

# OPEXA THERAPEUTICS, INC.

## **FORM 8-K** (Current report filing)

Filed 09/13/11 for the Period Ending 09/13/11

|             |                                                         |
|-------------|---------------------------------------------------------|
| Address     | 2635 TECHNOLOGY FOREST BLVD.<br>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                                                   |

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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, 2011**

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**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)

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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 September 13, 2011, Opexa Therapeutics, Inc. (the “ **Company** ”) will deliver a corporate presentation at the Rodman & Renshaw Annual Global Investment Conference – Healthcare, 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](http://www.opexatherapeutics.com). The Company does not undertake to update this presentation.

**Item 9.01            Financial Statements and Exhibits**

(d) Exhibits

| <b><u>Exhibit No.</u></b> | <b><u>Description</u></b>                                                                                                                         |
|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| 99.1                      | Opexa Therapeutics, Inc. Corporate Presentation for Rodman & Renshaw Annual Global Investment Conference – Healthcare, held on September 13, 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.

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## 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, 2011

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma  
Neil K. Warma  
President & Chief Executive Officer

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**Exhibit Index**

| <b><u>Exhibit No.</u></b> | <b><u>Description</u></b>                                                                                                                         |
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OPEXA THERAPEUTICS



# Opexa Therapeutics, Inc.

Corporate Presentation  
September 2011

*(NASDAQ:OPXA)*

*Neil K. Warma  
President & CEO*

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# Forward-Looking Statements

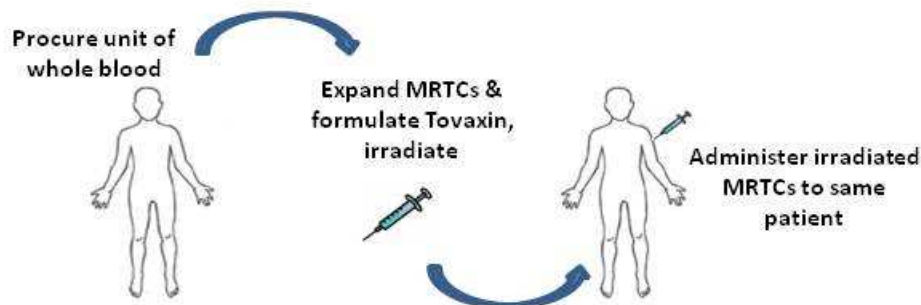
This presentation contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The forward-looking statements in this presentation do not constitute 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, 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, the success of third party development and commercialization efforts with respect to products covered by intellectual property rights transferred by the Company, 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: a Leading Cell Therapy Company

- **Pioneering the development of cell therapies for autoimmune diseases through proprietary T-cell platform**
- **Lead drug candidate Tovaxin® shows promising clinical efficacy in Multiple Sclerosis patients**
- **Promising efficacy and favorable safety profile supports multiple late stage clinical trials**
- **cGMP manufacturing facility supports clinical development needs and allows close oversight of quality control and costs**
- **Strong management team to execute on opportunity**

# Tovaxin: a Personalized T-cell Therapy for MS

Autologous: the patient's own cells act as the drug



- Unique approach to induce regulation of pathogenic T-cells
- Reintroduction of attenuated T-cells elicits targeted immune response against patient's existing myelin reactive T-cells
- Personalized through selection and expansion of auto-reactive T-cells from each patient and re-injected after irradiation to induce protective immunity
- Converging data points demonstrate prevention or treatment of autoimmune disease in clinical setting



# Tovaxin highlights

- 5 clinical studies have been conducted (in Relapsing Remitting and Secondary Progressive MS patients), enrolling 356 patients with 182 treated with Tovaxin
- Over 850 Tovaxin preparations have been manufactured: reproducibility and consistency established, commercially viable process implemented
- Safety demonstrated and clinical efficacy promising across broad spectrum of patients for relapsing and progressive MS
- Multiple commercial opportunities:
  - **Secondary Progressive MS**
    - Promising efficacy shown in slowing disease progression and reducing relapse rates
    - Significantly differentiates Tovaxin
  - **Relapsing Remitting MS**
    - FDA concurrence for Phase 3 studies
    - Clinical benefit shown with reduction of relapse rates and improvement in disability
    - Mechanism supports combination therapy
- Dose and regimen have been confirmed as effective and practical
- In-house cGMP manufacturing enables close control of process and COGS
- Opexa owns 100% worldwide rights for all indications



