in human host
- » Colonization is self-limited in humans
- » No systemic phase
- » No direct transmission
- » Ova stable
- » Oral dosing; 1 tbsp solution taken once every 2 weeks
  - Clear, odorless, tasteless



# Effect of TSO in Crohn's Disease

## Patients and Methods

- 29 CD patients with CDAI > 220 (mean = 296)
- Median duration of the disease : 4 yrs
- Baseline meds – 5ASA, low dose steroids, 6-MP or Aza, washout of TNF $\alpha$  inhibitors
- 2500 TSO every 3 weeks for 24 weeks
- Remission defined as a CDAI of < 150 points
- Response defined as a CDAI > 100 point drop from baseline

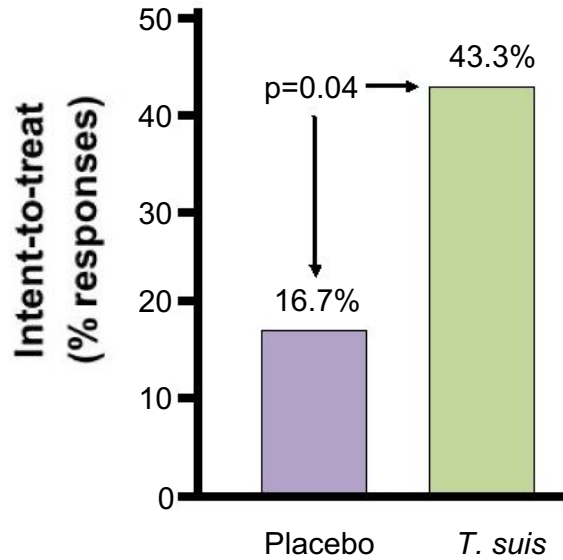


Summers, *et.al.*, GUT 2005

# Effect of TSO in Ulcerative Colitis

## Patients and Methods

- n = 54 UC patients with a UCDAI score > 4 points
- Average score 8.7-8.8
- Duration of disease averaged 8 years
- 2500 TSO every 2 weeks for 3 months
- Most patients refractory to previous therapy
- Response was defined as > 4 point drop



