

**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): September 4, 2012

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.)**

**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)

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 7.01. Regulation FD Disclosures.

On September 5, 2012, executives of Coronado Biosciences, Inc. (the “Company”) will make a presentation about the Company to certain analysts and investors at the Stifel Nicolaus 2012 Healthcare Conference in Boston, Massachusetts. A copy of the slide presentation is furnished as exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	September 5, 2012 Slide Presentation

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, we have duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CORONADO BIOSCIENCES, INC.

By: /s/ Lucy Lu

Name: Lucy Lu

Title: Chief Financial Officer

Dated: September 4, 2012

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	September 5, 2012 Slide Presentation

coronado

B I O S C I E N C E S

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

Bobby W. Sandage, Jr., PhD
President & Chief Executive Officer

September 2012

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: 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; 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	→	4Q2012	→		
Psoriasis	→	4Q2012	→		
Type-1 Diabetes	→	1Q2013	→		
Other indications**	→	2013	→		

CNDO-109 (Tumor-Activated Natural Killer Cells)

Acute Myeloid Leukemia	→ 2H2012				
Multiple Myeloma, Solid Tumors	→				

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

** Other indications include Rheumatoid Arthritis and Psoriatic Arthritis

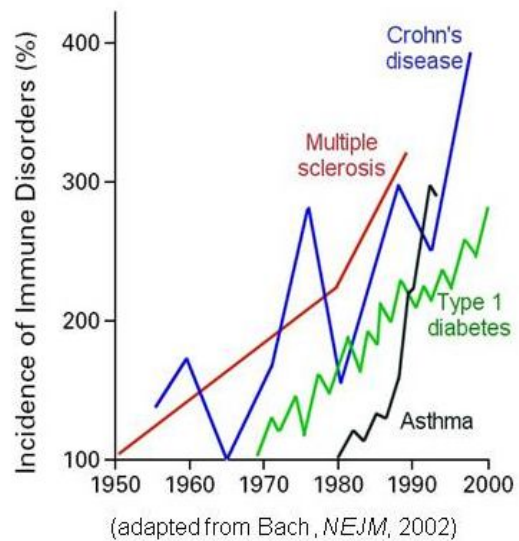
Planned

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
- » Ongoing 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



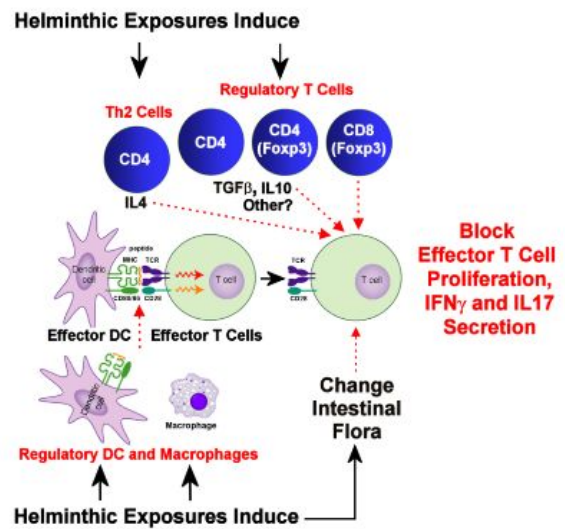
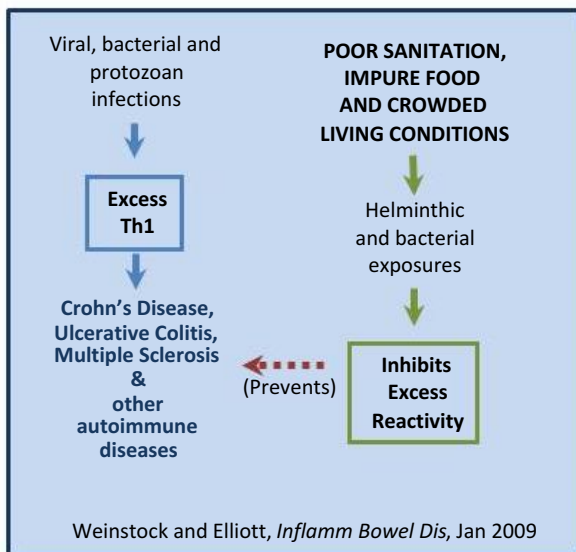
Helminths infestation incidence



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)

