

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 09/13/12 for the Period Ending 09/13/12

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
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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): September 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))

Item 7.01 Regulation FD Disclosure

On September 13, 2012, Opexa Therapeutics, Inc. (the “**Company**”) will deliver a corporate presentation at the 8th Annual Burrill Personalized Medicine Meeting, 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 Tcelna™, the Company’s lead therapy for multiple sclerosis. The attached materials will be made available on 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>
99.1	Opexa Therapeutics, Inc. Corporate Presentation for the 8 th Annual Burrill Personalized Medicine Meeting, held on September 13, 2012.

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: September 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 the 8th Annual Burrill Personalized Medicine Meeting, held on September 13, 2012.



OPEXA THERAPEUTICS



A REVOLUTION IN
CELL THERAPY

Opexa Therapeutics, Inc.

September 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 Tcelna™, 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 rights and preferences provided to the Series A Convertible Preferred Stock and investors in the convertible secured notes issued by the Company in July 2012 (including a secured interest in all of our assets), the ability of the Company to enter into and benefit from a partnering arrangement for the Company's product candidate, Tcelna™, on reasonably satisfactory terms (if at all), our dependence (if partnered) on the resources and abilities of any partner for the further development of Tcelna™, 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 development programs, including to undertake and complete any ongoing or further clinical studies for Tcelna™, the success of our clinical trials, the efficacy of Tcelna™ 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 Tcelna™), the risk of litigation regarding our intellectual property rights or the rights of third parties, the success of third party development and commercialization efforts with respect to products covered by intellectual property rights that we may license or transfer, 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

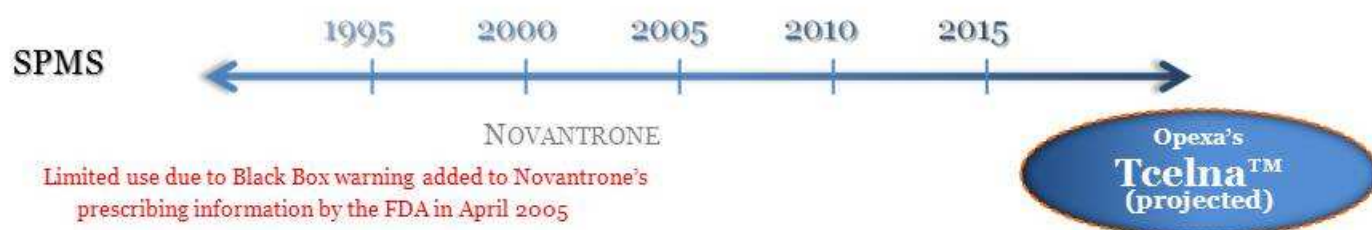
- Proprietary T-cell technology platform allows for the production of patient-specific T-cell therapies for a variety of autoimmune diseases
- Lead program, Tcelna™, a personalized cellular immunotherapy for the first-line treatment of multiple sclerosis (MS)
- Fast Track designation granted November 2011 by FDA for Tcelna™ 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



Opexa Initiates Abili-T™ trial

- **Abili-T** Phase 2b clinical trial in SPMS has been initiated
- Double-blind, 1:1 randomized, placebo-controlled
- 180 Patients
 - SPMS population
 - Approximately 30 sites in USA and Canada
- **Efficacy Endpoints:**
 - Whole-brain atrophy
 - Sustained progression measured by EDSS
 - T2 lesions progressing to hypointense lesions (black holes)
 - Change in EDSS (disability)
 - Annualized Relapse Rate (ARR)
- 2 annual courses of therapy
- 2 years of assessment



