# OPEXA THERAPEUTICS, INC.

## FORM 8-K
(Current report filing)

Filed 09/24/08 for the Period Ending 09/19/08

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| 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 |

# 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 19, 2008**

# Opexa Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

| | |
|---|---|
| **Texas** | |
| (State or Other Jurisdiction of Incorporation) | |
| **001-33004** | **76-0333165** |
| (Commission File Number) | (I.R.S. Employer Identification No.) |
| **2635 N. Crescent Ridge Drive**<br>**The Woodlands, Texas** | **77381** |
| (Address of Principal Executive Office) | (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 communication 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 communication pursuant to Rule 144d-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 8.01. Other Event.**

On September 19, 2008, we reported on top-line data from our Phase IIb TERMS (Tovaxin ® for Early Relapsing Multiple Sclerosis) study. Top-line results from the study demonstrated a positive trend in the reduction in annualized relapse rate (ARR) for patients treated with Tovaxin as compared to placebo. However, this finding did not achieve statistical significance. In addition, the study did not achieve statistical significance with its primary endpoint, the cumulative number of gadolinium-enhanced brain lesions.

Top-line results from the study showed that Tovaxin-treated patients experienced an ARR of 0.214 as compared to 0.339 for placebo-treated patients. Despite the low relapse rate in the placebo arm, this still represented a 37 percent decrease in ARR for Tovaxin as compared to placebo in the general population. Additionally, in the group of patients who had an ARR > 1 in the one year prior to study entry, Tovaxin demonstrated a 55 percent reduction in ARR compared to placebo.

The study also demonstrated that Tovaxin was safe and well tolerated with no serious adverse events related to treatment. The most common adverse event related to Tovaxin was mild injection site reaction. We believe that this favorable safety profile may be an important advantage as patient compliance represents a significant challenge due to serious side effects associated with many currently available MS treatments.

Copy of the press release is attached as Exhibit 99.1.

**Item 9.01 Financial Statements and Exhibits**

(c) Exhibit 99.1

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

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release issued September 19, 2008 |

**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/ Lynne Hohlfeld
Lynne Hohlfeld
Chief Financial Officer

DATE: September 24, 2008

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press release issued September 19, 2008 |

**Exhibit 99.1**

OPEXA THERAPEUTICS

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**FOR IMMEDIATE RELEASE**

**Opexa Announces Top-Line Results from Phase IIb Clinical Trial of Tovaxin ® for the Treatment of Multiple Sclerosis**

*Tovaxin Shows Favorable Annualized Relapse Rate and Excellent Safety Profile*

**MONTREAL, Canada (September 19, 2008)** – Opexa Therapeutics, Inc. (NASDAQ: OPXA), a company dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases such as multiple sclerosis (MS) and diabetes, today announced top-line data from the company's Phase IIb TERMS (Tovaxin ® for Early Relapsing Multiple Sclerosis) study. Top-line results from the study demonstrated a positive trend in the reduction in annualized relapse rate (ARR) for patients treated with Tovaxin as compared to placebo. However, this finding did not achieve statistical significance. In addition, the study did not achieve statistical significance with its primary endpoint, the cumulative number of gadolinium-enhanced brain lesions.

Top-line results from the study showed that Tovaxin-treated patients experienced an ARR of 0.214 as compared to 0.339 for placebo-treated patients. Despite the low relapse rate in the placebo arm, this still represented a 37 percent decrease in ARR for Tovaxin as compared to placebo in the general population. Additionally, in the group of patients who had an ARR > 1 at study entry, Tovaxin demonstrated a 55 percent reduction in ARR as compared to placebo.

The study also demonstrated that Tovaxin was safe and well tolerated with no serious adverse events related to treatment. The most common adverse event related to Tovaxin was mild injection site reaction. Opexa believes that this favorable safety profile may be an important advantage as patient compliance represents a significant challenge due to serious side effects associated with many currently available MS treatments.

It is important to note that initial review of data revealed that patients in the study's Tovaxin arm, on average had a substantially greater number of MRI brain lesions and corresponding lesion volumes at baseline compared to the average number of MRI brain lesions and lesion volumes per patient in the placebo group. The company believes that this unexpected imbalance may have contributed to the study not achieving its primary and secondary endpoints as patients in the Tovaxin arm began the study with greater disease burden and increased severity of disease.

"The annualized relapse rate of 0.214 seen in the Tovaxin treatment arm is on par with the lowest relapse rates observed with currently available MS treatments which range from 0.2 to 0.9. This rate is also consistent with ARRs that we have seen in the Tovaxin treatment arms in each of the three previously conducted Tovaxin clinical studies," stated Neil K. Warma, president and chief executive officer of Opexa. "Findings further showed Tovaxin to possess an impressive safety profile with no serious adverse events related to treatment. This level of safety and tolerability addresses a critical unmet need for MS patients. We believe that these positive ARR results combined with an excellent safety profile and convenient dosing place Tovaxin in a very favorable position for continued development as an innovative MS therapy."

Top-line data from the TERMS study were presented today by Edward J. Fox, M.D., Ph.D., director of the Multiple Sclerosis Clinic of Central Texas and the study's principal investigator, at the World Congress on Treatment and Research in Multiple Sclerosis in Montreal, Canada.

"Multiple sclerosis is a disease that affects individual patients in distinctly different ways, highlighting the desire for a safe, effective and patient-specific therapy such as Tovaxin. With this in mind, we are pleased with the positive efficacy trend and excellent safety results witnessed in the TERMS study," stated Dr. Fox. "The Tovaxin-induced reduction in ARR is particularly exciting as it suggests a reduction of clinical activity associated with MS. These study results are encouraging and supportive of further analysis of Tovaxin."