Summers, *et.al.*, *Gastroenterology* 2005

# TSO Phase 2 Crohn's Disease Studies

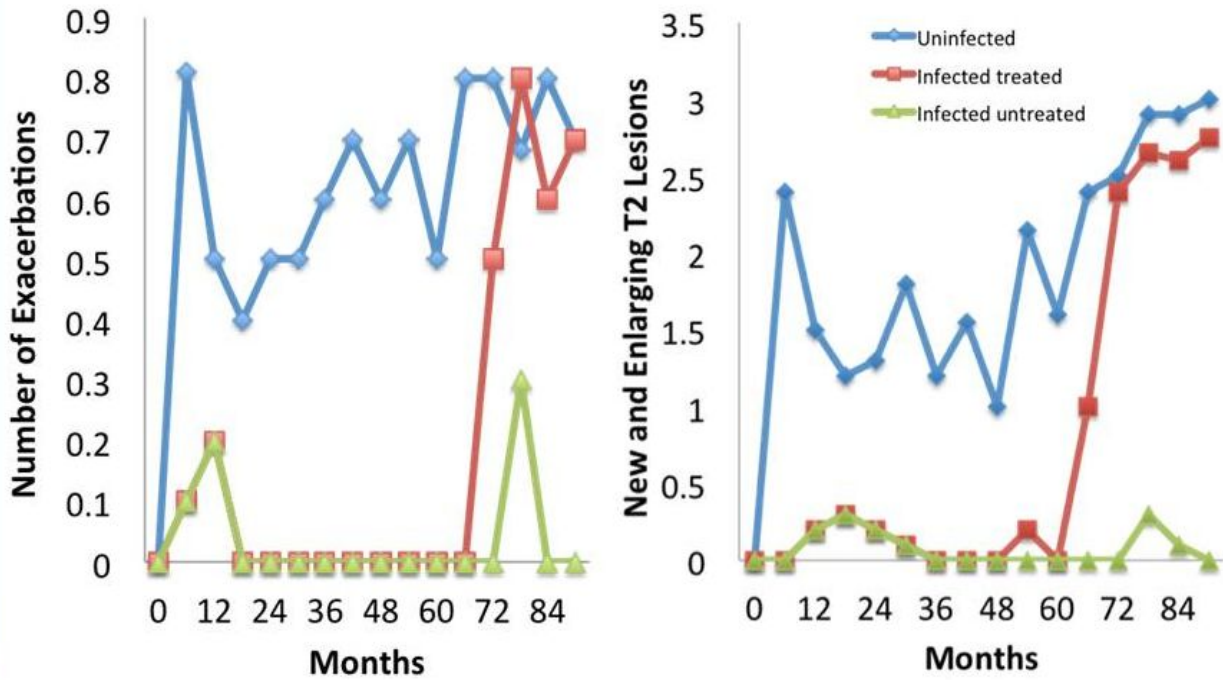
## TRUST - I

- » 12 week study
  - Double-blind, randomized, placebo controlled
  - TSO 7500 or placebo
  - N=220
  - Crohn's patients
    - CDAI = 220-450
    - Endoscopic evidence of inflammation
- » Outcome – Response rates
- » Topline data – 2H 2013

## TRUST - II

- » 12 week, dose ranging study
  - Double-blind, randomized, placebo controlled
  - TSO 250, 2500, 7500 or placebo
  - N=250 (2<sup>nd</sup> interim)
  - Crohn's patients
    - CDAI = 220-350
    - CRP 2X ULN or Calprotectin 1X ULN
- » Outcome – Remission rates
- » 2<sup>nd</sup> Interim – 2H 2013

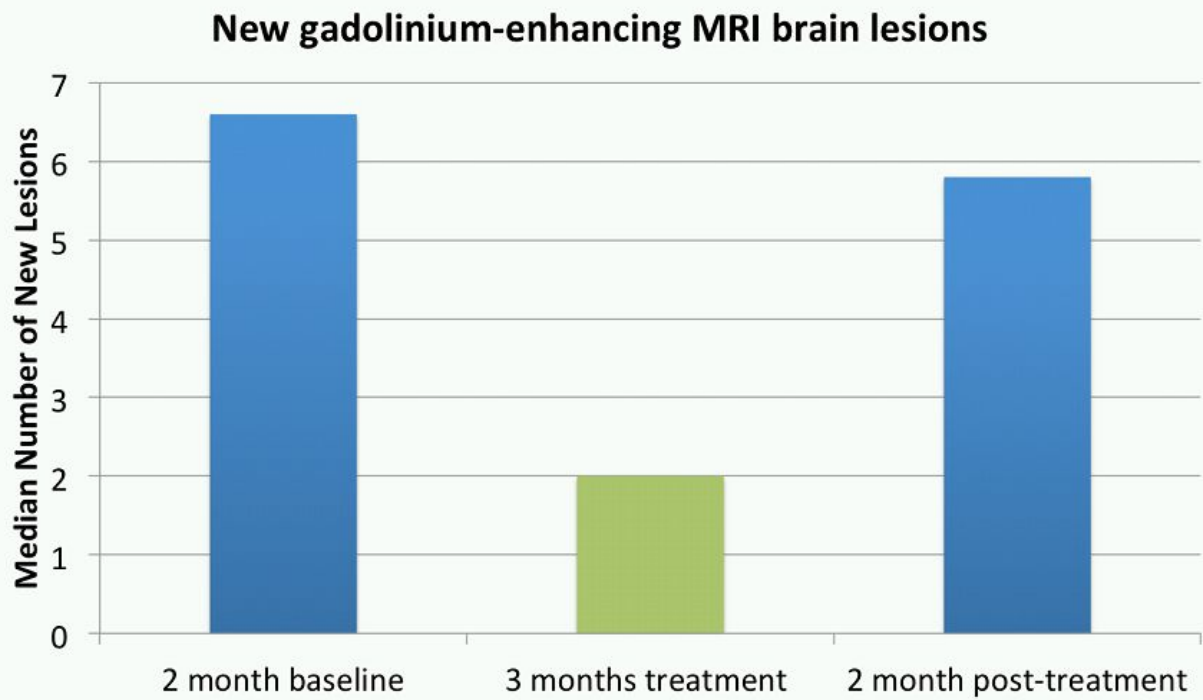
# Impact of Parasitic Infections on the Course of Multiple Sclerosis