Tcelna™

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

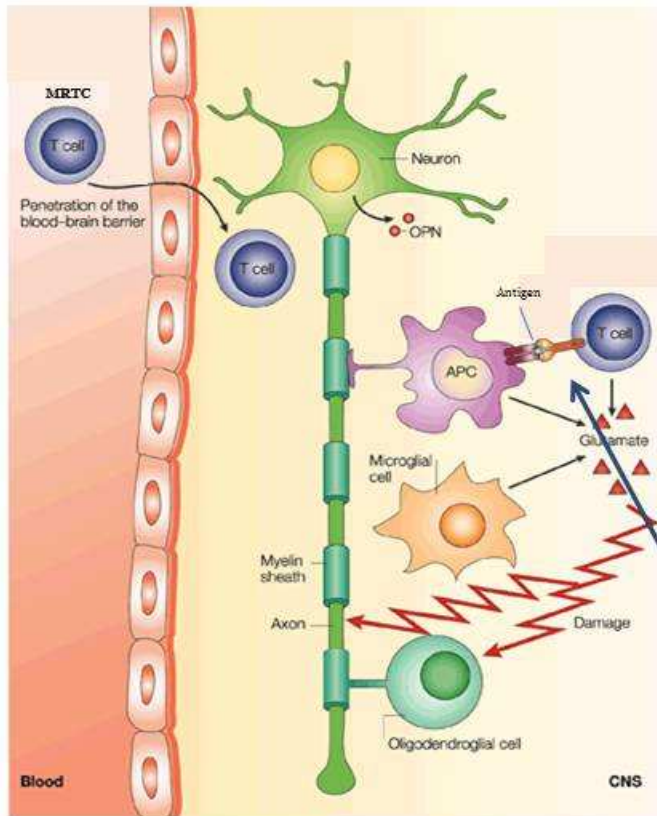
Proposed Mechanism

The subcutaneous injection of a therapeutic dose (30-45 million cells) of Tcelna™ stimulates the body's immune system to recognize the bolus of injected cells as a peripheral source of 'over represented' MRTCs, 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



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

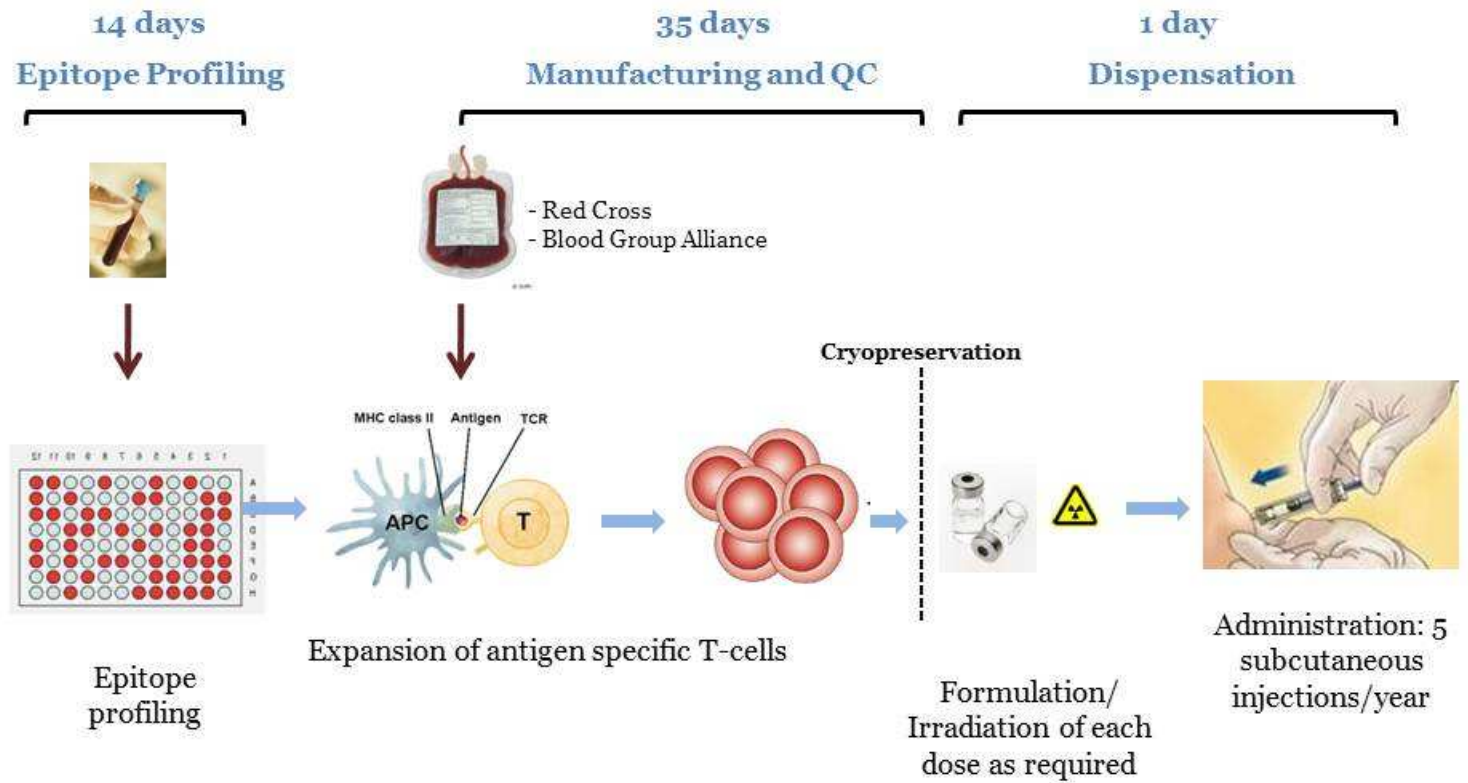
Develop new formulation based on evolved epitope profile