# Tovaxin Development Goals

**Targeting 1<sup>st</sup> line treatment for Relapsing Remitting MS and Secondary Progressive MS patients**

- **Next planned clinical trials**
  - **Phase 2b in Secondary Progressive MS (SPMS)**
  - **Phase 3 Pivotal in Relapsing Remitting MS (RRMS)**

# Business Strategy for Secondary Progressive MS (SPMS)

- **Supportive data**
  - 36 patients treated in three clinical studies
  - 80% showed no disease progression, significant reduction in relapse rate
  - Well tolerated, no Serious Adverse Events (SAEs)
  - Supports Tovaxin mechanism of action
- **Possibility for streamlined clinical development path to approval (i.e. single pivotal study)**
- **Strong interest from Key Opinion Leaders, clinical investigators and patients**
- **Area of increased focus by Pharma companies**
- **Positive result supports RRMS indication**
- **Substantial unmet medical need in SPMS**
  - Only one product currently approved for SPMS indication with limited use due to cardio toxicity
- **Positive data could differentiate Tovaxin even further from competitors**
- **Rapid study accrual possible due to limited treatment options**



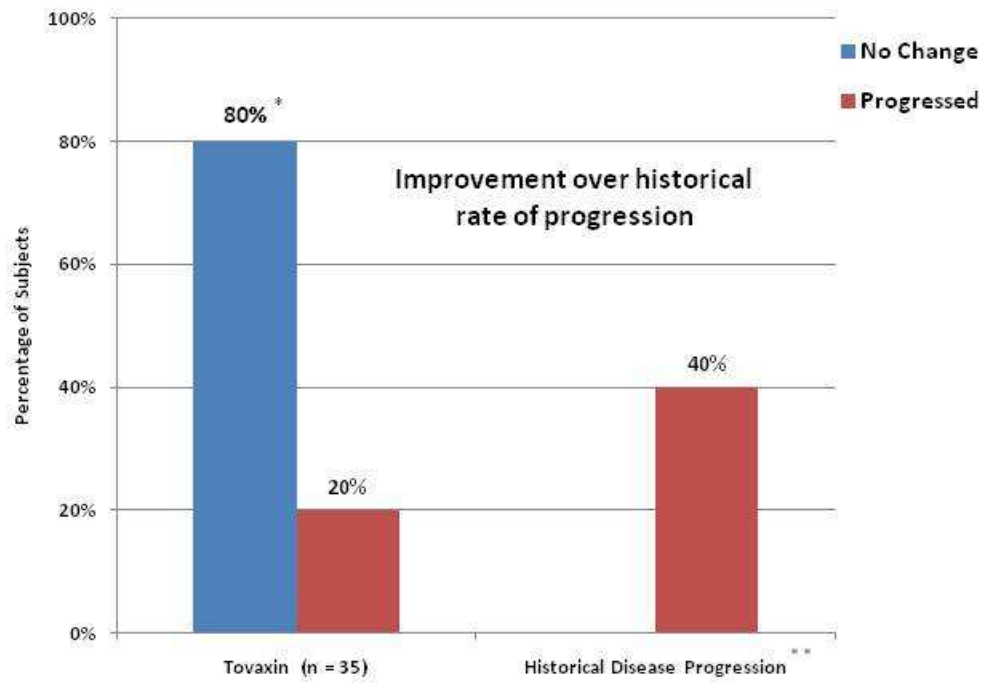
# Tovaxin Experience in SPMS

- **Tovaxin administered to 36 subjects with SPMS in three clinical studies**
  - Baylor College of Medicine sponsored study; led by KOL Dr. J. Zang
  - Opexa Sponsored Studies: Protocols 2000-03 and 2001-01
- **Safe and well-tolerated in long term evaluation**
  - No serious adverse events (SAEs)
- **Promising efficacy in SPMS patient population**
  - **Significant reduction in progression of disease (at 2 years)**
    - 80% of patients showed no sign of disease progression by EDSS
    - Only 20% of patients progressed compared to over 40% historical progression
  - **Substantial reduction in relapse rate**
    - 50% reduction in Baylor sponsored study
    - 89% reduction in Opexa sponsored studies 2000-03 and 2001-01
- **SPMS affects 50% of total MS population**
- **Only one drug approved specifically for SPMS**
  - Novantrone (mitoxantrone) approved in 2000; black box warning due to toxicity



