

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 11/14/12 for the Period Ending 11/14/12

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): November 14, 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 November 14, 2012, Opexa Therapeutics, Inc. (the “ **Company** ”) will deliver a corporate presentation at the Lazard Capital Markets 9th Annual Healthcare 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 Abili-T clinical study for Tcelna™, the Company’s lead therapy, in subjects with secondary progressive 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>
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99.1	Opexa Therapeutics, Inc. Corporate Presentation for Lazard Capital Markets 9th Annual Healthcare Conference, held on November 14, 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: November 14, 2012

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President & Chief Executive Officer

Exhibit Index

Exhibit No.

Description

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OPEXA THERAPEUTICS



A REVOLUTION IN
CELL THERAPY

Opexa Therapeutics, Inc.

Precision Medicine

November 14, 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 Toelna™, 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, Toelna™, on reasonably satisfactory terms (if at all), our dependence (if partnered) on the resources and abilities of any partner for the further development of Toelna™, 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 Toelna™, including in this regard our ability to satisfy various conditions required to access the financing potentially available under the purchase agreements with Lincoln Park (such as the minimum closing price for our common stock, the registration of the underlying shares of common stock under the Securities Act of 1933, as amended, and the requirement for an ongoing trading market for our stock), the success of our clinical trials, the efficacy of Toelna™ 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 Toelna™), 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

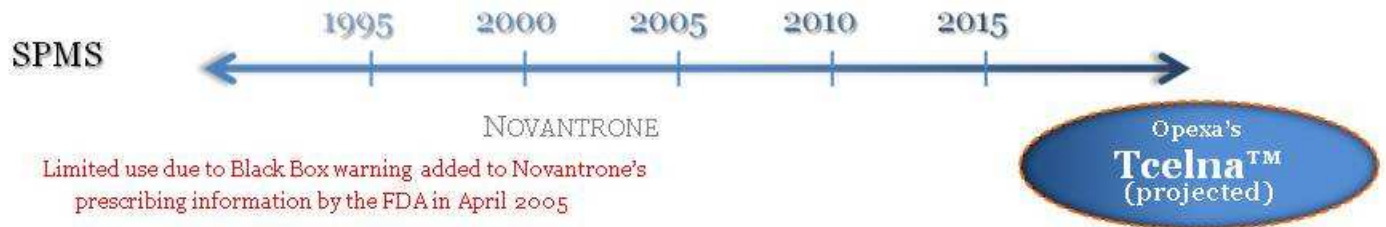
- Dedicated cell therapy company developing **Tcelna™**, a T-cell immunotherapy for Multiple Sclerosis (MS)
- Currently conducting a Phase 2b clinical trial in Secondary Progressive MS (SPMS)
- Tcelna positioned as first personalized T-cell therapy for MS patients
- Opexa has **Fast Track** Designation for Tcelna in SPMS
- In-house cGMP manufacturing enables close control of process and COGS
- In previous MS clinical studies, Tcelna has demonstrated superior safety and important indications of clinical efficacy
- Success in the ongoing clinical study should not only advance Tcelna as a treatment for SPMS but may also impact positively on its development for the treatment of Relapsing Remitting MS (RRMS)



Opexa's Focus: Filling the Void in SPMS Treatment

Over 1 million people affected by SPMS worldwide...

...only ONE FDA approved product for SPMS



SPMS represents ~ 40% of entire MS market

Treating SPMS with a
Safe and **Effective** Therapy



Opexa Initiates Abili-T™ trial

- **Abili-T Phase 2b clinical trial in SPMS is ongoing**
 - Enthusiasm among MS community (patients and sites) is high
 - Over 10 % of patients enrolled to date, one-half of clinical sites activated
 - Recent approval by Health Canada enables expansion into Canada
- **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™: Precision Medicine

