

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 07/23/08 for the Period Ending 07/22/08

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
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**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): **July 22, 2008**



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 obligation 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 Event.

On July 22, 2008, Registrant reported on the completion of an internal assessment of data from its Phase I/II two year extension study with Tovaxin® in patients with multiple sclerosis. While confirming the favorable safety and efficacy profile of Tovaxin, the further analysis also confirms both the benefit of consecutive annual treatments with Tovaxin and the advantage of tailoring each vaccination to the patient's changing disease profile.

A 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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued July 22, 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/ Neil K. Warma
Neil K. Warma
President and Chief Executive Officer

DATE: July 22, 2008

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued July 22, 2008

Opexa Conducts Additional Analysis on Phase I/II Extension Study with Tovaxin® for Multiple Sclerosis

Annual treatments with patient specific vaccine appear beneficial

THE WOODLANDS, Texas--(BUSINESS WIRE)-- **Opexa Therapeutics, Inc. (NASDAQ:OPXA)** , a company leading in the development of cell therapies for multiple sclerosis (MS) and diabetes, has completed an internal assessment of data from its Phase I/II two year extension study with Tovaxin in patients with MS. While confirming the favorable safety and efficacy profile of Tovaxin, further analysis also confirms both the benefit of consecutive annual treatments with Tovaxin and the advantage of tailoring each vaccination to the patient's changing disease profile.

The extension study evaluated 22 intent-to-treat patients that had enrolled in two Phase I/II open-label clinical studies with Tovaxin. 13 patients were enrolled with Relapse Remitting Multiple Sclerosis (RRMS) and 9 with Secondary Progressive Multiple Sclerosis (SPMS). After the first annual course of treatment the company conducted an analysis of each patient's specific disease profile and myelin peptide epitope profile using Opexa's proprietary Epitope Analysis Assay (EAA). The analysis showed that 19 of the 22 patients (86%) had undergone an epitope shift, or change in disease pattern since the original course of treatment. Based on the epitope analysis, Opexa manufactured a new and specific vaccine for each of these patients for their second course of treatment. This enabled Opexa to tailor each vaccine to the individual's current disease profile, thereby maximizing the effect.

The treatment regimen of five subcutaneous injections per year for each of the two years with two different vaccines tailored to each patient's disease profile produced promising results. Pooled data from the RRMS and SPMS patients showed that, as a group, 73% remained relapse free after two years and 86% demonstrated no worsening of disease (27% of these showed sustained improvement). Additionally, there was an overall decrease in the Annualized Relapse Rate (ARR) of 82% (from 1.38 to 0.21 relapses/patient/year). Each of these endpoints was compared to the patient's own baseline reading, taken prior to enrollment in the trials.

A further analysis of several effectiveness parameters showed that Tovaxin effectively decreased the number of circulating Myelin Reactive T-Cells (MRTC) but did not cause any detectable reduction in the general lymphocyte populations. The lack of generalized immune suppression observed at this stage of development is one important aspect that distinguishes the safety of Tovaxin from certain marketed drugs. Side effects observed over the two year treatment period have been limited to moderate injection site reactions. There have been no serious adverse events related to treatment.

“The results from this extension study support our clinical strategy for Tovaxin of annual treatments tailored to each patient’s clinical disease state,” commented Dr. Jim Williams, Opexa’s Chief Operating Officer. “And although the safety and efficacy data from the two year Tovaxin studies are based on a limited MS patient sample across two open-label clinical studies, comparing the annualized relapse rates of the RRMS patient population treated with Tovaxin at 0.2, places this treatment at the lower end of documented relapse rates of the major marketed drugs which range from 0.2-0.9. We believe Tovaxin’s safety profile and a treatment regimen of five subcutaneous injections per year will also position the therapy favorably from a patient compliance perspective,” added Dr. Williams.

The company is currently completing a larger Phase IIb study in 150 patients in a multi-center, randomized, double blind, and placebo-controlled study in patients with RRMS or Clinically Isolated Syndrome (CIS). The company expects to announce top line results in September 2008.

About Tovaxin

Tovaxin is an autologous attenuated whole T-cell vaccine manufactured by specifically selecting MRTCs from a patient’s blood, and expanding them *ex-vivo* to a therapeutic dose. In this way, the vaccine is tailored to each patient’s disease state. The reintroduction of the attenuated T-cells via subcutaneous inoculation induces an immune response against the MRTCs, thereby triggering the immune system to attack the pathogenic T-cells in the body.

Treatment with Tovaxin results in a decrease in the number of pathogenic T-cells by anti-idiotypic mechanisms and restores the immune regulatory network by anti-ergotypic immune responses. Although Tovaxin administration results in the depletion and regulation of pathogenic T-cells, there is no generalized immune suppression.

About Opexa

Opexa Therapeutics develops and commercializes cell therapies to treat autoimmune diseases such as multiple sclerosis, rheumatoid arthritis and diabetes. The Company is focused on autologous cellular therapy applications of its proprietary T-cell and stem cell therapies. The Company’s lead product is Tovaxin, a T-cell therapy for multiple sclerosis which is in Phase IIb trials. The Company holds an exclusive worldwide license for adult multipotent stem cells derived from mononuclear cells of peripheral blood. The technology allows large quantities of monocyte-derived stem cells to be produced efficiently for use in autologous therapy, thus circumventing the threat of rejection. The Company is in the preclinical stages of the development of insulin-producing monocyte-derived islets as a replacement therapy for diabetes mellitus. 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," including statements about Opexa Therapeutics' growth and future operating results, discovery and development of products, strategic alliances and intellectual property, as well as other matters that are not historical facts or information. These forward-looking statements are based on management's current assumptions and expectations and involve risks, uncertainties and other important factors, specifically including those relating to Opexa Therapeutics' ability to obtain additional funding, develop its stem cell technologies, obtain FDA approval for its therapeutic products, achieve its operational objectives, and obtain patent protection for its discoveries, that may cause Opexa Therapeutics' actual results to be materially different from any future results expressed or implied by such forward-looking statements. Opexa Therapeutics undertakes no obligation to update or revise any such forward-looking statements, whether as a result of new information, future events or otherwise.

CONTACT:

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