

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 02/13/12 for the Period Ending 02/13/12

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
CIK	0001069308
Symbol	OPXA
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

**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): February 13, 2012

OPEXA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Texas
(State or other jurisdiction of
incorporation)

001-33004
(Commission File Number)

76-0333165
(IRS Employer Identification
No.)

2635 Technology Forest Blvd., The Woodlands, Texas
(Address of principal executive offices)

77381
(Zip Code)

Registrant's telephone number, including area code: **(281) 272-9331**
N/A
(Former name or former address, if changed since last report)

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 7.01 Regulation FD Disclosure

On February 13, 2012, Opexa Therapeutics, Inc. (the “ **Company** ”) will deliver a corporate presentation at the BIO CEO & Investor 14th Annual Conference, which will be available via webcast, using slides containing the information attached to this Current Report on Form 8-K as Exhibit 99.1. The presentation includes an overview of the Company’s ongoing clinical development program for Tovaxin®, the Company’s lead therapy for multiple sclerosis. The attached materials have also been posted to the Investor Relations page of the Company’s website at www.opexatherapeutics.com. The Company does not undertake to update this presentation.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Opexa Therapeutics, Inc. Corporate Presentation for BIO CEO & Investor 14 th Annual Conference, held on February 13, 2012.
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The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities under that Section, nor be deemed to be incorporated by reference into the filings of the registrant under the Securities Act of 1933.

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, thereunto duly authorized.

Dated: February 13, 2012

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President & Chief Executive Officer

Exhibit Index

Exhibit No.

Description

99.1

Opexa Therapeutics, Inc. Corporate Presentation for BIO CEO & Investor 14th Annual Conference, held on February 13, 2012



OPEXA THERAPEUTICS



A REVOLUTION IN
CELL THERAPY

Opexa Therapeutics, Inc.

February 2012

Neil Warma
President & CEO



Forward-Looking Statements

This presentation contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The forward-looking statements in this presentation do not constitute guarantees of future performance. Investors are cautioned that statements in this presentation which are not strictly historical statements, including, without limitation, statements regarding the Company's clinical development plans for Tovaxin, constitute forward-looking statements. Such forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated, including, without limitation, risks associated with the Company's capital position, the ability of the Company to enter into and benefit from a partnering arrangement for the Company's product candidate, Tovaxin, on reasonably satisfactory terms (if at all), and our dependence (if partnered) on the resources and abilities of any partner for the further development of Tovaxin, our ability to compete with larger, better financed pharmaceutical and biotechnology companies, new approaches to the treatment of our targeted diseases, our expectation of incurring continued losses, our uncertainty of developing a marketable product, our ability to raise additional capital to continue our treatment development program and to undertake and complete any further clinical studies for Tovaxin, the success of our clinical trials, the efficacy of Tovaxin for any particular indication, such as for relapsing remitting MS or secondary progressive MS, our ability to develop and commercialize products, our ability to obtain required regulatory approvals, our compliance with all Food and Drug Administration regulations, our ability to obtain, maintain and protect intellectual property rights (including for Tovaxin), the risk of litigation regarding our intellectual property rights, our limited manufacturing capabilities, our dependence on third-party manufacturers, our ability to hire and retain skilled personnel, our volatile stock price, and other risks detailed in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this presentation. We assume no obligation or undertaking to update or revise any forward-looking statements contained herein to reflect any changes in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make in our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the SEC.



Opexa Highlights

- Proprietary T-cell technology platform allows for the production of patient-specific T-cell therapies for a variety of autoimmune diseases
- Lead program, Tovaxin[®], a personalized cellular immunotherapy for the first-line treatment of multiple sclerosis (MS)
- Fast Track designation granted November 2011 by FDA for Tovaxin for treatment of Secondary Progressive Multiple Sclerosis (SPMS)
- In-house cGMP manufacturing enables close control of process and COGS



Opexa's Focus: Filling the Void in SPMS Treatment

Over 1 million people affected by SPMS worldwide...