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

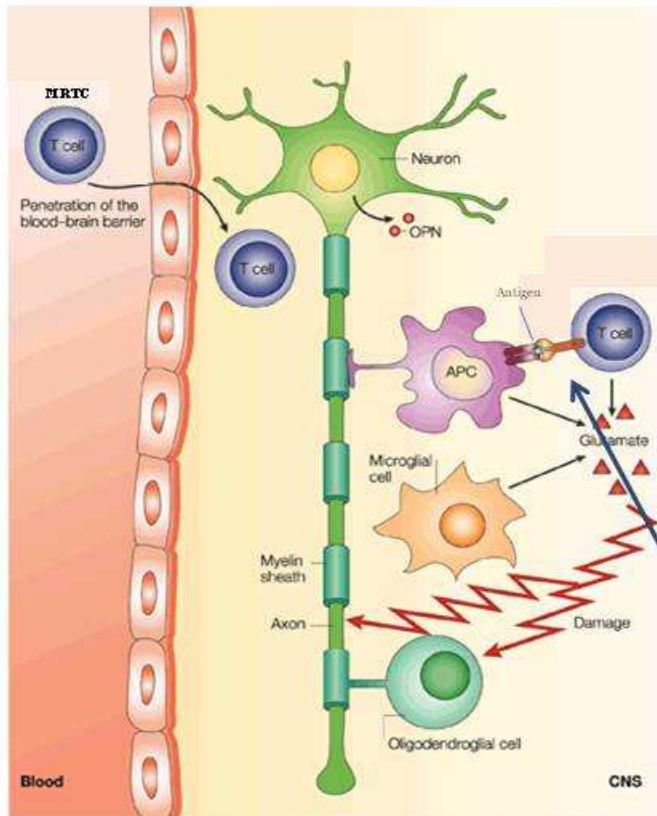
Proposed Mechanism

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*

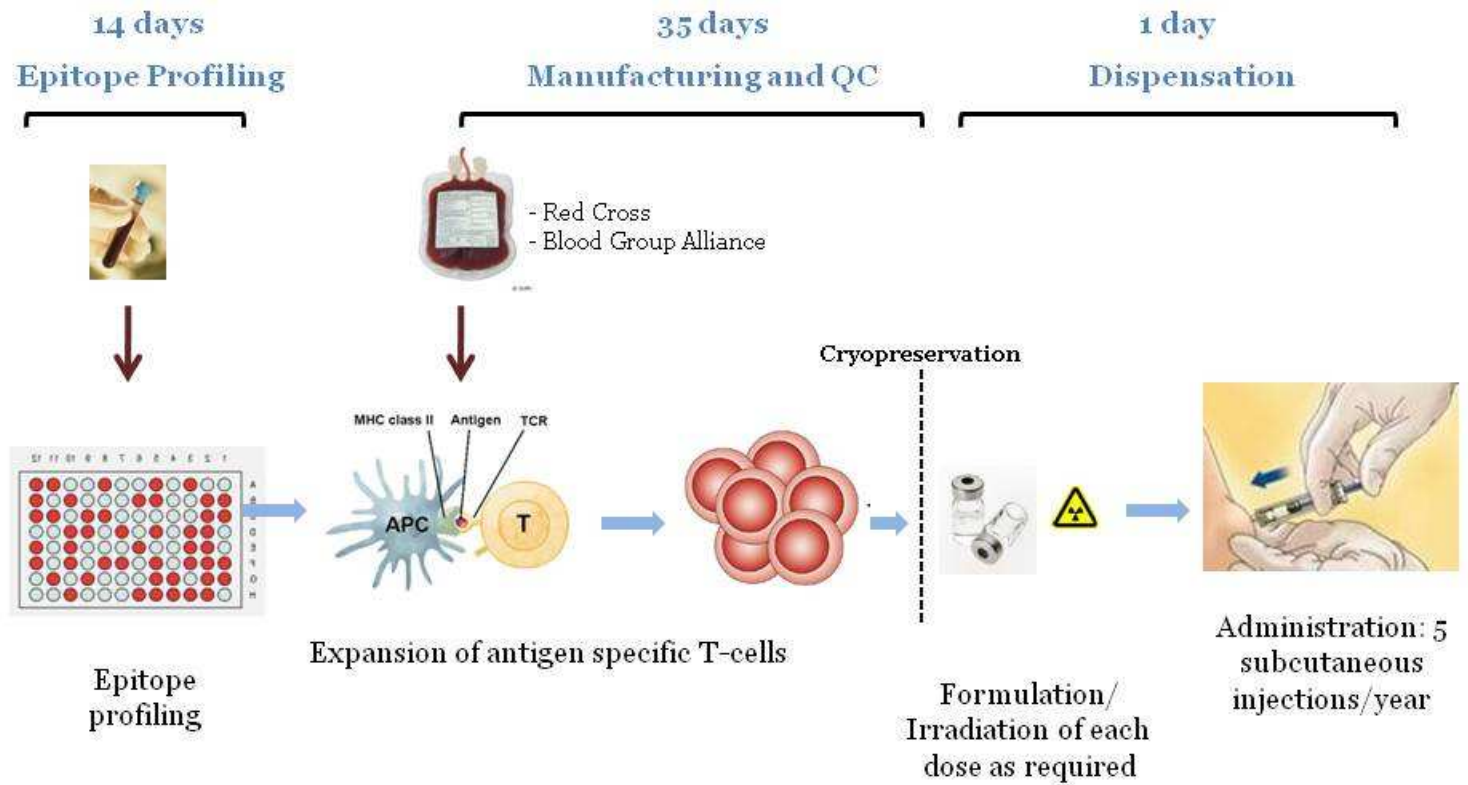
- T-cells that clonally accumulate in the lesion are driven by defined protein antigens