# Tovaxin SPMS Experience

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

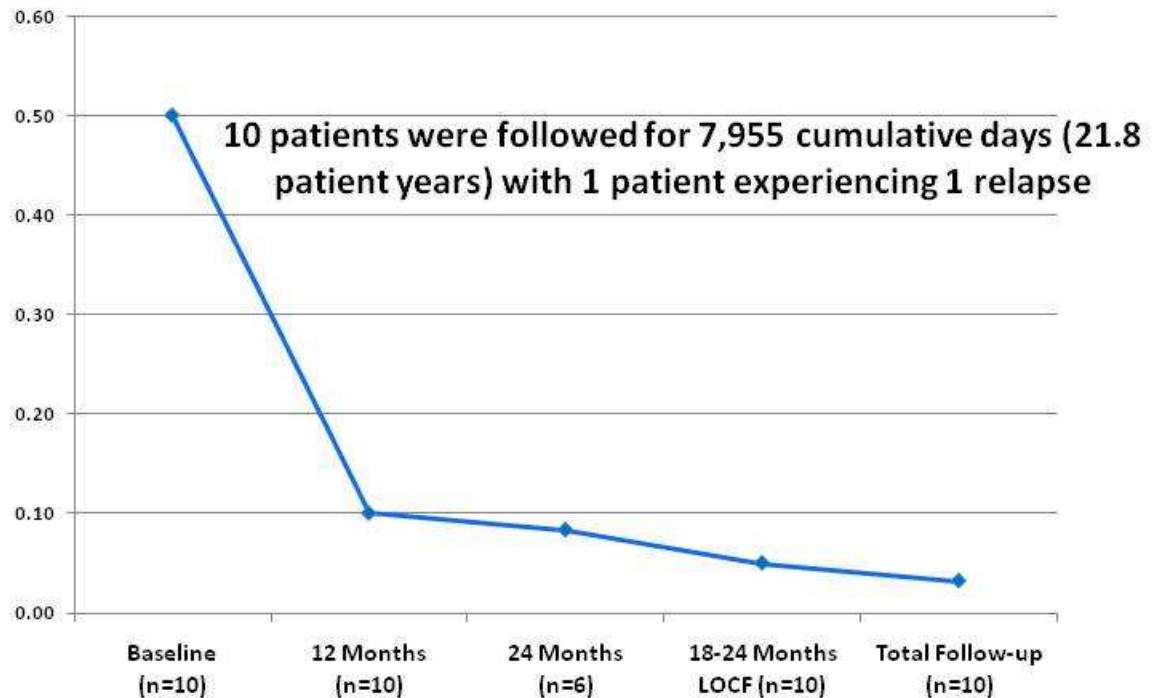


\* A small percentage of patients showed an improvement in progression (by EDSS)