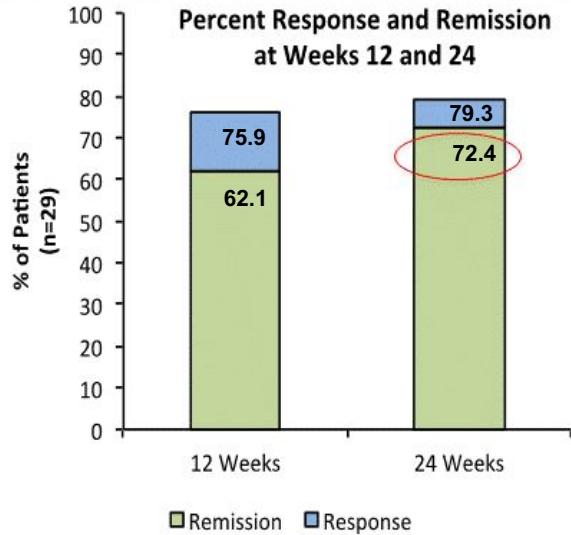
- » Does not multiply in human host
- » Colonization is self-limited in humans
- » No systemic phase
- » No direct transmission
- » Ova stable
- » Oral dosing; 1 tbsp solution taken once every 2 weeks
 - Clear, odorless, tasteless



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 α 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

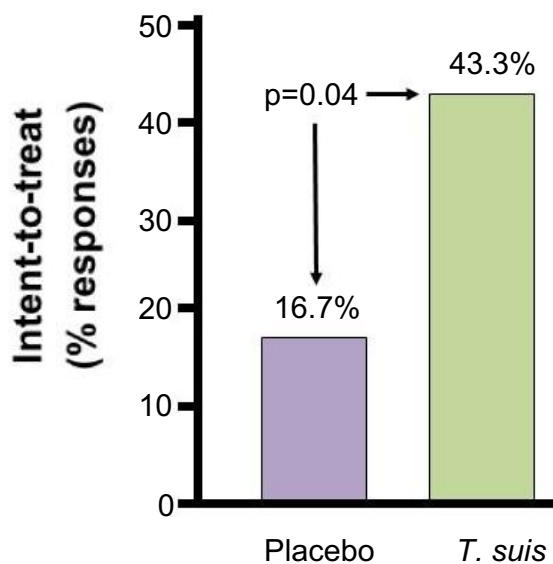


Summers, *et.al.*, GUT 2005

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

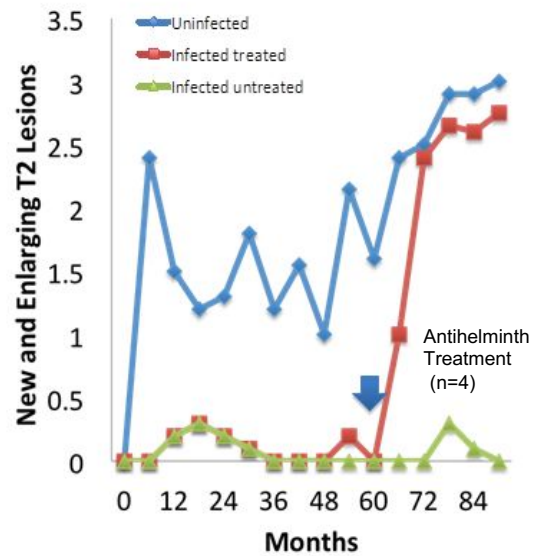
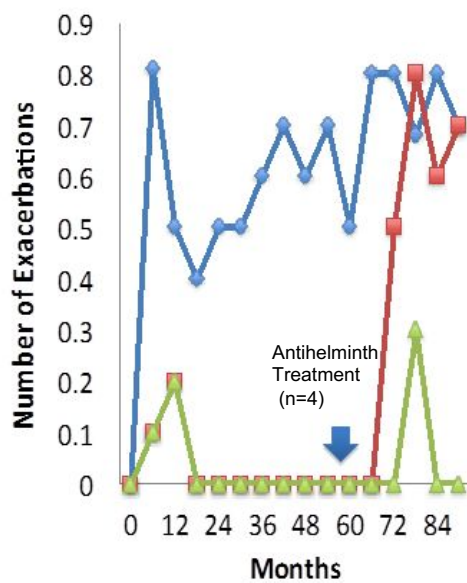
TRUST - I

- » 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 (2nd interim)
 - Crohn's patients
 - CDAI = 220-350
 - CRP 2X ULN or Calprotectin 1X ULN
- » Outcome – Remission rates
- » 2nd Interim – Mid-2013