...only ONE FDA approved product for SPMS



Treating SPMS with a
Safe and Effective Therapy



Tovaxin®

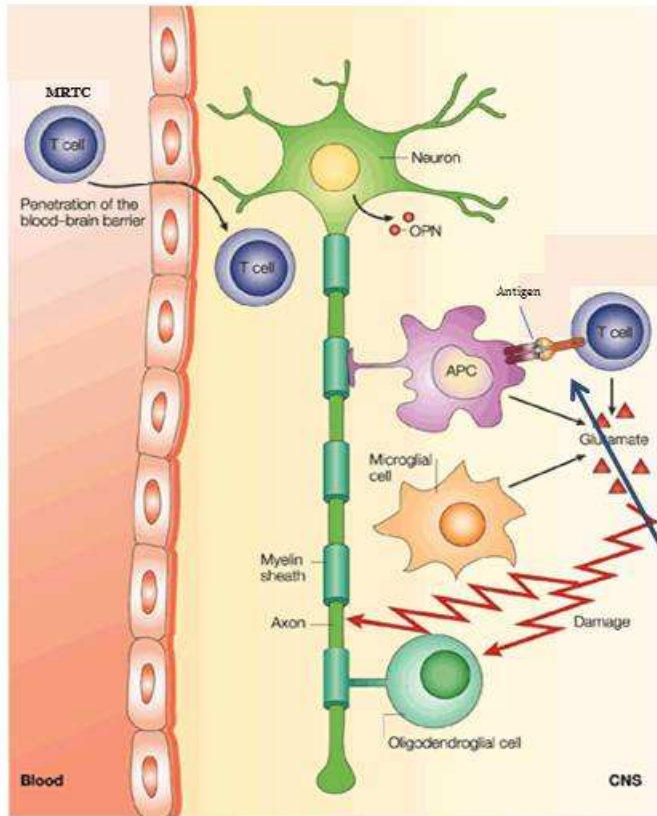
A personalized autologous T-cell immunotherapy, consisting of attenuated, patient-specific myelin reactive T-cells (MRTCs) against peptides of the three primary myelin proteins

Proposed Mechanism

The subcutaneous injection of a therapeutic dose (30-45 million cells) of Tovaxin stimulates the body's immune system to recognize the bolus of injected cells as a peripheral source of 'over represented' MRTC , resulting in the induction of an opposing dominant negative 'regulatory T-cell' response:

- Selective targeting by immune cells to down-regulate and eliminate similar myelin reactive T-cells within the CNS
- An up-regulation of important regulatory cells (Foxp3⁺ and Tr1 cells) to reduce inflammation and provide possible neuroprotection

MRTCs' Role in Multiple Sclerosis



Nature Reviews | Immunology

- MRTCs cross the Blood Brain Barrier (BBB) into the central nervous system (CNS) from the periphery and bind to specific antigen presenting cells (APC)

- Macrophages and microglial cells release OPN, IL-12/23, accompanied by T-cell dependent secretion of IFN- γ , IL-17 and tumor-necrosis factor alpha (TNF α)