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																	



Tcelna™ Manufacturing





Overview of Tcelna™ Clinical Development

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

RRMS	
	Patients
Phase IIb	150
[Phase IIb Subpopulation (ARR>1)]	[50]
Phase I/II Dose Range study	16
Phase I/II Extension study	13

SPMS	
	Patients
Phase I/II trials Pooled	10
Baylor Trial	26

Safety: ITT

Previously conducted RRMS Phase 2b clinical trial (n=150)

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



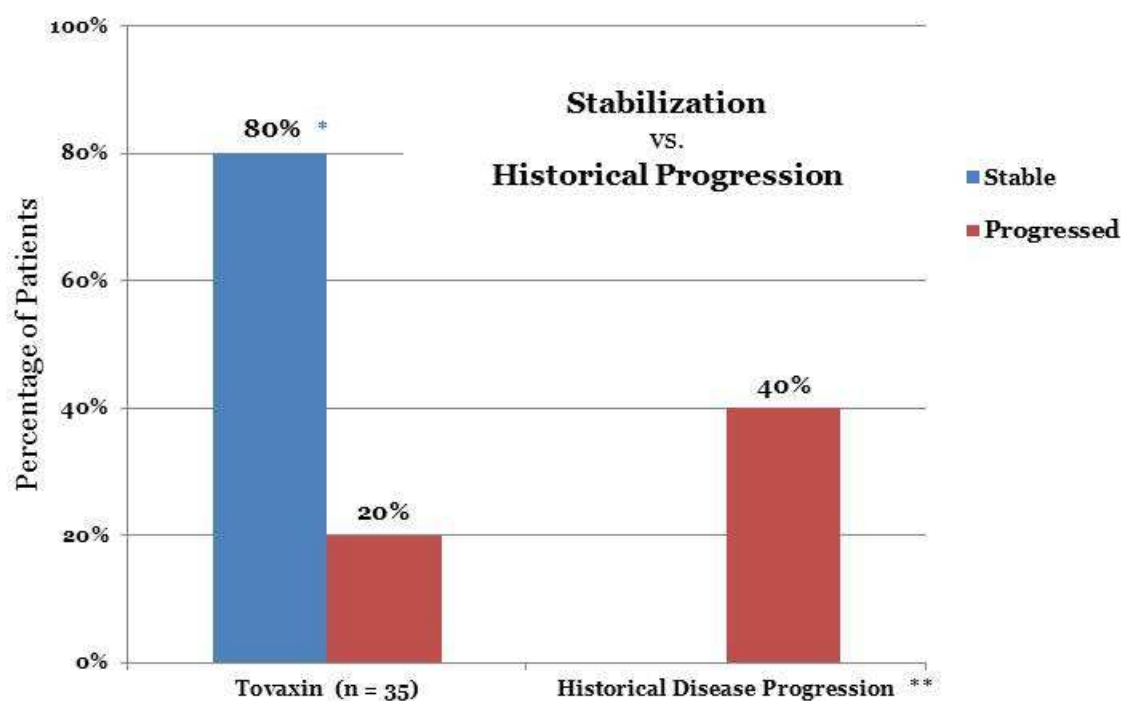
Secondary Progressive MS: Clinical Overview