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



## Protocols 2000-03 and 2001-01 Pooled Annualized Relapse Rate Over Time

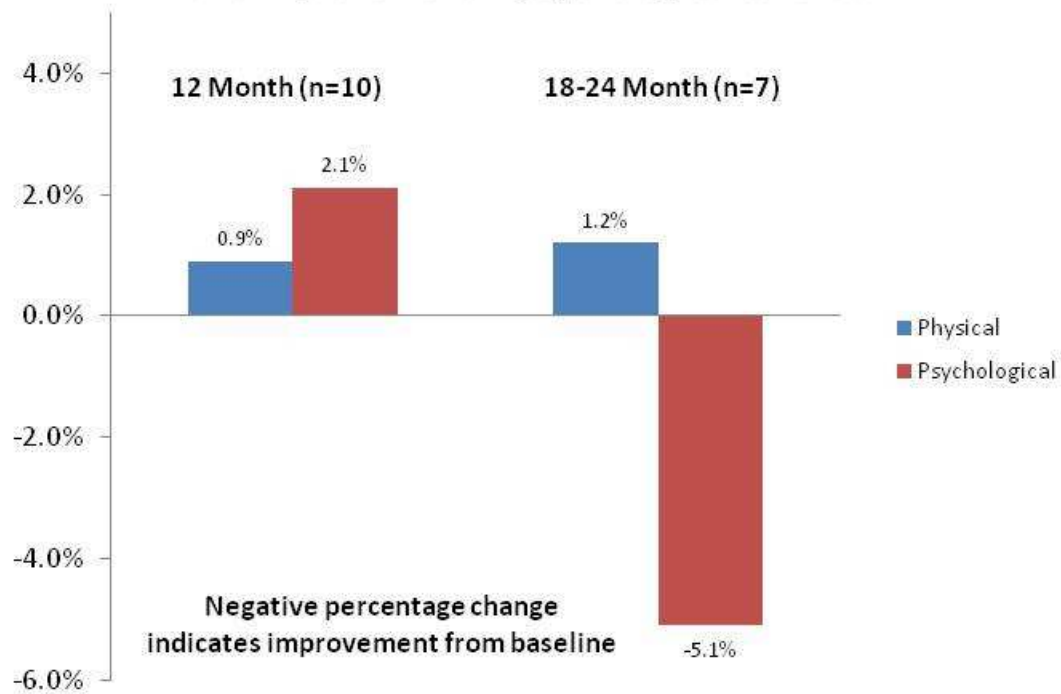




# Protocols 2000-03 and 2001-01 Pooled

## Change in MSIS Scores

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





## Phase 2b SPMS Clinical Study Design

- **Double-blind, 1:1 randomized, placebo-controlled**
- **180 Subjects**
  - SPMS population with history of relapses or an active MRI
- **Up to 30 KOL sites in USA and Canada**
- **2 annual courses and 2 years of assessment**
- **Primary endpoint - sustained progression by EDSS**
- **Secondary efficacy endpoints**
  - Atrophy
  - Progression to black holes
  - Change in EDSS
  - ARR