Result $\rightarrow$ *Destruction of the myelin sheath*

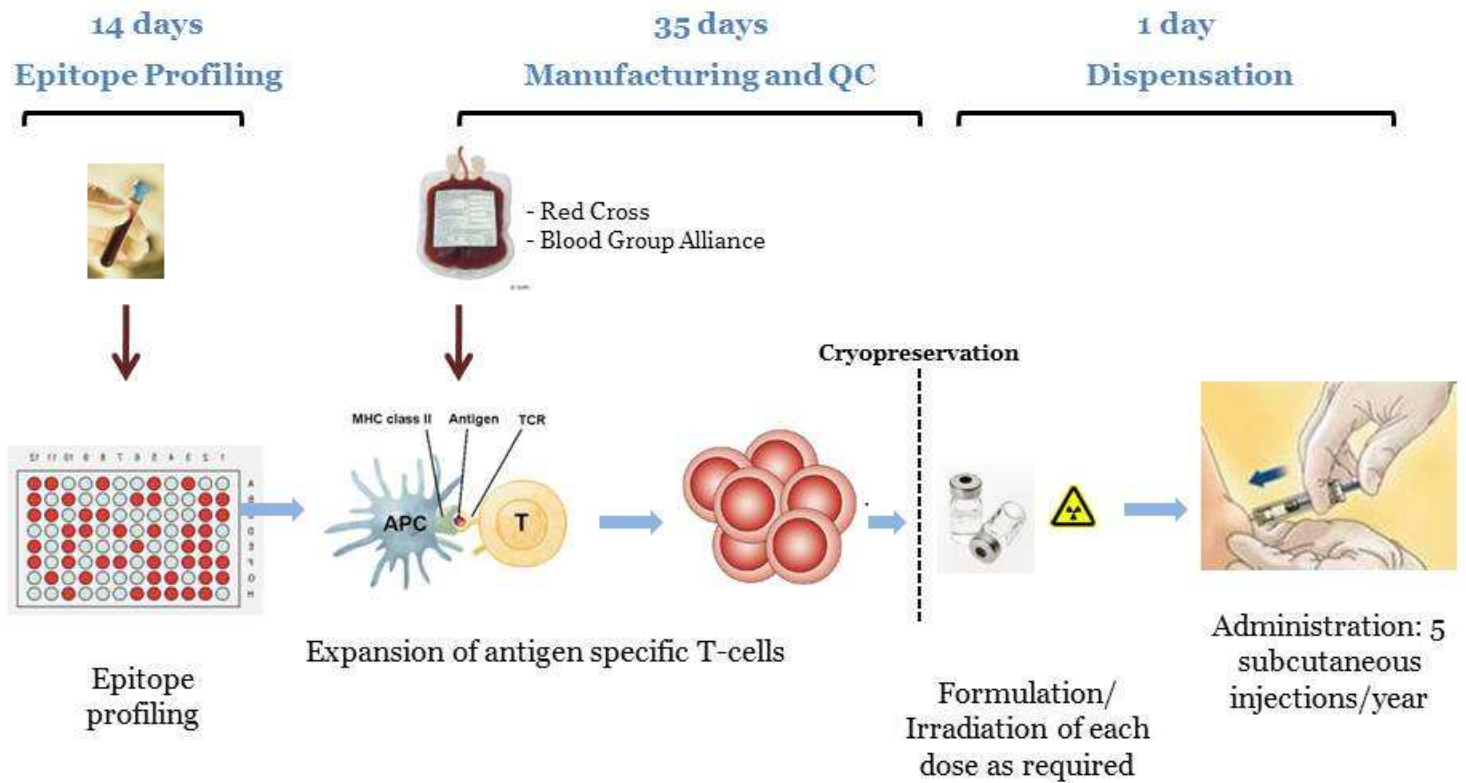
- T-cells that clonally accumulate in the lesion are driven by defined protein antigens

Opexa's Strategy

Identify which *specific* antigens within each *individual* patient may be targeted by the immune response



Tovaxin Manufacturing





Proprietary Assay Enables Annual Personalized Treatments

Year 1

Conduct analysis of 109 peptides from all three key myelin proteins (MBP, MOG, PLP)

Patient XX	Peptide 1	Peptide 2	Peptide 3	Peptide 4	Peptide 5	Peptide 6	Peptide 7	Peptide 8	Peptide 9	Peptide 10	Peptide 11	Peptide 104	Peptide 105	Peptide 106	Peptide 107	Peptide 108	Peptide 109
MBP																	
MOG																	
PLP																	

Year 2

Patient XX	Peptide 1	Peptide 2	Peptide 3	Peptide 4	Peptide 5	Peptide 6	Peptide 7	Peptide 8	Peptide 9	Peptide 10	Peptide 11	Peptide 104	Peptide 105	Peptide 106	Peptide 107	Peptide 108	Peptide 109
MBP																	
MOG																	
PLP																	

Re-assess epitope profile annually to identify epitope drift

Develop new formulation based on evolved epitope profile

Year 3

Patient XX	Peptide 1	Peptide 2	Peptide 3	Peptide 4	Peptide 5	Peptide 6	Peptide 7	Peptide 8	Peptide 9	Peptide 10	Peptide 11	Peptide 104	Peptide 105	Peptide 106	Peptide 107	Peptide 108	Peptide 109
MBP																	
MOG																	
PLP																	



Overview of Tovaxin Clinical Development

- Five clinical trials have been conducted (in RRMS and SPMS patients)
 - 356 patients enrolled
 - 196 treated with Tovaxin
- Safety demonstrated and clinical efficacy promising across broad spectrum of patients for relapsing and progressive MS