Opexa's Strategy

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



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 and Tolerability

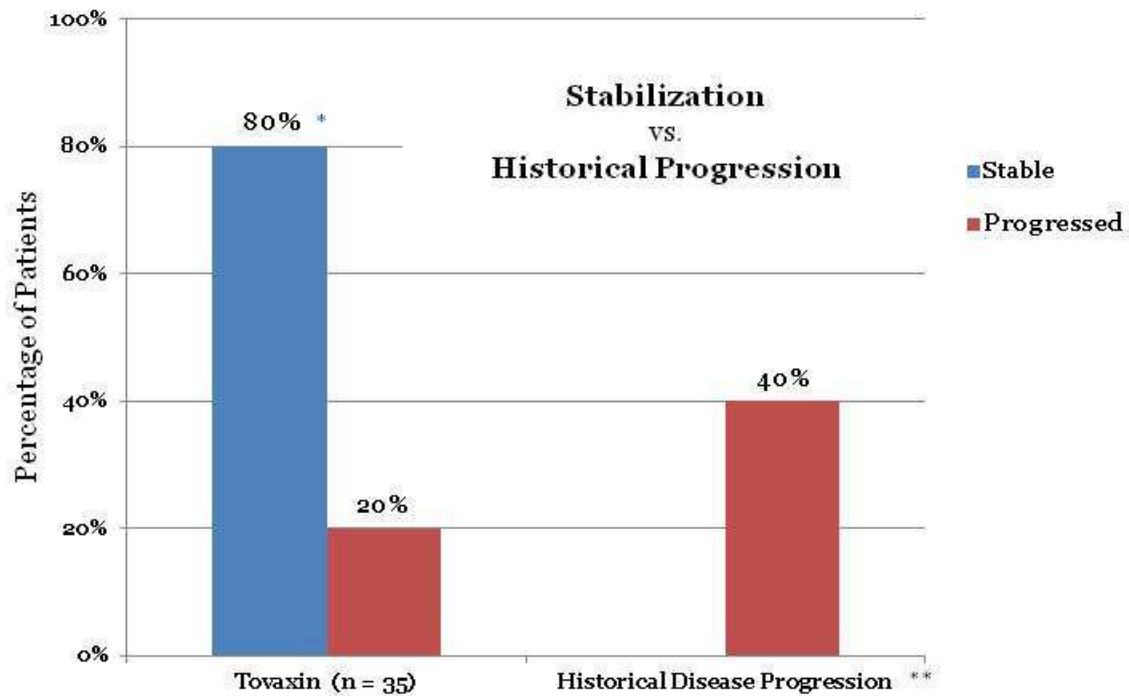
Previously conducted RRMS Phase 2b clinical trial (n=150)