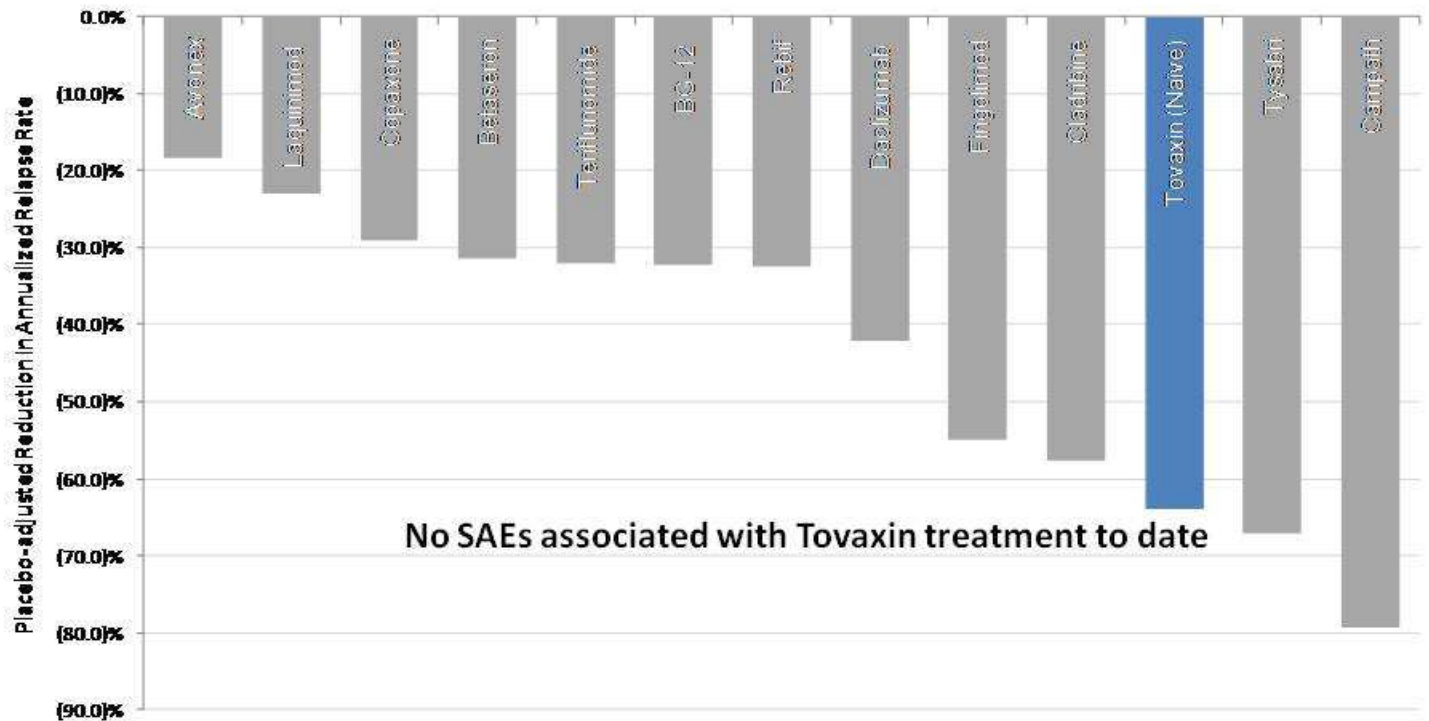
## Relapsing Remitting MS Status

- **Completed Phase 2b clinical study in 150 RRMS patients**
- **Completed two *End of Phase 2* meetings with FDA**
- **Phase 3 pivotal studies are planned**
- **Successful meeting with Health Canada to pave way for conducting clinical studies in Canada**
- **Tovaxin positioned well in RRMS – superior safety, promising efficacy**
  - Newly diagnosed
  - Non-compliant patients key targets



## Tovaxin Competitive Positioning: RRMS

### Reduction in Annualized Relapse Rate



# Phase 3 RRMS Clinical Study Design

- **Double-blind, 1:1 randomized, placebo-controlled**
- **260 Subjects**
  - Patients with relapsing MS who are naïve to previous Disease Modifying Treatments
- **Up to 65 KOL sites in USA and Canada**
- **1 year of assessment**
- **Primary endpoint - Annualized relapse rate at 12 months**
- **Secondary efficacy endpoints**
  - Percentage of subjects relapse-free at one year
  - Percentage of brain volume change (atrophy) at one year
  - Change from baseline in EDSS at 1 year

# Tovaxin Manufacturing Process

- cGMP and GTP compliant
  - Compliant with all relevant FDA, National and State wide regulations
  - Incorporates European Cell Therapy Regulations
- Current capacity sufficient for all North American clinical trial needs



- Improvements to process
  - Reduced manufacturing time by 50% time to 45 days
  - Improved specificity and potency of Tovaxin
  - Significantly reduced costs, improved efficiency



## Previous 12 Month Company Milestones

- ✓ Q4'10 Secured FDA concurrence for Phase 3 RRMS studies
  - Completed two formal *End of Phase 2* meetings with FDA
    - Manufacturing, full CMC Review
    - Clinical Review, Future Development Plan
- ✓ Q1'11 Secured financing to advance toward Phase 3 trial initiation
  - Gross proceeds \$8.5 million
- ✓ Q2'11 Presented Tovaxin 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. to provide blood collection services to support future clinical development of Tovaxin
- ✓ Q2'11 Initiated the design and development of a proprietary Web-based system to manage patient and product flow throughout future clinical studies
- ✓ Q3'11 Met with Health Canada's Biologics and Genetics Therapies Directorate as part of the process to secure approval for Opexa to conduct a portion of future clinical development in Canada

# Targeted Near-Term Company Milestones

- **Secure financing to advance clinical development**
- **Initiate discussions with European Medicines Agency (EMA)**
- **Evaluate further expansion of platform to other indications and geographical territories**

## Stock Information

|                                 |               |
|---------------------------------|---------------|
| • Stock Exchange                | NASDAQ        |
| • Stock Symbol                  | OPXA          |
| • Basic Shares Outstanding      | 23 M          |
| • Fully Diluted Shares          | 35 M          |
| • Current Market Capitalization | ~\$30 M       |
| • 52 week range                 | \$1.05-\$2.99 |
| • Cash Position (6/30/11)       | \$9.8 M       |
| • Monthly Burn Rate             | ~\$470,000    |