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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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): **June 12, 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 **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 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))

Item 8.01 Other Event.

On June 12, 2008, Registrant reported two-year safety and efficacy data results from its open label Phase I/II retreatment studies of Tovaxin®, its investigational T-cell vaccine for multiple sclerosis.

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:

Exhibit No.	Description
99.1	Press release issued June 12, 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 hereto duly authorized.

OPEXA THERAPEUTICS, INC.

By: /s/ Lynne Hohlfeld
Lynne Hohlfeld, Chief Financial Officer

DATE: June 12, 2008

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued June 12, 2008

Exhibit 99.1

Opexa Therapeutics Reports Favorable Two-Year Data in Phase I/II Retreatment Studies of Tovaxin ® for Multiple Sclerosis

73% of patients remained relapse-free at two years

THE WOODLANDS, Texas--(BUSINESS WIRE)-- **Opexa Therapeutics, Inc.** (NASDAQ:OPXA), a cell therapy development and commercialization company, today announced favorable safety and efficacy data for Tovaxin®, the Company's investigational T-cell vaccination therapy for multiple sclerosis (MS), in the second year of open-label clinical retreatment studies in patients with MS.

The "intent to treat" population of 22 patients included 13 with relapsing remitting multiple sclerosis (RRMS) and nine with secondary progressive multiple sclerosis (SPMS). An analysis of disease progression of disability over a two year period, as measured by a 1.0 or greater change in Expanded Disability Scoring Scale (EDSS), showed that 27.3% of patients demonstrated sustained improvement, 59.1% had no disease progression and 13.6% experienced sustained worsening of disability. The improvement in the EDSS scores ranged from 1.0 to 4.5 (average 2.41). During the two-year study period 72.7% of patients remained relapse-free.

Brian Loftus, M.D., of Bellaire Neurology and the principal investigator of the studies, commented, "I'm pleased to see that subjects in the study experienced sustained positive clinical outcomes over the two-year period. It was especially encouraging to see a lack of disease progression in more than 86% of the patients after two years, given the later stage of disease of this subject population."

The annualized relapse rate analysis of 17 patients (which excludes five patients with no prior relapses in their two-year pre-study baseline) showed Tovaxin therapy achieved an 82% reduction in annualized relapse rate (ARR) in patients over a two-year period ($p<0.0001$) to 0.21 relapses per year, compared with 1.38 relapses per year in the patients' prior two-year baseline. For RRMS patients ($n=12$) the ARR over a two-year period was 0.26 relapses per year, compared with 1.63 relapses per year in the patients' prior two-year baseline; for SPMS patients ($n=5$) the ARR over a two-year period was 0.10 relapses per year, compared with 0.80 relapses per year in the patients' prior two-year baseline.

"Approximately three out of four patients re-treated in the second year exhibited a change in their myelin-reactive T-cell profile, which was the basis for producing their individualized T cell vaccine," said David McWilliams, president and chief executive officer of Opexa. "We believe this new data supports the continuation of our development strategy of individually monitoring patients with our proprietary epitope analysis assay and re-treating them with a patient-specific therapeutic vaccine that associates with their clinical status."

The combined analysis included patients participating in second-year extension protocols from the Phase I/II dose-escalation study and the Phase I/II re-treatment study, and 19 of 22 patients were re-treated with Tovaxin during the study period. Patients did not receive any other disease modifying therapies during the two-year study period.

Tovaxin was well-tolerated throughout the two-year study period. The safety profile revealed only mild-to-moderate injection site reactions and no serious adverse reactions related to T-cell vaccination.

About Multiple Sclerosis

In the U.S. approximately 400,000 people suffer from MS, a chronic progressive autoimmune disease of the central nervous system that is caused by myelin autoreactive T-cells progressively eroding the myelin that surrounds and insulates nerve fibers of the brain and spinal cord resulting in varying amounts of disability. Globally, there are approximately 2.5 million MS patients representing a drug therapy market believed to be approximately $5 billion in 2005. The US markets accounted for slightly more than half of global MS sales in 2005.

MS remains a challenging autoimmune disease to treat because the pathophysiologic mechanisms are diverse, and the chronic, unpredictable course of the disease makes it difficult to determine whether the favorable effects of short-term treatment will be sustained. Therapies that are easy to use and can safely prevent or stop the progression of disease represent the greatest unmet need in MS. The most common phase of MS at the time of diagnosis is relapsing-remitting, which affects approximately 70% of MS patients. This group experiences clearly defined flare-ups (relapses), followed by partial or complete remissions between attacks that are free of disease progression. Approximately 50% of the relapsing-remitting patients develop the secondary-progressive form of the disease within 10 years of diagnosis. This phase is characterized by an initial period of relapsing-remitting disease followed by steady worsening with or without flares or minor remissions.

About Tovaxin for Multiple Sclerosis

Tovaxin is an individualized T-cell therapeutic vaccine that consists of attenuated patient-specific myelin-reactive T-cells (MRTCs) against peptides of proteins from Myelin basic protein (MBP), Myelin oligodendrocyte glycoprotein (MOG) and Proteolipid protein (PLP) or combinations thereof. Patient-specific MRTCs are expanded in culture with specific peptides identified by assaying peripheral blood mononuclear cell reactivity against peptides derived from the three myelin proteins. Studies have shown that T-cell vaccination resulted in the in vivo induction of CD8+ cytotoxic T-cells and CD4+CD25+FoxP3 Tregs specific for T-cell vaccine. The induction of anti-idiotypic cytotoxic CD8+ effector T-cells and anti-ergotypic CD4+CD25+FoxP3 positive Tregs is believed to provide a therapeutically effective dual mechanism of protection to patients treated with Tovaxin. The observed regulatory immune responses have been shown to collectively relate with clinical improvement in treated patients. Tovaxin has been previously studied in two Phase I/II open-label trials. A 150-patient Phase IIb one-year double blind placebo controlled study to evaluate the efficacy, safety and tolerability of Tovaxin in subjects with clinically isolated syndrome (CIS) or relapse-remitting multiple sclerosis (RR-MS) is nearing completion.

About Opexa Therapeutics

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 is in Phase IIb trials. The Company holds the 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 preclinical development 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.

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