OPEXA THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

Filed 11/16/11 for the Period Ending 11/16/11

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
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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 16, 2011

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

Texas	**001-33004**	**76-0333165**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2635 Technology Forest Blvd., The Woodlands, Texas	**77381**
(Address of principal executive offices)	(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 obligations 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 November 16, 2011, Opexa Therapeutics, Inc. (the "Company") will deliver a corporate presentation at the Lazard Capital Markets 8th 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 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

Exhibit No.	**Description**
99.1	Opexa Therapeutics, Inc. Corporate Presentation for Lazard Capital Markets 8th Annual Healthcare Conference, held on November 16, 2011.

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 16, 2011

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 Lazard Capital Markets 8th Annual Healthcare Conference, held on November 16, 2011

Exhibit 99.1

OPEXA THERAPEUTICS

Opexa Therapeutics, Inc.

November 2011

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)
- Promising efficacy and strong safety profile support late stage clinical trials in both Relapsing Remitting MS (RRMS) and Secondary Progressive MS (SPMS)
- Fast Track designation granted by FDA for Tovaxin for treatment of SPMS
- Service agreements with both the Blood Group Alliance and the American Red Cross to provide blood procurement services
- Strong intellectual property position
- In-house cGMP manufacturing enables close control of process and COGS
- Opexa owns 100% worldwide rights for all indications

Tovaxin in Multiple Sclerosis

The Challenge in Treating Multiple Sclerosis is Finding a ***Safe*** and ***Effective*** Therapy

- Current therapies do not provide adequate treatment for MS patients and are characterized by serious adverse events (SAEs)
- T-cell therapy as an alternative treatment for MS
- Personalized therapy for each individual MS patient, may provide strongest benefit/risk profile

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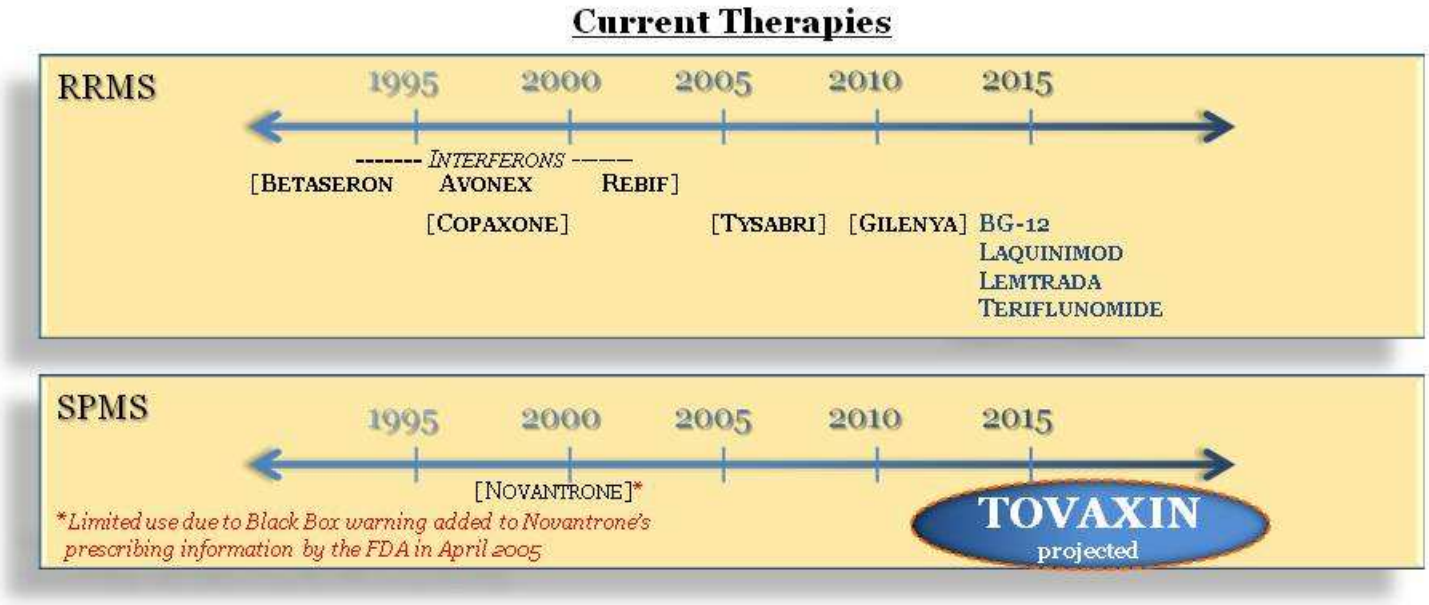
Current MS Treatment Paradigm



