



## Company Profile

**Opexa Therapeutics (NASDAQ:OPXA)** is a biotechnology company dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases. The company's leading product candidate has the potential to address the significant unmet medical needs of the large multiple sclerosis (MS) patient population.

**Opexa's lead therapy, Tovaxin®**, a personalized T-cell vaccine for the treatment of multiple sclerosis (MS), is specifically tailored to each patient's disease profile. Opexa believes the potential combination of efficacy, superior safety, improved tolerability and patient-friendly administration schedule may position Tovaxin as the MS treatment of choice as compared to existing therapeutic options.

**Positive results from Phase IIb Clinical Study:** Tovaxin for Early Relapsing Multiple Sclerosis (TERMS) study demonstrated key indications of therapeutic activity, as well as an excellent safety profile.

**Planning for Phase III underway:** Following meetings with the US FDA, Opexa is preparing to initiate Phase III studies

## Tovaxin®

Tovaxin possesses a unique mechanism of action that combats the demyelination of the nerve fibers in the central nervous system, the underlying cause of MS. Opexa believes Tovaxin may possess a number of advantages compared to other MS therapies currently available or in development, including:

**Efficacy** - Clinical trials conducted to date demonstrate that Tovaxin may result in a reduction in the Annualized Relapse Rate (ARR) for patients with MS. Tovaxin has also been shown to improve disability in a number of MS patients and may have a neuroprotective benefit.

**Safety and Tolerability** - It is believed that Tovaxin treatment selectively targets and depletes the pathogenic T-cell population. It is not a general immune suppressant and, accordingly, is not associated with the serious side effects seen by those MS treatments that function by systemically suppressing the immune system. In clinical trials conducted to date, there have been no serious adverse events associated with Tovaxin treatment.

**Improved Compliance** - Currently, available therapies are administered monthly and, in some cases, daily. Tovaxin's treatment regimen of five subcutaneous injections per year may provide compliance benefits to patients and physicians.

**Personalized Therapy** - Using Opexa's proprietary technology, the company customizes Tovaxin treatments to specifically target an individual's disease progression and/or modification.

## INVESTMENT HIGHLIGHTS

Opexa is competitive on three levels:

- 1. Company level: A leading cell therapy company**
    - Cellular therapies will have significant impact in curing human diseases
    - Opexa internal expertise built up to highest level, strong advisory network
  - 2. Technology Level: Proprietary T-Cell Technology Platform**
    - Potential to generate multiple drug opportunities
    - Primary focus: Multiple Sclerosis
    - Other areas: Rheumatoid Arthritis, Type 1 Diabetes
  - 3. Drug level: Tovaxin®**
    - Personalized T-cell vaccine
    - Phase III development in MS
    - Efficacy: as good as best drug on market
    - Safety: Superior
- Broad intellectual property portfolio
  - cGMP and GTP compliant in-house manufacturing
  - Tovaxin is being developed as first line treatment; may address significant market with unmet needs
    - Current MS therapies generate approximately \$9B sales annually, estimated to exceed \$15B by 2015;
    - 50% of patients are non-compliant due to side effects and treatment regimens of current therapies.

## TOVAXIN POINTS OF DIFFERENTIATION

- Superior safety profile
- The only personalized therapy for MS
- Especially compliant for newly diagnosed patients
- Mechanism supports combination therapy
- Most favorable benefit/risk ratio
- Fast Track Designation likely as this indication still represents an unmet medical need



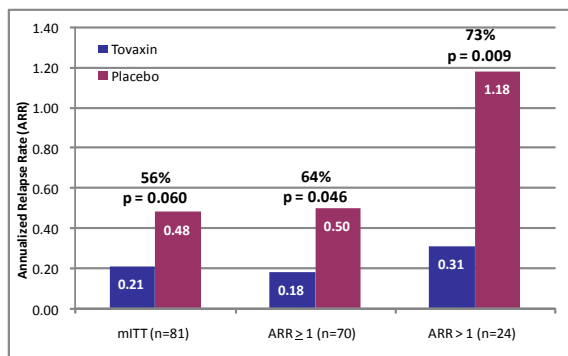
## TOVAXIN PHASE IIb RESULTS

**Tovaxin for Early Relapsing Multiple Sclerosis (TERMS)** was a Phase IIb clinical study that showed compelling evidence that Relapsing Remitting MS (RRMS) patients treated with Tovaxin saw overall clinical benefits over the placebo group.