- 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



Tcelna™ Stabilizes Disease in SPMS

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

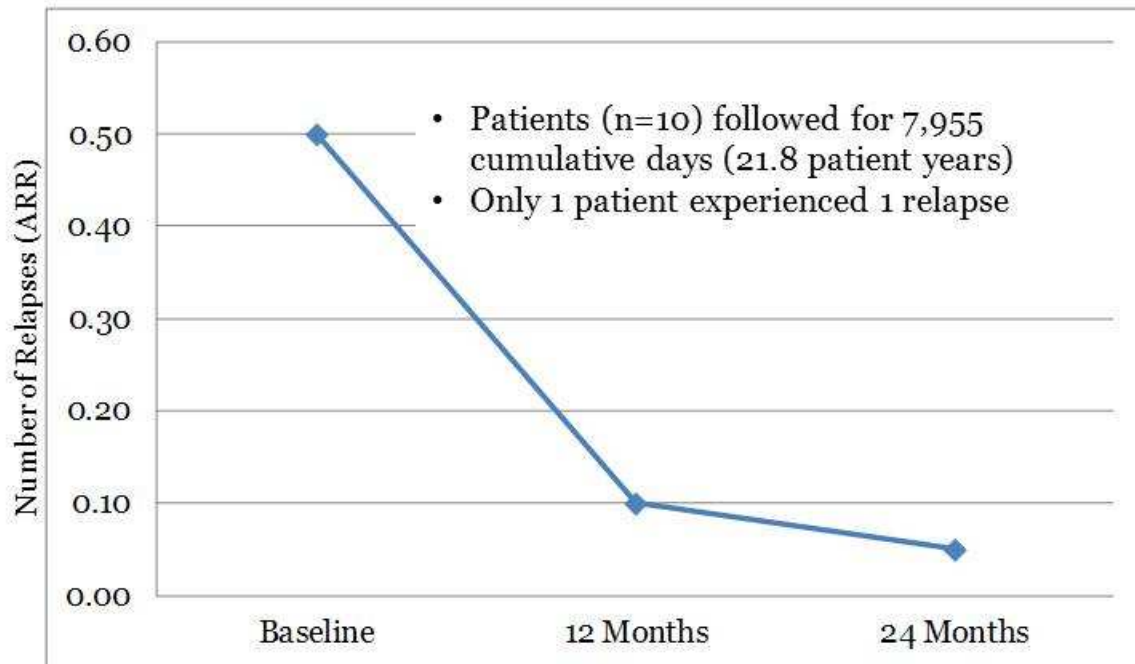


*A small percentage of patients showed an improvement (i.e. decrease in progression)

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



Phase I and Phase I/II Studies Pooled - Annualized Relapse Rate (ARR)

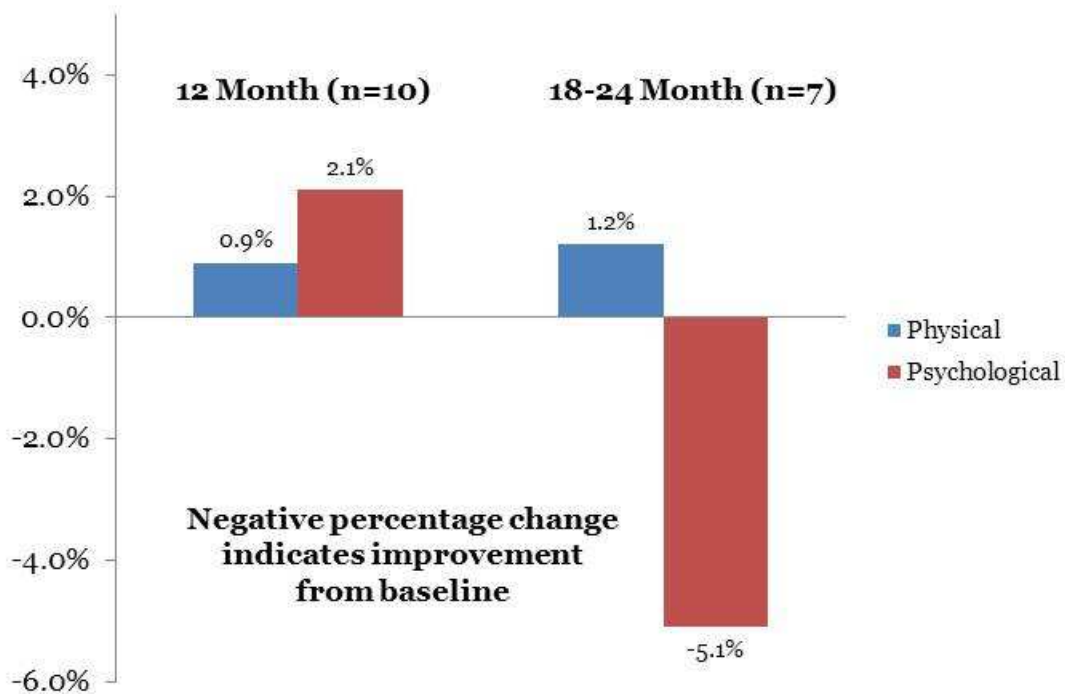


One relapse observed in 21 years of cumulative patient follow up



Phase I and Phase I/II Studies

Pooled - Change in MSIS Scores at 2 years



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



Overview of Tcelna™ Clinical Development

Clinical Status: Five clinical trials completed with Tcelna™ in 142 patients, many with multiple years of treatment