Safety endpoints	
Mortality	• 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



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)

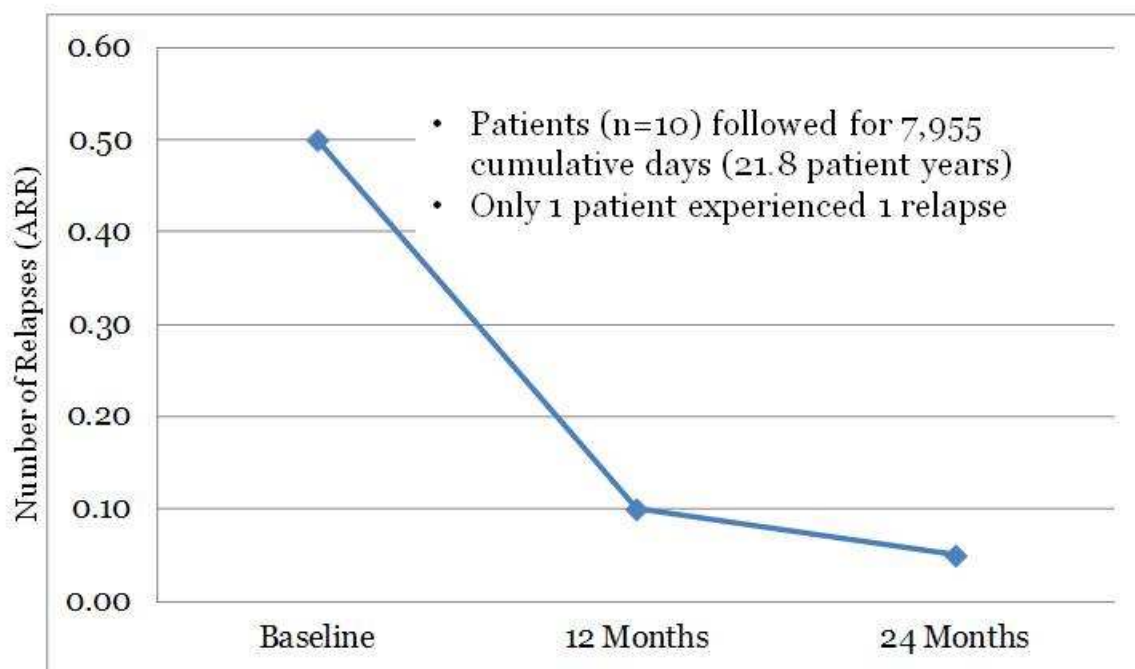
**Historical control: ESIMS Study, published *Honmes Lancet* 2004

Phase I and Phase I/II Studies

Pooled - Annualized Relapse Rate (ARR)