Correale J, Farez MF. *J Neuroimmunol.* 2011;233:6



# Effect of TSO in Multiple Sclerosis



coronado  
BIOSCIENCES

Fleming, et al., *Multiple Sclerosis Journal* 2011

# TSO Pipeline

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

Indication	Pre-Clinical	Phase 1	Phase 2a*	Phase 2	Phase 3	Design
Crohn's Disease			Two phase 2 studies			~500pts, DB, PC
Ulcerative Colitis				1Q2013		120 pt, DB, PC
Ulcerative Colitis (MOA)						18 pt, OL
Multiple Sclerosis (US)						16 pt, SB
Multiple Sclerosis (EU)						50 pt, DB, PC
Autism						10 pt, DB, Cross
Psoriasis			1Q2013			20 pt, OL
Type-1 Diabetes			1H2013			60 pt, DB, PC Early Intervention
Type-1 Diabetes			1H2013			150 pt, DB, PC Prevention
Psoriatic Arthritis			1H2013			20-30 pt, DB, PC
Rheumatoid Arthritis			1H2013			50 pt, DB, PC

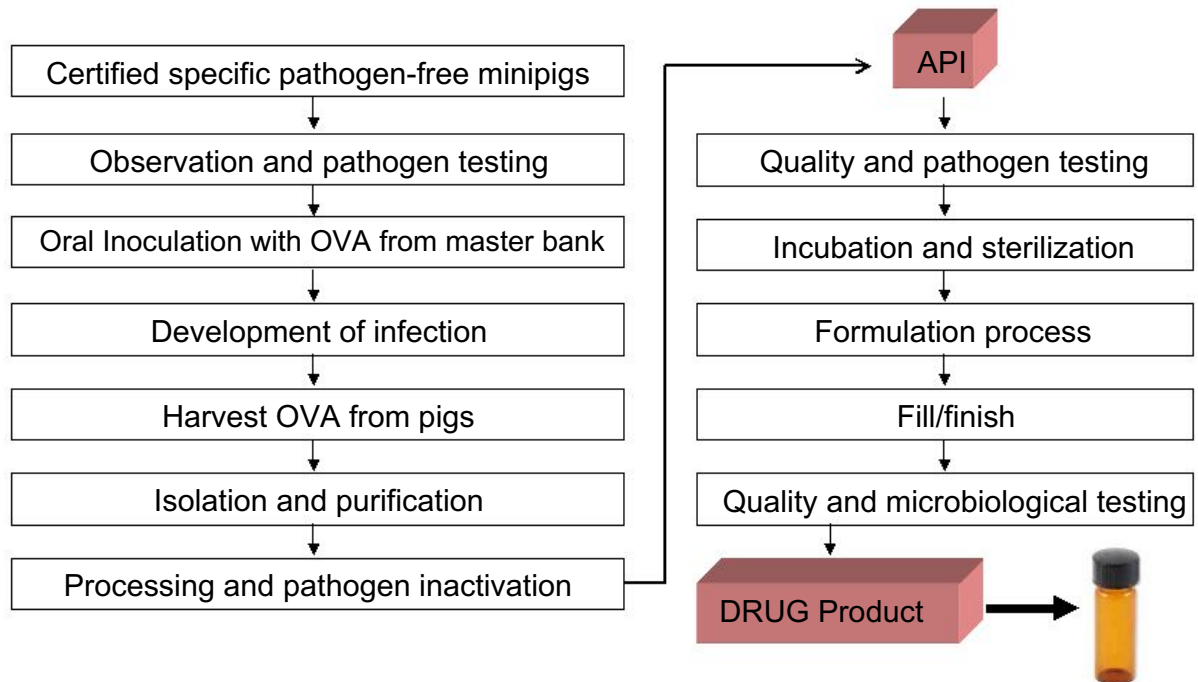
OL = Open-Label DB = Double-Blind,  
SB = Single-Blind PC = Placebo-Controlled