**About the TERMS Study**
The TERMS study was a Phase IIb multi-center, randomized, double blind, placebo-controlled trial in 150 patients with Relapsing-Remitting Multiple Sclerosis or high risk Clinically Isolated Syndrome (CIS). The study involved 2:1 randomization with 100 patients receiving Tovaxin and 50 receiving placebo. According to the study protocol, patients received a total of five subcutaneous injections at weeks 0, 4, 8, 12 and 24. The primary efficacy endpoint of the TERMS trial was the cumulative number of gadolinium-enhanced brain lesions (CELs) using MRI scans summed over weeks 28, 36, 44 and 52. The trial's secondary efficacy endpoints included annualized relapse rate (ARR), new CELs at weeks 28 through 52 and T2-weighted lesion volume compared to baseline.

Top-line data from the TERMS trial is as follows:

- ARR for Tovaxin-treated patients was 0.214 as compared to 0.339 for placebo-treated patients. Consistent with ARRs seen in previously conducted clinical trials for Tovaxin, this result is at the lower end of the spectrum of documented relapse rates demonstrated in controlled two-year clinical studies of currently marketed products (range from 0.2 to 0.9).

- For patients who had an ARR > 1 in the year prior to the study, Tovaxin demonstrated a 55 percent reduction in ARR as compared to placebo.

- Tovaxin was safe and well tolerated with no serious adverse events related to Tovaxin treatment. The most common adverse event was injection site irritation.

- Only 18 patients (12 percent) withdrew from the study prior to completion. The dropout percentage was identical for the Tovaxin and placebo arms of the study, providing further evidence of Tovaxin's excellent safety and tolerability.

"We are especially pleased with the TERMS study's ARR results, as this represents the most common efficacy endpoint evaluated by the FDA when approving MS therapeutics. Opexa expects that ARR will serve as the primary endpoint in any pivotal Phase III Tovaxin study," commented Mr. Warma.

Opexa intends to complete a comprehensive analysis of all data from the TERMS study over the next several months. Based on the TERMS study results, Opexa expects to conduct a Phase II close-out meeting with the United States Food and Drug Administration during the first half of 2009. This meeting, along with the comprehensive results of the TERMS study, will provide important guidance as Opexa plans to advance Tovaxin into Phase III development.

Additionally, Opexa is conducting a one-year, open-label extension trial of the TERMS study called OLETERMS. Approximately 90 percent of patients in the TERMS study have elected to enroll in the OLETERMS trial.

**Investigator Q&A Session**
Opexa will host an investigator Q&A session following the conclusion of today's programs at the World Congress on Treatment and Research in Multiple Sclerosis. A live webcast of the Q&A session will be available on Opexa's web site at www.opexatherapeutics.com beginning at 6:00pm Eastern. The webcast will be archived until October 19, 2008.

**Conference Call and Webcast**
Opexa will host a conference call and webcast with company management to discuss the Phase IIb TERMS data and provide a corporate update on Monday, September 22, 2008, at 8:30 a.m. Eastern. The conference call can be accessed by dialing 800-230-1074 from the U.S. and 612-332-0228 internationally. Additionally a live webcast of the call will be available on Opexa's web site at www.opexatherapeutics.com . The webcast will be archived until October 22, 2008.

A replay of the call can be accessed until September 29, 2008 at 11:59 p.m., by dialing 800-475-6701 from the U.S. and 320-365-3844 internationally, and entering the following access code: 960761.

**About Tovaxin**
Tovaxin is developed using Opexa's proprietary method for the production of patient-specific T-cell vaccines. To produce the Tovaxin vaccine, Opexa isolates disease-causing T-cells from blood taken from an MS patient and expands them in the laboratory to create an appropriate therapeutic dose. The attenuated T-cells, which comprise the Tovaxin vaccine, are reintroduced into the patient via subcutaneous injection to trigger a therapeutic immune system response. Tovaxin is manufactured in Opexa's in-house cGMP facility.

Opexa believes that Tovaxin may possess the following competitive advantages:

- ***Efficacy –*** Clinical trials conducted to date demonstrate that Tovaxin may result in a reduction in ARR (a key measure of MS treatment effectiveness) for patients with Clinically Isolated Syndrome (CIS), Relapsing-Remitting MS (RRMS) and Secondary-Progressive MS (SPMS) patients comparable to currently available MS therapeutics.

- ***Safety and Tolerability –*** 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 with those MS treatments that function by systemically suppressing the immune system. In clinical trials conducted to date, including the 150-patient Phase IIb study, there have been no serious adverse events associated with Tovaxin treatment.

- ***Improved Compliance –*** In clinical trials, Tovaxin is administered only five times per year. This patient-friendly treatment regimen may provide significant compliance benefits compared to currently available MS treatments (at least once per month and, in some cases, as frequently as every day).

- ***Customized Therapy –*** Using the company's proprietary Epitope Analysis Assay (EAA) to profile an individual's disease profile, Opexa can continually customize treatments to specifically target an individual's disease progression and/or modification.

**About Opexa Therapeutics**

Opexa Therapuetics is a biotechnology company dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases. The company's leading therapies currently in development have the potential to address significant unmet medical needs in several large patient populations including multiple sclerosis (MS) and diabetes. The company's lead product is Tovaxin, a T-cell therapy for MS which recently completed a Phase IIb trial. The company also holds an exclusive worldwide license for adult multi-potent stem cells derived from mononuclear cells of peripheral blood. The technology provides means to differentiate these stem cells into other tissue types such as pancreatic islets. By using an individual's own cells, this approach may minimize threat of treatment rejection. This technology serves as the basis for Opexa's preclinical diabetes program, which is focused on the generation of insulin-secreting pancreatic-like cells. For more information visit the Opexa Therapeutics website at 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 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 collaborative relationships, 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.*

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