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

Safety & Tolerability: No Serious Adverse Effects (SAEs) observed to date related to Tcelna™ treatment



Company Leadership

Neil Warma, President & CEO, Director

- 18+ years of international healthcare experience with large Pharma and emerging biotechnology companies
- 9 years of Senior Management within Novartis Pharmaceuticals in Basel, Switzerland
- Formerly, President & CEO and Member of the Board of Directors of Viron Therapeutics, a private clinical stage biopharmaceutical company developing a novel class of protein therapeutics
- Co-founder and President of MedExact Inc. – medical Internet company – which was successfully sold
- Neuroscience and MBA degrees

Jaye Thompson, Ph.D., SVP, Clinical Development & Regulatory Affairs

- President and founder of SYNERGOS, Inc., a full service contract research organization which was successfully sold to inVentiv Health in 2006
- Directed and managed statistical analysis, data management, report writing and the conduct of clinical trials for a wide variety of indications including MS
- PhD, Biostatistics

Don Healey, Ph.D., VP, Scientific Development and Manufacturing

- Over 25 years experience in cellular immunology and immune regulation in both academic and biotech environments
- Former Director of Immunology for Argos Therapeutics, responsible for the development of novel autologous dendritic cell therapies for the treatment of renal carcinoma and HIV
- Post-doctoral positions in the Department of Pathology, Cambridge University, UK, conducting studies on immunoregulation in animal models of autoimmunity, including Type I Diabetes and Multiple Sclerosis



Company Leadership

Donna Rill, SVP Operations and Quality Systems

- 30 years of extensive clinical and research laboratory experience in cell and gene therapy research and clinical application, immunological techniques and assessments
- Designed, and validated cGMP Cell & Gene Therapy Laboratories, cGMP Vector Production facilities, and Translational Research Labs
- Actively involved in the development of cell based therapies as well as the formulation and review of related regulatory guidelines for over 20 years

David Jorden, (Acting) Chief Financial Officer, Director

- 20+ years of public and private company investment experience; Morgan Stanley PWM, Genometrix, Inc., CFO, principal at Fayed Sarofim & Co.
- Received a MBA from Kellogg School of Management at Northwestern University and a BBA from the University of Texas
- Chartered Financial Analyst and Certified Public Accountant designations

Dawn McGuire, M.D., Clinical Consultant, Acting-Chief Medical Officer

- Board certified neurologist
- Led development of Tysabri for Multiple Sclerosis as VP Clinical Research and Medical Affairs at Elan Pharmaceuticals
- Dr. McGuire received her B.A. with high honors from Princeton University and her M.D. from Columbia University, College of Physicians & Surgeons. She was trained in Neurology at the University of California, San Francisco

Joyce Frey-Vasconcells, Ph.D., Regulatory Consultant

- Over 12 years previously at FDA as Deputy Director at the Office of Cellular, Tissue and Gene Therapies with the Center for Biologics Evaluation and Research (CBER)
- Recognized FDA expert in the Regulation of Cellular Therapies
- One of the foremost regulatory experts regarding tissues, cell therapies, combination products, gene therapies, and tumor vaccines, and brings extensive regulatory expertise and experience for this unique group of products



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

➤ **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

- ✓ 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)
- ✓ Obtained FDA Fast Track approval for Tcelna™ in SPMS (Q4'11)
- ✓ Submitted the Chemistry, Manufacturing and Control ("CMC") update to the FDA for final review (Q3'12)
- ✓ Advanced preparations and final contract negotiations with key clinical trial sites across North America to support the Phase IIb SPMS clinical trial (Q3'12)
- ✓ Secured resources to advance clinical development and initiate a Phase IIb SPMS clinical trial in North America (Q3'12)
- ✓ Initiated 180 patient Phase IIb SPMS clinical trial (Q3'12)
- ❑ Secure additional resources through strategic partnership and/or additional capital raise(s) to continue and complete Phase IIb SPMS trial
- ❑ Initiate discussions with European Medicines Agency (EMA) for future pivotal studies
- ❑ Evaluate expansion of platform to other autoimmune indications and geographical territories



Financial Highlights

(at 6/30/12 per Q2 Earnings Release, but cash and fully diluted shares updated for July 2012 \$4.1M financing)

- Basic Shares Outstanding **23 M**
Fully Diluted **44 M**
- Market Capitalization (Basic) **~\$18 M**
- 52 week range **\$0.29-\$1.53**
- Monthly Burn **\$925,000**
- Cash Position **\$5.6 M**



OPEXA THERAPEUTICS



A REVOLUTION IN
CELL THERAPY

Thank You