\* TSO Phase 2a studies being conducted  
as Investigator-Initiated Studies

Planned

# TSO Manufacturing Process



# Acquisition of TSO Manufacturing Rights

- » Coronado acquired manufacturing rights from Ovamed GmbH in North America, South America, and Japan (Coronado's licensed territory)
  - » Establishes control over TSO manufacturing
- » Facility to be built out in Woburn, MA in 2013, and to supply TSO Phase 3 studies and beyond
  - » OvaMed will continue to supply phase 2 and IIS requirements
- » Coronado will pay Ovamed a total of \$1.5M in three equal installments in Dec. 2014-2016, and a "Manufacturing Fee" for product made and sold by us in lieu of the transfer price for manufacture of TSO
- » 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, and is subject to certain adjustments and credits
- » The agreement contemplates that each of Coronado and Ovamed would act as Second Source to the other at agreed transfer prices

# TSO Intellectual Property

- » Three issued US patents entitled 'Use of Parasitic Biological Agents for Prevention and Control of Autoimmune Disease' directed to compositions, methods of producing compositions, and methods of autoimmune disease with helminths – exp. 12/2018
- » Five additional pending patents
  - 'Use of Parasitic Biological Agents for Disease Prevention and Control' - directed to the treatment of animals/man with a Th1 or Th2 mediated autoimmune disease – exp. 11/2023
  - 'Production of a Viable, Storable Worm Egg Suspension' - directed to a process for preparation of TSO using an acid wash - exp. 3/2028
  - 'Method for Characterizing the Biological Activity of Helminth Eggs, in particular *Trichuris* Eggs' – exp. 5/2029
  - 'Treatment with Helminths' directed to methods of treating obesity and IBS - exp. 10/2029
  - 'Compositions and Methods for Treating IBD' - directed to a method of treating IBD by contacting an isolated dendritic/macrophage cell with a helminth – exp. ~9/2032

*\* Expiration dates do not include any patent term extension*

# TSO Market Opportunity

The mechanism of action of TSO should, if approved, allow it to be positioned in a variety of autoimmune disorders, including inflammatory bowel diseases and multiple sclerosis as well as other potential disorders such as rheumatoid arthritis and psoriasis.

Potential TSO Target Indications	U.S./Japan Prevalence	U.S./Japan Annual Market Sales (USD Mil)
Ulcerative Colitis	669,000	\$1,300
Crohn's Disease	534,000	\$2,600
Multiple Sclerosis	485,000	\$6,400

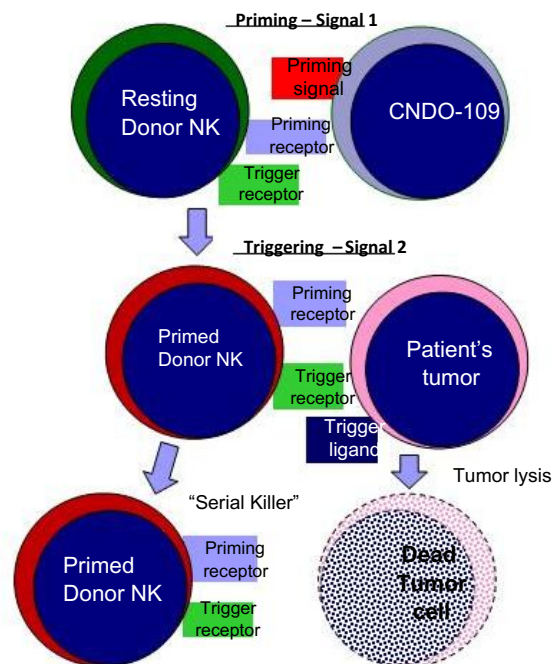
Sources: Decision Resources 2012

# CNDO-109: Activated Natural Killer Cells

- » NK cells represent the key component of the body's innate immune surveillance system
- » Proof of principle established in patients with high-risk refractory or relapsed acute myeloid leukemia (AML)
- » 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

# 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 2 or 3 (CR2 or CR3)
  - 1 patient in partial relapse (PR)
- » 3/5 experienced a longer CR than their previous CR, in addition PR patient achieved CR

Kottaridis, *et al.*, ASH 2011

# CNDO-109 Clinical Development

- » Initiated Phase 1/2 allogeneic clinical trial for the treatment of relapsed AML
- » Once the dose is selected, plan to initiate a randomized Phase 2 trial
  - Potential for regulatory approval with single randomized, controlled clinical trial if data are clinically meaningful and statistically persuasive
- » Future autologous studies planned in other tumor types (including multiple myeloma, breast, ovarian and prostate)