OPEXA THERAPEUTICS

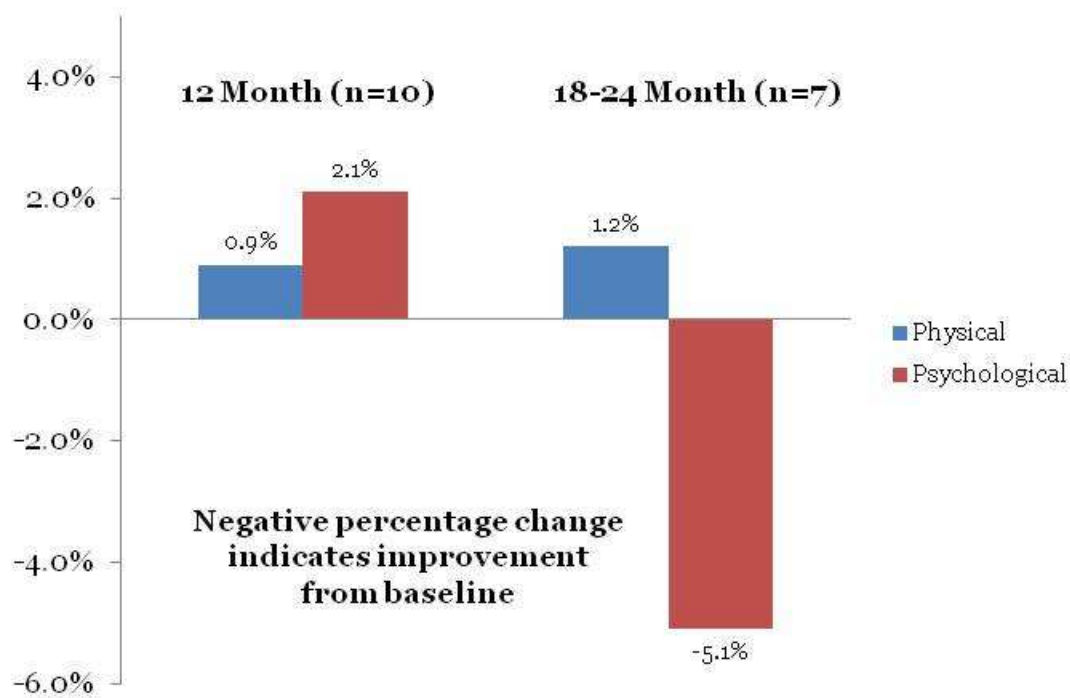


One relapse observed in 21 years of cumulative patient follow up



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



Opexa's Immune Monitoring Program

Overview

- Opexa is undertaking a comprehensive Immune Monitoring Program to capture valuable information from the **Abili-T** trial in SPMS patients
- The Immune Monitoring Program will harvest multiple samples from 180 SPMS patients over two years and will be analyzed in real time
- The longitudinal assessment of both placebo and active patient samples will provide valuable first time information for a key underserved patient population

Purpose

- Identify potential biomarkers for SPMS
- Investigate the impact of Tcelna treatment on systemic immunity
- Further elucidate the Mechanism of Action of Tcelna
- Further elucidate the Immunopathology of SPMS



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 the Ottawa Hospital
- Professor of Medicine (Neurology), University of Ottawa
- Senior Scientist, the Ottawa Hospital Research Institute
- Secretary/Treasurer – Americas Committee for Treatment and Research in MS
- Clinical Trials Committee, National MS Society (USA)
- Education Committee, the Consortium of MS Centres



Scientific Advisory Board

➤ **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

➤ **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

- ✓ Obtained FDA Fast Track approval for Teelna™ in SPMS (Q4'11)
- ✓ Submitted the Chemistry, Manufacturing and Control ("CMC") update to the FDA for final review (Q3'12)
- ✓ Closed \$4.1 million financing to enable initiation of a Phase IIb SPMS clinical trial in North America (Q3'12)
- ✓ Initiated "Abili-T" 180 patient Phase IIb SPMS clinical trial in U.S. (Q3'12)
- ✓ Received approval from Health Canada enabling expansion of Abili-T clinical trial into Canada (Q4'12)
- ✓ Entered into two purchase agreements in which Opexa has the right to sell, over a 30 month period, up to \$16.5 million in shares of its common stock to an institutional investor, subject to certain conditions and limitations (Q4'12)
- 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 9/30/12 per Q3 Earnings Release)

- Basic Shares Outstanding **23 M**
Fully Diluted **44 M**
- Market Capitalization (Basic) **~\$13 M**
- 52 week range **\$0.29-\$1.45**
- Monthly Burn **\$885,000**
- Cash Position **\$2.2 M**



Opexa Summary

- **Lead therapy, Tcelna, targeting Secondary Progressive MS**
 - Limited or no treatment options currently for SPMS
- **Promising efficacy signal**
 - Slowing of disease progression in SPMS patients and possible stabilization in quality of life indicators
- **Superior in safety and tolerability**
 - Compared to existing MS drugs (marketed or in development) at this stage of development
- **Personalized therapy**
 - Tcelna positioned as first personalized T-cell therapy for MS patients, precision medicine on an annual basis
- Enrollment of the “Abili-T” Phase 2 SPMS clinical trial is on schedule, enthusiasm strong, reached 10% enrollment in first 2 months
- Company focus is on securing capital to enable continuation and completion of clinical trial



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Thank You