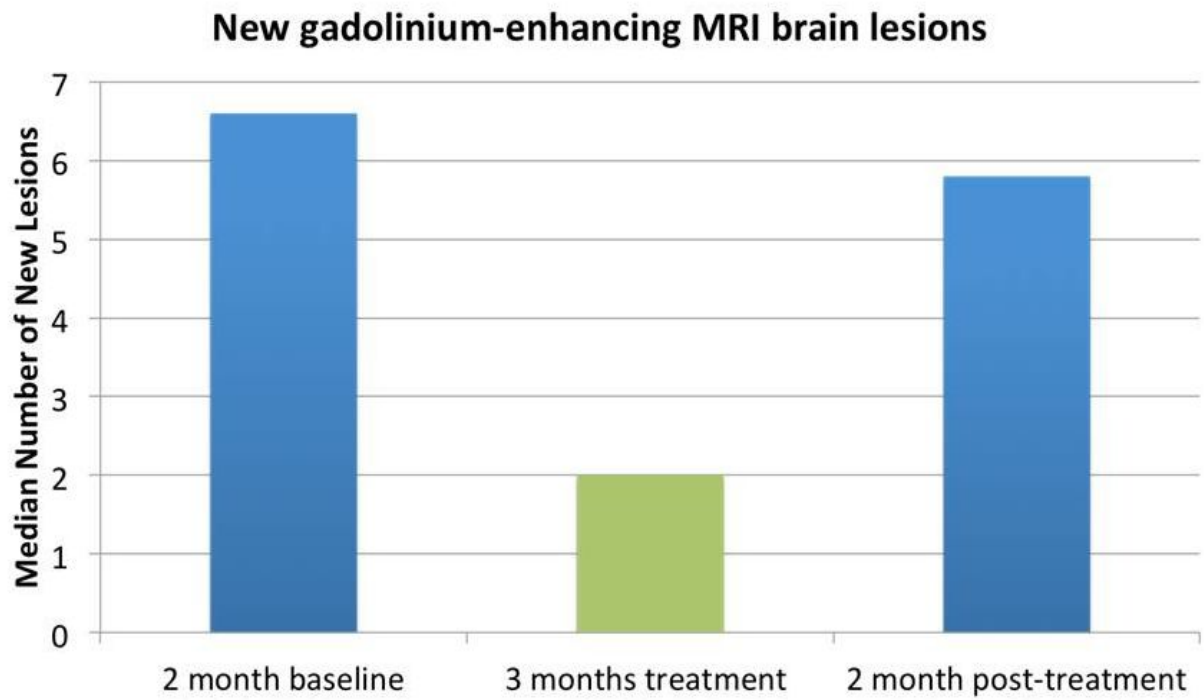
Impact of Parasitic Infections on the Course of Multiple Sclerosis



12 patients/group

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

Effect of TSO in Multiple Sclerosis



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		4Q2012				10 pt, DB, Cross
Psoriasis		4Q2012				20 pt, OL
Type-1 Diabetes (early intervention)		1Q2013				60 pt, DB, PC
Type-1 Diabetes (prevention)		1Q2013				150 pt, DB, PC
Psoriatic Arth/RA		2013				20-30 pt, DB, PC

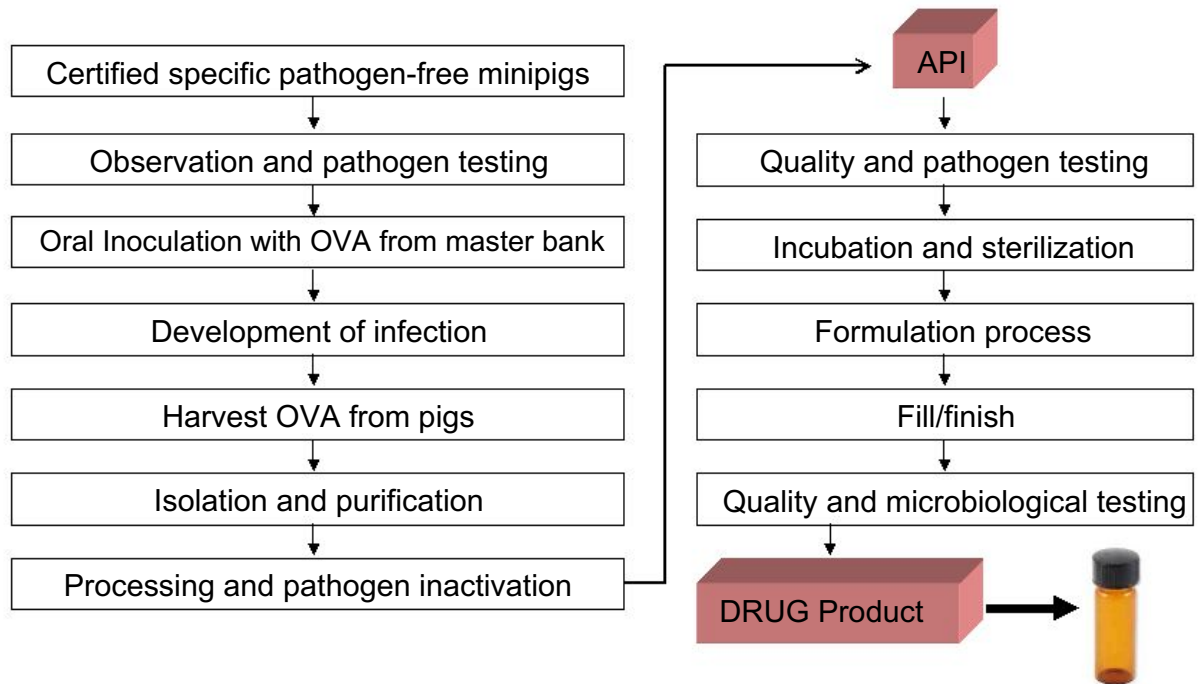
OL = Open-Label DB = Double-Blind, SB= Single-Blind PC = Placebo-Controlled