RRMS		
	Patients	Endpoints
Phase IIb	150	MRI (lesion #) ARR
<i>[Phase IIb Subpopulation (ARR>1)]</i>	[50]	EDSS Atrophy ARR
Phase I/II Dose Range study	16	ARR EDSS
Phase I/II Extension study	13	ARR EDSS

SPMS		
	Patients	Endpoints
Phase I/II trial	10	EDSS ARR
Baylor Trial	26	EDSS ARR

Safety: ITT

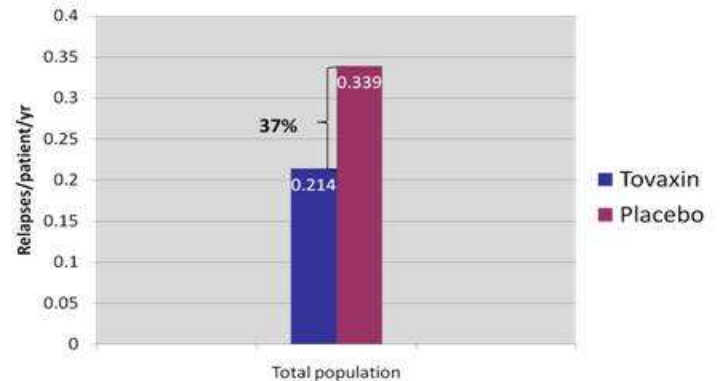
Complete Phase IIb Patient Population (n=150)

Safety endpoints	
Deaths	• No deaths occurred
Serious Adverse Events (SAEs)	• There were no SAEs related to Tovaxin treatment
Most common adverse events	• Mild to moderate injection site reaction only



Tovaxin RRMS Clinical Data Overview

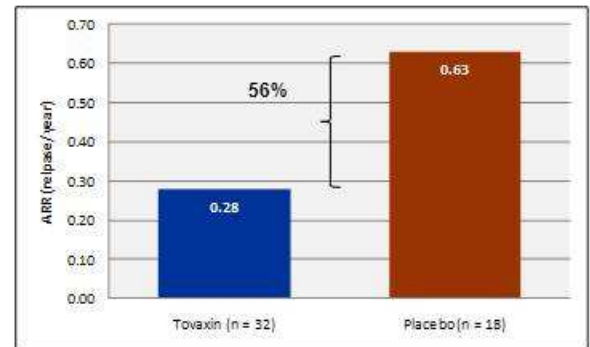
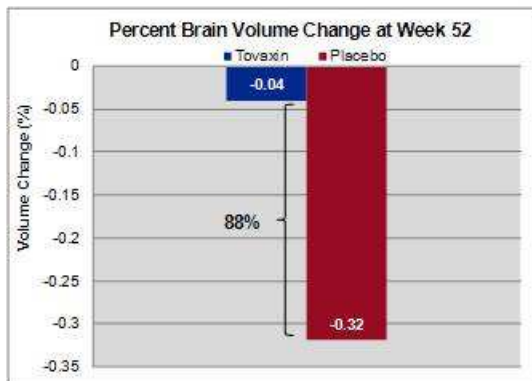
- Completed Phase IIb clinical trial in 150 RRMS patients; 33 sites in U.S.
- mITT population (n=142)
 - 37% reduction in ARR vs. placebo
 - ARR 0.214 vs. 0.339
 - 77% relapse free in Tovaxin group
- Superior safety and promising efficacy demonstrated
- Two *End-of-Phase 2* meetings with FDA successfully completed





Tovaxin RRMS Prospective Study

- Sub-population of patients (n=50) with more progressed/active disease profile (baseline ARR >1) most closely mirrors SPMS patients
 - 73% relapse free
 - Significant improvement in disability (p=0.05)
 - 56% reduction in ARR
 - 88% reduction in whole-brain atrophy