Over 1 million people affected by SPMS worldwide...
...only ONE FDA approved product for SPMS

Current Therapies have Significant Limitations in Treating MS Patients

About Tovaxin

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: Restores the function of the defective immune system, depletes MRTCs

Status: Five clinical studies completed with Tovaxin in 356 patients, many with multiple years of treatment

ADVANTAGES

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

Safety & Tolerability: No SAEs observed to date related to Tovaxin treatment

Personalized Therapy: Specifically targets an individual's disease profile and progression (re-tested after one year to account for epitope drift)

Improved Compliance: Five subcutaneous injections per year may provide significant compliance benefits to both patients and physicians

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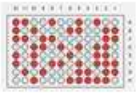
Tovaxin Manufacturing

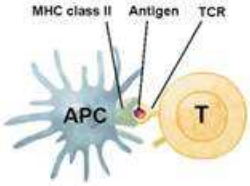
14 days
Epitope Profiling

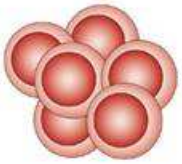
35 days
Manufacturing and QC

1 day
Dispensation

- Red Cross
- Blood Group Alliance







Cryopreservation

Epitope profiling

Expansion of antigen specific T-cells

- **Up to 6 T-cell lines (based on epitope profile)**
- **Manufacture all five doses simultaneously**
- **Full course of annual therapy from one blood draw**

Formulation/ Irradiation of each dose as required

Administration: 5 subcutaneous injections/year

Proprietary Assay Enables Annual Personalized Treatments

Year 1 Personalized Treatment

- Asses epitope profile
  - ➢ *Conduct analysis of 109 peptides from all three key myelin proteins*

Epitopes Used in Tovaxin Formulation in Year 1

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				■	■								■					

Proprietary Assay Enables Annual Personalized Treatments

Year 2 Personalized Treatment

- Re-assess epitope profile
  - ➢ Identify epitope drift
    - ➢ Develop new formulation based on evolved epitope profile

Epitopes Used in Tovaxin Formulation in *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																	■	

Proprietary Assay Enables Annual Personalized Treatments

Year 3 Personalized Treatment

- Re-assess epitope profile
  - ➢ Identify epitope drift
    - ➢ Develop new formulation based on evolved epitope profile

Epitopes Used in Tovaxin Formulation in *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																		

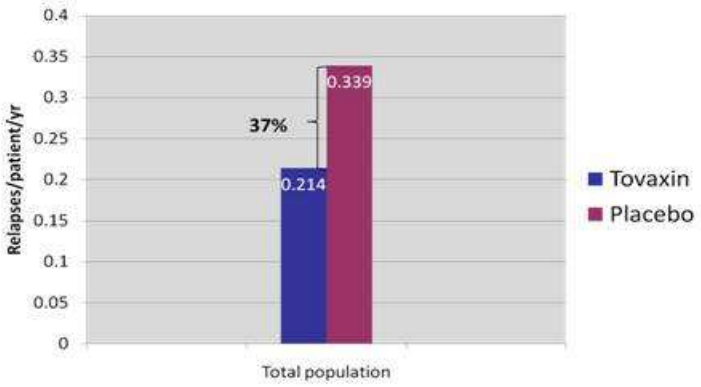
Tovaxin RRMS Clinical Data Overview

- 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

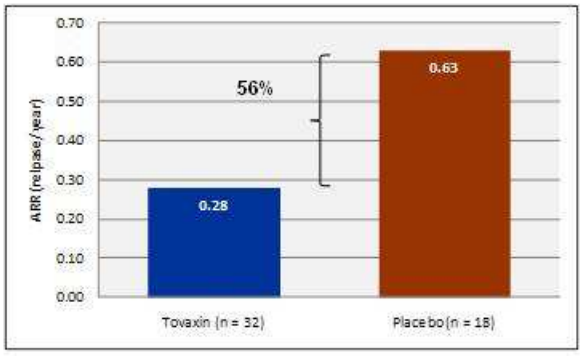
- Superior safety and promising efficacy demonstrated