The TERMS study was a multi-center, randomized, double blind, placebo-controlled trial in 150 patients with Relapsing-Remitting Multiple Sclerosis (RRMS) or high risk Clinically Isolated Syndrome (CIS). Patients received a total of five subcutaneous injections at weeks 0, 4, 8, 12 and 24. Key results from the TERMS trial include:

- In the Modified Intent to Treat (mITT) patient population the ARR for Tovaxin-treated patients was 0.214 as compared to 0.339 for placebo-treated patients, which represented a 37% decrease in ARR for Tovaxin as compared to placebo in the general population ( $n=142$ );
- In a prospective group of patients with more active disease ( $ARR > 1$ ), Tovaxin demonstrated a 55% reduction in ARR as compared to placebo; and an 73% reduction in relapse rate was observed in Tovaxin patients in this population compared to placebo during the 24 week period following the administration of the full course of treatment ( $n=50$ );
- In a retrospective analysis in patients naïve to previous Disease Modifying Treatment (DMT) (i.e. patients who had not previously used any drugs other than steroids to treat their disease) the results showed that patients, when treated with Tovaxin, had a 64% reduction in annualized relapse rate versus placebo ( $p=0.046$ ,  $n=70$ ).

### Statistically Significant Reduction in ARR in Patients with No Prior MS treatment



## MANUFACTURING

Tovaxin is manufactured in-house at Opexa's cGMP (Good Manufacturing Practice) facility. For the procurement and shipping stages of the manufacturing process, Opexa leverages several of the well established worldwide logistics and distribution channels that have become standardized and regulated over the past 10-15 years by the FDA and practiced on a large scale across the industry by agencies such as the American Association of Blood Banks and the International Red Cross. The manufacturing process has been shown to be very consistent and reproducible with attractive Cost of Goods at this stage of development.

## RECENT COMPANY MILESTONES

- 2010: Strengthened management team with critical new hires - World class individuals recruited to manage Clinical Development, Regulatory Affairs, Process Development and R&D;
- Q1-Q2 2010: Strengthened patent estate - Three key patents issued, substantially increasing asset value of Tovaxin;
- Q2 2010: Prepayment of convertible notes - Eliminated debt and one year of future interest payments and removed security interest in assets including IP;
- Q2 2010: Reconstituted world-class Scientific Advisory Board - Industry leaders in the MS field joined Opexa's advisory board to advise on and help propel Tovaxin program forward.
- Q4 2010: Secured FDA support for Phase III studies
  - Completed two face-to-face meetings with FDA
- April 2011: Key data presented at American Academy of Neurology meeting
- Q1 2011: Secured financing to advance toward Phase III trial initiation
  - Gross proceeds \$8.5 million

## CORPORATE INFORMATION (As of 04/25/11)

- Stock Symbol NASDAQ Capital Markets.....OPXA
- Stock Price.....\$1.92
- 52 Week Range .....\$1.02 - \$2.99
- Market Capitalization.....\$44 M
- Shares Outstanding .....23.0 M
- Fiscal Year End .....12/31

## MANAGEMENT

- Neil Warma, President and Chief Executive Officer
- Jaye Thompson, Ph.D., SVP, Clinical Development
- Donna Rill, SVP, Operations
- Donald Healey, Ph.D., VP, Scientific Development
- John Ginzler, VP, Finance

## CONTACT

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