**Data Provide Support for
Phase IIb Program in SPMS**



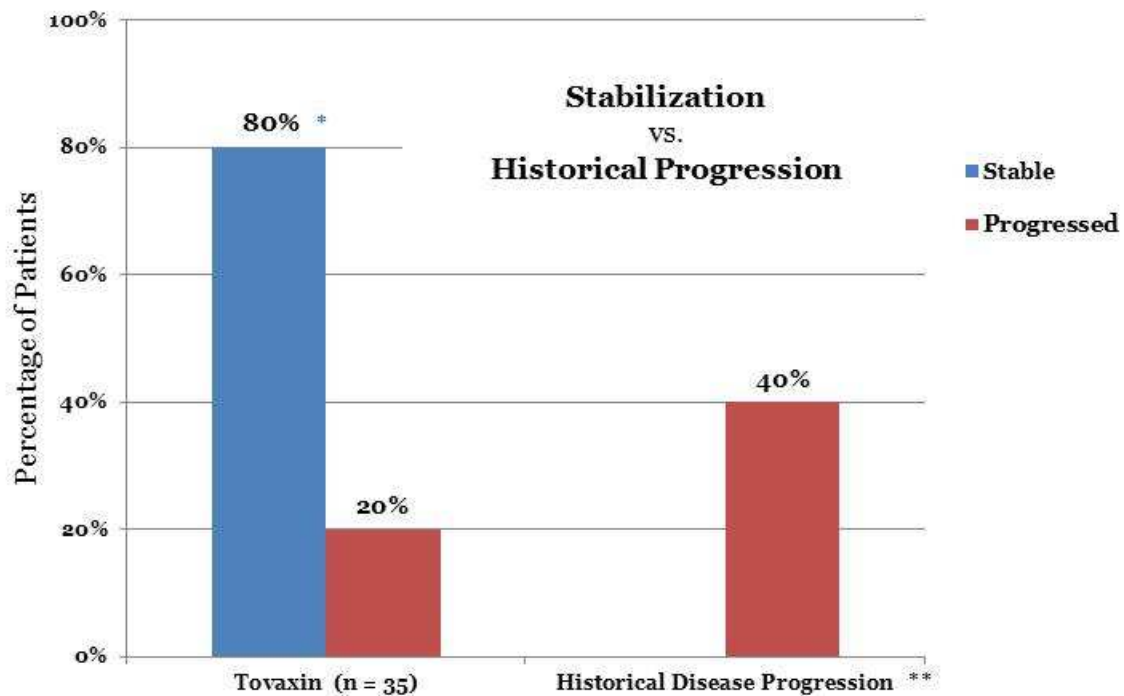
Secondary Progressive MS: Clinical Overview

- 36 patients treated in three clinical trials
- Promising efficacy observed
 - Disease stabilization in 80% of patients at two years
 - Significant reduction in relapse rates
- Well-tolerated, no SAEs



Tovaxin Stabilizes Disease in SPMS

80% of subjects had no disease progression by EDSS at 2 years



*A small percentage of patients showed an improvement (i.e. decrease in progression)

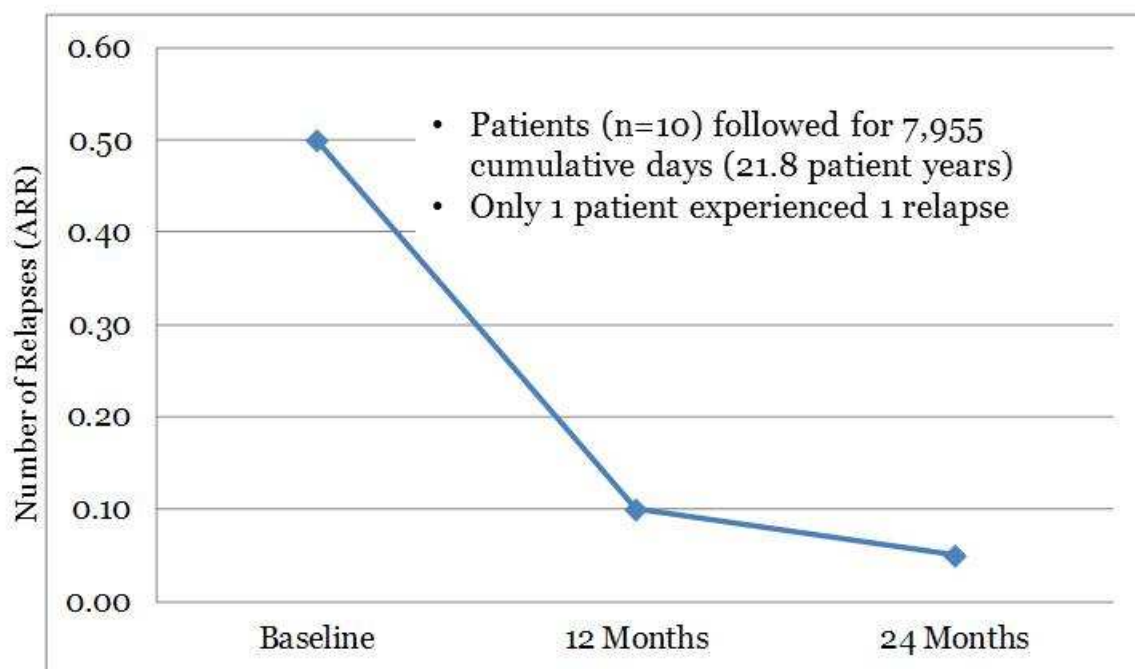
**Historical control: ESIMS Study, published *Honmes Lancet* 2004