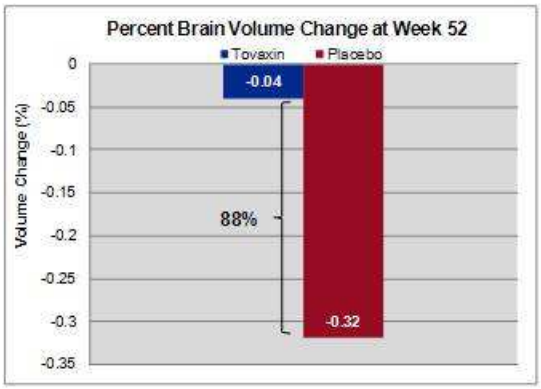
- Two *End-of-Phase II* meetings with FDA successfully completed



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





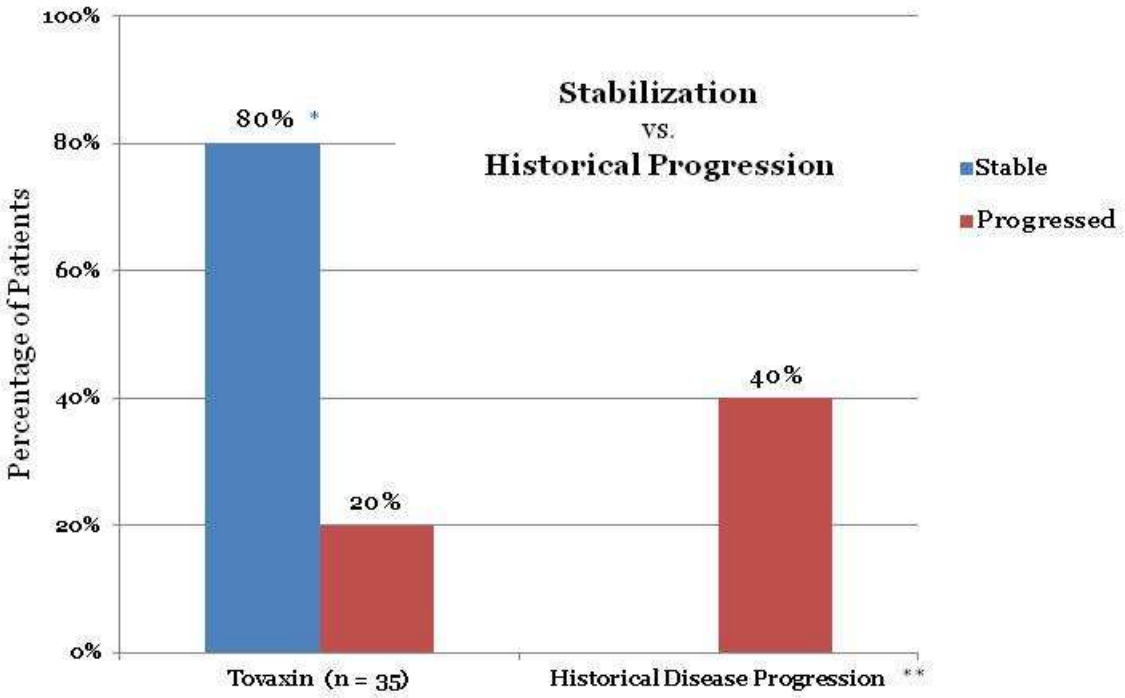
Data Provide Support for Phase IIb Program in SPMS

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

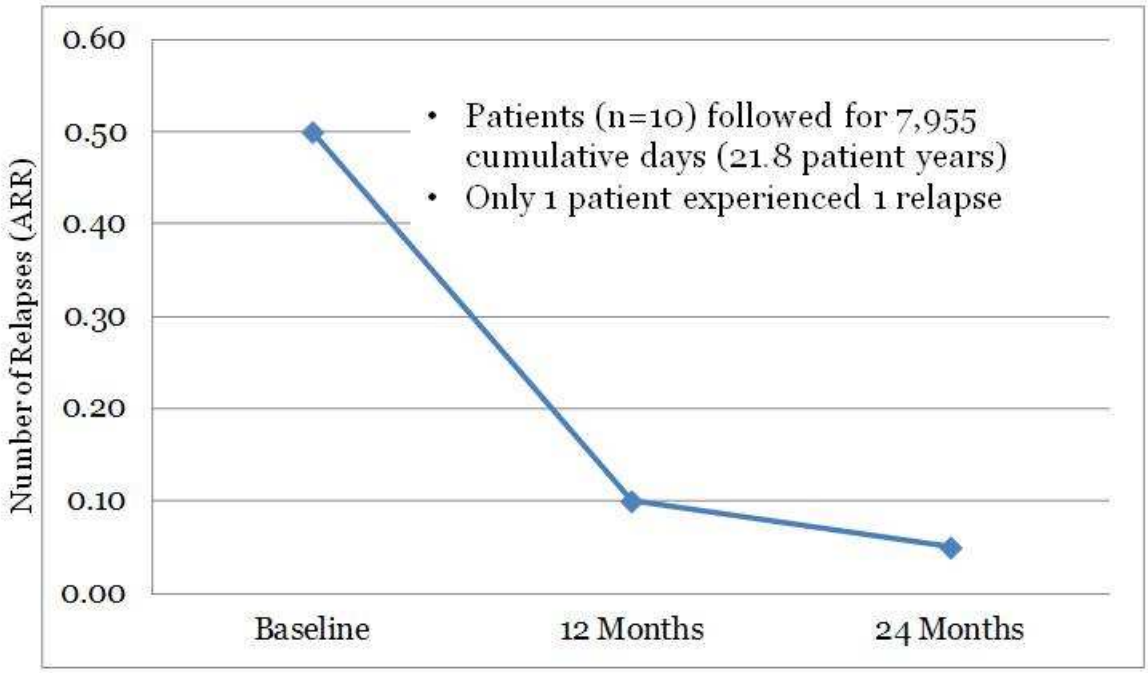
80% of subjects had no disease progression by EDSS at 2 years



