

# OPEXA THERAPEUTICS, INC.

## FORM 8-K

(Current report filing)

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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
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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**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 8, 2009**



**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**

(I.R.S. Employer Identification No.)

**2635 N. Crescent Ridge Drive  
The Woodlands, Texas**

(Address of Principal Executive Office)

**77381**

(Zip Code)

Registrant's telephone number, including area code: **(281) 272-9331**

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 (see General Instruction A.2 below) :

- 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 8.01. Other Events.**

On September 8, 2009, Opexa Therapeutics, Inc. (the "Company") issued a press release reporting additional analyses of TERMS data for Tovaxin®, a personalized T-cell immunotherapy for multiple sclerosis (MS). A copy of the press release is attached as Exhibit 99.1.

The Company issued a second press release on September 8, 2009 announcing that Neil K. Warma, the Company's president and chief executive officer, will deliver a corporate presentation at Rodman & Renshaw's 11th Annual Healthcare Conference. The Company's presentation will take place at 10:50 a.m. (EST) on Friday, September 11, 2009 in the Henry Salon (5th floor) of the NY Palace Hotel. The presentation will include an overview of the company's ongoing development program for Tovaxin®, the company's lead therapy for MS and an overview of the recently announced stem cell agreement with Novartis. The presentation will be webcasted and the link to access the audio webcast and presentation will be available at [www.opexatherapeutics.com](http://www.opexatherapeutics.com).

**Item 9.01. Financial Statements and Exhibits.**

- (c) Exhibit 99.1
- Exhibit 99.2

The following exhibit is to be filed as part of this 8-K:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued September 8, 2009 relating to Tovaxin data
99.2	Press release issued September 8, 2009 relating to presentation at Rodman & Renshaw's 11th Annual Healthcare Conference.

**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 hereunto duly authorized.

**OPEXA THERAPEUTICS, INC.**

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

DATE: September 9, 2009

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## EXHIBIT INDEX

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99.1	Press release issued September 8, 2009 relating to Tovaxin data
99.2	Press release issued September 8, 2009 relating to presentation at Rodman & Renshaw's 11th Annual Healthcare Conference.

## Opexa Reports Additional Favorable Data with Tovaxin® for Multiple Sclerosis

### *Further Analysis of TERMS Phase IIB Data Shows That 85% of Patients Treated with Tovaxin Responded Favorably, 16 % Showing Actual and Sustained Improvement in Disability*

THE WOODLANDS, Texas--(BUSINESS WIRE)--September 8, 2009-- **Opexa Therapeutics, Inc** . (NASDAQ:OPXA), a company developing Tovaxin<sup>®</sup>, a personalized T-cell immunotherapy for multiple sclerosis (MS), today announced results from further analysis of the double-blind, placebo-controlled, 52-week Phase IIB TERMS clinical study of 150 patients with Relapsing Remitting MS (RRMS). This analysis evaluated patients with an annualized relapse rate of one or greater at study entry ( $ARR \geq 1$ ). More than 83% of the Tovaxin-treated group (n=85) remained relapse free at one year and the annualized relapse rate after treatment decreased to 0.20, a 42% reduction compared to placebo.

The results of this expanded analysis confirm those found in the previously-reported per-protocol analysis of patients in the TERMS study with  $ARR > 1$ . This post-hoc analysis which represents 86% of the total patient population in the TERMS study was conducted to evaluate Tovaxin treatment among study patients with the same baseline disease activity that is being targeted for inclusion in the forthcoming Phase IIB study. Along with a marked reduction in relapses, 73% of the Tovaxin-treated patients with  $ARR \geq 1$  showed stabilization or improvement in MS disability, including 16.5% with a sustained improvement in the Expanded Disability Status Scale (EDSS) of at least one full point. On MRI, the Tovaxin-treated group also demonstrated a reduction in brain atrophy and fewer inflammatory brain lesions that progressed to “black holes,” as compared to the placebo-treated group. Treatment with Tovaxin was well tolerated, with no serious adverse events reported in any Tovaxin-treated patient.

“The expanded analysis represents the MS patient population with active relapsing-remitting disease planned for recruitment into the next Phase IIB trial of Tovaxin,” stated Dawn McGuire, MD, a board certified neurologist and a member of Opexa’s Clinical Advisory Board. “Clinical benefits include not only reduction in relapses, but a surprising reversal of disability in over 16% of Tovaxin-treated patients. Along with MRI data suggesting a reduction in neuronal cell loss, these results raise the possibility that Tovaxin-treatment may have neuroprotective as well as disease-modifying effects. Tovaxin’s favorable safety profile and these early efficacy signals strongly support moving forward with a confirmatory Phase IIB trial.”