Phase I and Phase I/II Studies

Pooled - Annualized Relapse Rate (ARR)



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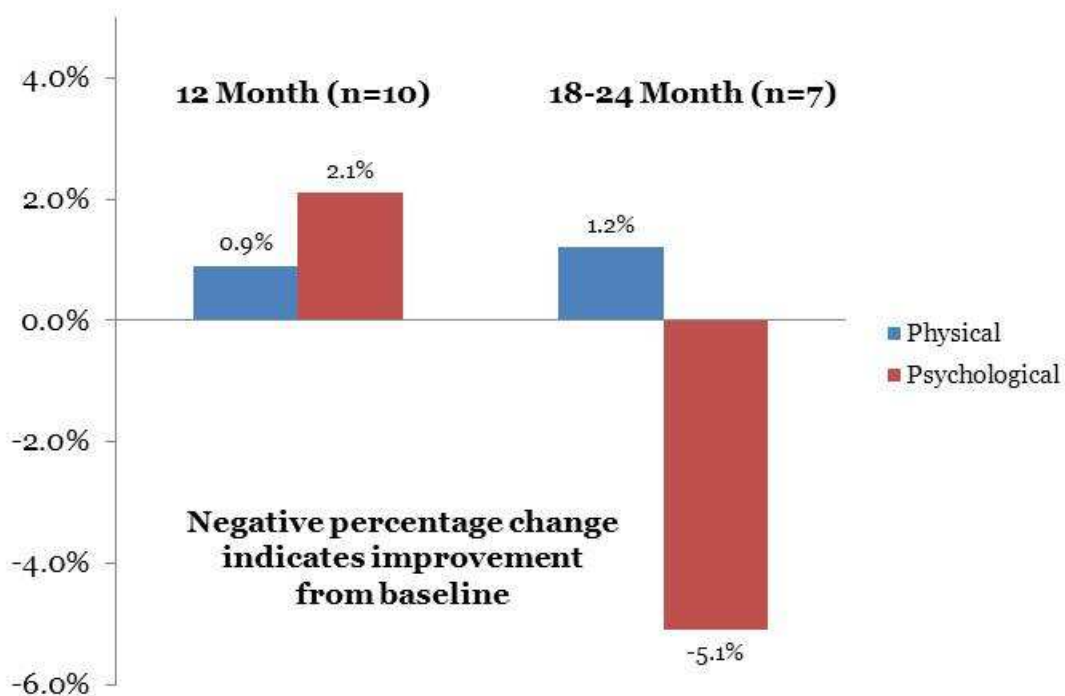
One relapse observed in 21 years of cumulative patient follow up

Phase I and Phase I/II Studies

Pooled - Change in MSIS Scores at 2 years



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Following two years of treatment, no worsening of physical condition and improvement in psychological condition



Overview of Tovaxin Clinical Development

Clinical Status: Five clinical trials completed with Tovaxin in 196 patients, many with multiple years of treatment

Efficacy: Data shows reduction in Annualized Relapse Rate (ARR), slowing disease progression

Safety & Tolerability: Appears superior to all marketed and developmental MS drugs