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

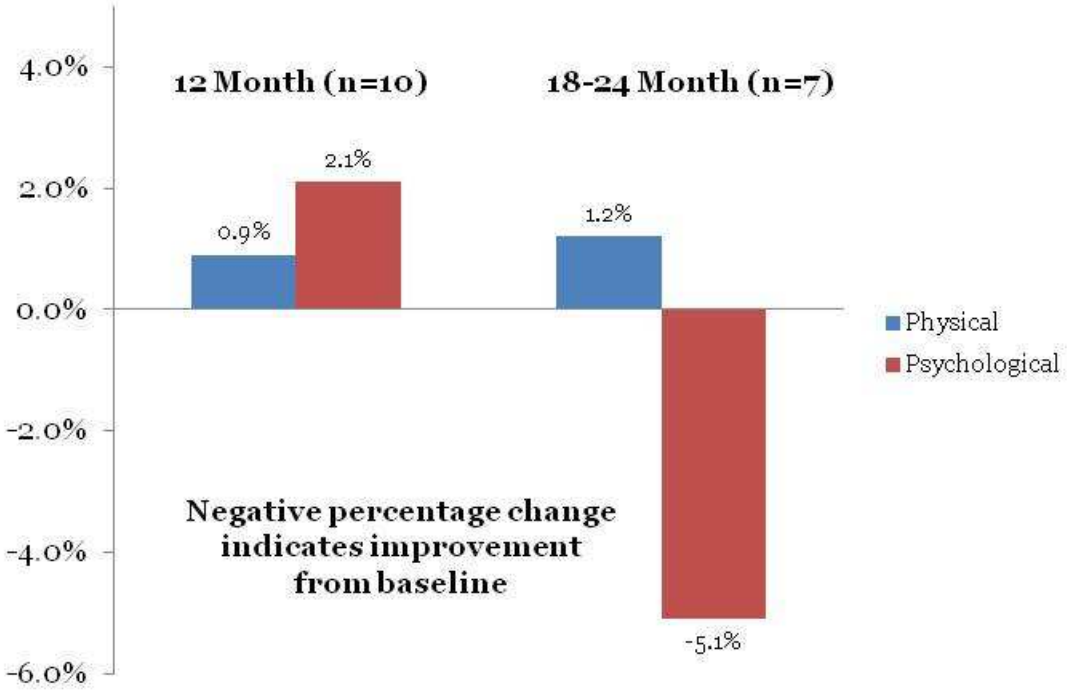
**Historical control: ESIMS Study, published Hommes Lancet 2004

Phase I/II Clinical Trial Results
Annualized Relapse Rate (ARR)



One *relapse observed in 21 years of cumulative patient follow up*

Phase I/II Clinical Trial Results
Change in MSIS Scores at 2 years



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

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)
- 2 years of treatment and assessment
  - Initiation 1H'2012, subject to securing necessary resources; Completion 2H'2014

Regulatory Path

- Fast Track designation granted for Tovaxin in SPMS in November 2011
- Potential for streamlined clinical development path to approval (i.e., single pivotal study)
- Rapid trial accrual possible due to limited treatment options

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	**~$30 M**
• 52 week range	**$1.01-$2.99**
• Cash Position (9/30/11)	**$8.6 M**

OPEXA THERAPEUTICS

Thank You