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Tovaxin is a personalized T-cell vaccine based on a patient's individual immunologic profile. Detailed immunology data analysis from the TERMS trial indicate that Tovaxin can successfully induce changes in T-cell reactivity to all three targeted myelin antigens implicated in the autoimmune attacks causing neurologic damage in MS. These changes appear epitope-specific, are sustained for 6 months or more, and match each patient's Tovaxin formulation. Tovaxin is not broadly immunosuppressive, an important feature of its favorable safety profile.

"From an immunology perspective, the data generated thus far from the TERMS trial, from thousands of patient samples, appear to correlate nicely with the putative mechanism of action for Tovaxin. While additional analyses are still in progress, we are also seeing early associations between depletion of myelin reactive T-cells and favorable clinical outcomes," commented Dr. McGuire.

## About Opexa

Opexa Therapeutics, Inc. is dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases. The Company's leading therapy, Tovaxin<sup>®</sup>, is an individualized cellular immunotherapy treatment in Phase IIb clinical development for multiple sclerosis (MS). Tovaxin is derived from T-cells isolated from peripheral blood, expanded *ex vivo*, and reintroduced into the patients via subcutaneous injections. This process triggers a potent immune response against specific subsets of autoreactive T-cells known to attack myelin, believed to be a primary cause of MS attacks and nervous system damage.

For more information visit the Opexa Therapeutics website at [www.opexatherapeutics.com](http://www.opexatherapeutics.com).

## Cautionary Statement Relating to Forward - Looking Information for the Purpose of "Safe Harbor" Provisions of the Private Securities Litigation Reform Act of 1995

*This press release 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 release do not constitute guarantees of future performance. Investors are cautioned that statements in this press release which are not strictly historical statements, including, without limitation, statements regarding current or future financial payments, returns, royalties, performance and position, management's strategy, plans and objectives for future operations, plans and objectives for product development, plans and objectives for present and future clinical trials and results of such trials, plans and objectives for regulatory approval, litigation, intellectual property, product development, manufacturing plans and performance, 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 success of third party development and commercialization efforts with respect to products covered by intellectual property rights transferred by the Company, the success of third party patent prosecution efforts with respect to such products, 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 programs, 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 for our products, the risk of litigation regarding our intellectual property rights, our limited manufacturing capabilities, our dependence on third-party manufacturers and value added resellers, 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. We assume no obligation to update any forward-looking information contained in this press release or with respect to the announcements described herein.*

## CONTACT:

Opexa Therapeutics, Inc.  
Neil K. Warma, 281-719-3437  
President & CEO  
[nwarma@opexatherapeutics.com](mailto:nwarma@opexatherapeutics.com)

## Opexa to Present at the Rodman & Renshaw 11<sup>th</sup> Annual Healthcare Conference September 11, 2009

THE WOODLANDS, Texas--(BUSINESS WIRE)--September 8, 2009-- **Opexa Therapeutics, Inc.** (NASDAQ: OPXA), a company developing Tovaxin<sup>®</sup>, a personalized T-cell immunotherapy for multiple sclerosis (MS), today announced that Neil K. Warma, Opexa's president and chief executive officer, will deliver a corporate presentation at Rodman & Renshaw's 11<sup>th</sup> Annual Healthcare Conference. The conference will be held September 9-11, 2009, at the Palace Hotel in New York City.

Opexa's presentation will take place at **10:50 a.m. (EST) on Friday, September 11, 2009 in the Henry Salon (5<sup>th</sup> floor) of the NY Palace Hotel**. The presentation will include an overview of the company's ongoing development program for Tovaxin, the company's lead therapy for MS and an overview of the recently announced stem cell agreement with Novartis. The presentation will be webcasted and the link to access the audio webcast and presentation will be available at [www.opexatherapeutics.com](http://www.opexatherapeutics.com).

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For more information visit the Opexa Therapeutics website at [www.opexatherapeutics.com](http://www.opexatherapeutics.com)

### CONTACT:

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Neil K. Warma, 281-719-3437  
President & CEO  
[nwarma@opexatherapeutics.com](mailto:nwarma@opexatherapeutics.com)