SPMS Phase IIb Trial Design

- Double-blind, 1:1 randomized, placebo-controlled
- 180 Patients
 - SPMS population
 - Up to 30 sites in USA and Canada
- Efficacy Endpoints:
 - Sustained progression measured by EDSS
 - Whole-brain atrophy
 - T2 lesions progressing to hypointense lesions (black holes)
 - Change in EDSS (disability)
 - Annualized Relapse Rate (ARR)
- Safety Endpoints
- 2 years of treatment and assessment
 - Initiation 1H'2012, subject to securing the necessary resources; Completion 2H'2014



Scientific Advisory Board

- **Dawn McGuire, M.D., FAAN (Chair)**
 - Advisory Council of the Gill Heart Institute
 - American Academy of Neurology
 - National Institute of Neurological Disorders and Stroke of the National Institutes of Health
- **Hans-Peter Hartung, M.D.**
 - Chair of Neurology at Heinrich-Heine University
 - PresidentECTRIMS
 - European Neurological Society
 - International Society for Neuroimmunology
 - International Federation of Multiple Sclerosis Societies
 - World Health Organization Advisory Board on Multiple Sclerosis
- **Mark S. Freedman, M.D., FRCP, FAAN**
 - Director of the Multiple Sclerosis Research Unit at Ottawa Hospital
 - Multiple Sclerosis Society of Canada, National MS Society(USA)
 - Americas Committee for Treatment and Research in MS
 - Consortium of MS Centres
- **Paul O'Connor, M.D., FRCP**
 - MS Clinic Director at St. Michael's Hospital, University of Toronto
 - National Scientific and Clinical Advisor for the Multiple Sclerosis Society of Canada



Scientific Advisory Board

➤ **Clyde Markowitz, M.D.**

- Director of the Multiple Sclerosis Center at the University of Pennsylvania
- Professor of Neurology at the University of Pennsylvania School of Medicine in Philadelphia
- Chairman of the Clinical Advisory Committee for the Delaware Valley National MS Society
- American Academy of Neurology

➤ **Doug Arnold, M.D.**

- James McGill Professor Neurology and Neurosurgery at the Montreal Neurological Institute of McGill University

➤ **Arthur Vandenberg, Ph.D.**

- Co-Director of the Neuroimmunology Research Laboratory at the Portland Veterans Affairs Medical Center, Portland, Oregon
- Director of the Tykeson Multiple Sclerosis Research Laboratory at Oregon Health And Science University
- Professor of Neurology and Molecular Microbiology and Immunology

➤ **Edward Fox, M.D., Ph.D.**

- Director of Multiple Sclerosis Clinic of Central Texas
- Advisory Committee, Lone Star Chapter of the National Multiple Sclerosis Society
- Consortium of Multiple Sclerosis Centers
- Clinical Assistant Professor of Neurology, University of Texas Medical Branch



Milestones and Goals

- ✓ Secured \$8.5 million financing to advance clinical trials (Q1'11)
- ✓ Presented Tovaxin Phase IIb data at the American Academy of Neurology (AAN) Meeting (Q2'11)
- ✓ Executed strategic agreements with the American Red Cross and the Blood Group Alliance, Inc. (Q2'11)
- ✓ Initiated the design and development of a proprietary Web-based system to manage patient and product flow throughout future clinical trials (Q2'11)
- ✓ Furthered discussions with Health Canada's Biologics and Genetics Therapies Directorate to secure approval for future clinical trial development in Canada (Q3'11)
- ✓ FDA Fast Track approval for Tovaxin in SPMS (Q4'11)
- ❑ Secure resources to advance clinical development and initiate 24-month Phase IIb SPMS clinical trial in North America
- ❑ Initiate discussions with European Medicines Agency (EMA) for future pivotal studies
- ❑ Evaluate expansion of platform to other autoimmune indications and geographical territories



Financial Highlights

- Basic Shares Outstanding **23 M**
Fully Diluted **35 M**
- Current Market Capitalization **~\$23 M**
- 52 week range **\$0.89-\$2.99**
- Monthly Burn **\$470,000**
- Cash Position (9/30/11) **\$8.6 M**



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CELL THERAPY

Thank You