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



Planned

TSO Manufacturing Process



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

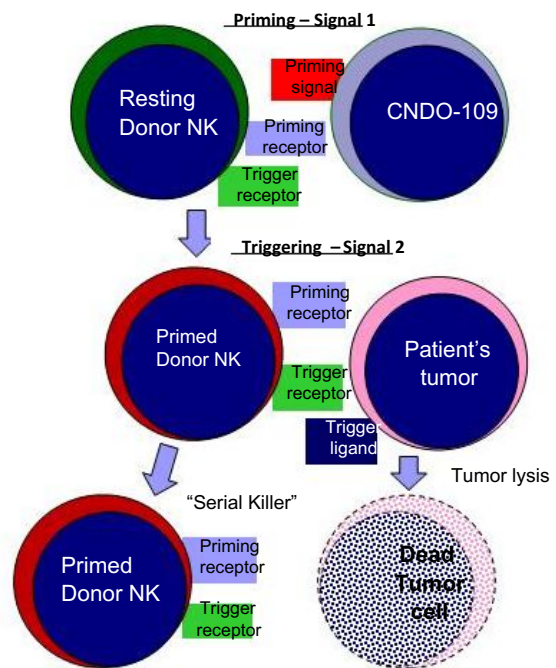
Sources: Decision Resources 2012

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

1Q 2012

- » Filed IND

2H 2012

- » Initiate Phase 1/2 allogeneic clinical trial for the treatment of relapsed AML
- » Once the dose is selected, 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 nd 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

Bobby W. Sandage, Jr., PhD

President & Chief Executive Officer

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

Noah D. Beerman

EVP & Chief Operating Officer

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

Karin Hehenberger, MD, PhD

EVP & Chief Medical Officer

- » Served in senior management positions at Juvenile Diabetes Research Foundation and at JNJ Diabetes
- » Over 12 years of pharmaceutical/biotechnology experience

Lucy Lu, MD

EVP & Chief Financial Officer

- » Served Senior Analyst Citi, Lazard and First Albany
- » Over 10 years of equity research experience

Glenn L. Cooper, MD

Executive Chairman

- » Served as Chairman & CEO of Indevus Pharmaceuticals, Inc.
- » Over 25 years of pharmaceutical/biotechnology 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	12/19/2011
Market Cap <i>as of 8/29/2012</i>	\$140M
Shares Outstanding	24.4M
- Additional 3.4M options and warrants	
Cash Position <i>as of 6/30/2012</i>	\$38.2M
- Additional \$15M loan secured in August	

\$15M Hercules Loan

Principal	\$15M
Interest	9.25%*
Payment Terms	42 Months
-First 12 months, interest only	
-Next 30 months, principal and interest	
Warrants	73,009
-Exercise price \$5.65	

*The loan bears interest at a rate per annum equal to the greater of (i) 9.25% or (ii) 9.25% plus the sum of the prevailing prime rate minus 3.25%

Upcoming Milestones

TSO

Initiate Phase 2 Crohn's study	Completed
Initiate Multiple Investigator Initiated Studies	2H 2012
TRUST-II (Falk) Crohn's study 2nd Interim Results	Mid-2013
TRUST-I (CNDO) Crohn's study Topline Results	2H 2013

CNDO-109

Initiate US Phase 1/2 study	2H 2012
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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
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 - **CNDO-109**: Tumor Activated NK Cells in relapsed Acute Myeloid Leukemia (AML)
- » Experienced management team and board of directors