# CNDO-109 Intellectual Property

- » Core patent - “Method for activating natural killer cells by tumor cell preparation *in vitro*”
  - Issued in U.S. - exp. 1/2029
  - Issued in Australia – exp. 3/2026
  - Pending in Europe, Canada, Japan and India
- » Patent pending - “Preserved Compositions of Activated NK Cells and Methods of Using the Same” – exp. 7/2030
- » Provisional application pending in the U.S. - “Compositions and Methods for Treating Viral Infections”

*\* Expiration dates do not include any patent term extension*

# CNDO-109 Market Opportunity

If Coronado establishes the efficacy of CNDO-109 activated NK cells in the treatment of AML, Coronado believes the market opportunity for CNDO-109 activated NK cell therapy is large due to the fact that many types of tumors are sensitive to killing by activated NK cells.

Potential CNDO-109 Target Indications	G7 Drug Treatable Population	G7 Market Sales (USD Mil)	Mortality
AML	43,500	\$165	5 year mortality rate is 85-90% but varies by age
Multiple Myeloma	44,000	\$2,870	Stage III: median survival of 29 months
Breast Cancer	494,000	\$10,100	Stage IV: 5 year mortality rate is 76%
Ovarian	57,110	\$424	Overall 5 year survival rate of 45%
Prostate	500,000	\$4,000	Overall 5-year survival rate of +99%, but 2 <sup>nd</sup> leading cause of cancer deaths in men

G7 = U.S., U.K., Germany, France, Italy, Spain, Japan

**Sources:** Decision Resources 2011/2012

# Key Management and Board Members

## **Harlan F. Weisman, MD**

### **Chairman and Chief Executive Officer**

- » Company Group Chairman, Research & Development for Pharmaceuticals at JNJ
- » President of Research & Development at Centocor
- » Over 20 years of pharmaceutical/biotechnology experience

## **Bobby W. Sandage, Jr., PhD**

### **President**

- » EVP & CSO of Indevus Pharmaceuticals, Inc.
- » Over 30 years of pharmaceutical/biotechnology experience

## **Noah D. Beerman**

### **EVP & Chief Operating Officer**

- » President & CEO of RXi Pharmaceuticals
- » Over 25 years of pharmaceutical/biotechnology experience

## **Karin Hehenberger, MD, PhD**

### **EVP & Chief Medical Officer**

- » Senior management positions at Juvenile Diabetes Research Foundation and at JNJ Diabetes
- » Over 13 years of pharmaceutical/biotechnology experience

## **Lucy Lu, MD**

### **EVP & Chief Financial Officer**

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

## **Eric K. Rowinsky, MD**

### **Vice Chairman**

- » World renown oncologist, former CMO at ImClone, board of Biogen/Idec
- » Over 25 years of healthcare experience

## **Lindsay Rosenwald, MD**

### **Director and Founder**

- » A prolific and successful investor in the life sciences industry for over 20 years

# Financials

Listed on NASDAQ: CNDO

Market Cap *as of 1/4/2013* \$130M

Shares Outstanding 24.4M  
- Additional 3.6M options and warrants

Cash Position *as of 9/30/2012* \$47.5M

# Anticipated Upcoming Milestones

## TSO

Initiate Multiple Investigator Initiated Studies	1H 2013
TRUST-II (Falk) Crohn's study 2nd Interim Results	2H 2013
TRUST-I (CNDO) Crohn's study Topline Results	2H 2013

## CNDO-109

Initiate Multiple Myeloma Study	2H 2013
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# Investment Highlights

- » Two **biologic product candidates** in clinical stage development
  - Focused on autoimmune diseases and cancer immunotherapy
  - Strong proprietary position
- » Novel treatments with **broad therapeutic applications** addressing multi-billion dollar markets
- » Four efficacy clinical trials completed and multiple additional trials ongoing
  - **TSO**: *Trichuris suis ova* (CNDO-201) in Crohn's Disease, Ulcerative Colitis (UC) and Multiple Sclerosis (MS)
  - **CNDO-109**: Tumor Activated NK Cells in relapsed Acute Myeloid Leukemia (AML)
- » Experienced management team and board of directors