OPEXA THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

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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): March 11, 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:

☐ 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 Events

On March 11, 2008, the Company provided an update of its ongoing 150-patient Phase IIb safety and efficacy study (TERMS) of Tovaxin® in multiple sclerosis. A copy of this press release is furnished as Exhibit 99.1 to this Current Report.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits:
99.1 Press Release dated March 11, 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/ David B. McWilliams
David B. McWilliams
President and Chief Executive Officer

DATE: March 11, 2008

Exhibit 99.1

Opexa Therapeutics Announces Completion of Mid Study Descriptive Analysis on Phase IIb Trial of Tovaxin ® for Treatment of Multiple Sclerosis

Data Safety Monitoring Board Recommends Continuing Trial as Scheduled

THE WOODLANDS, Texas--(BUSINESS WIRE)--Opexa Therapeutics, Inc. (NASDAQ:OPXA) today announced that the independent Data Safety Monitoring Board (DSMB) of its ongoing 150-patient Phase IIb safety and efficacy study (TERMS) of Tovaxin in multiple sclerosis recommended that the trial be continued as scheduled.

Opexa's Data Safety Monitoring Board is an independent group of multiple sclerosis experts which is responsible for monitoring the ongoing safety and conduct of the study. At each DSMB meeting, the board may recommend continuing the trial unmodified, continue the trial with modifications or discontinue the trial.

The DSMB meeting reviewed 28-week data for approximately 50% of the patients in the study. The DSMB noted in their report very few dropouts and that the study appears to be proceeding well. In addition, the report indicated that baseline MRI data is consistent with the assumptions used in the design of the study. Edward Fox, M.D., Ph.D. commented, "As the lead investigator of the TERMS trial, I continue to anticipate the conclusion of this experimental protocol, which has been designed to evaluate the efficacy, tolerability, and safety of Tovaxin in the treatment of patients in the early stages of Multiple Sclerosis."

David McWilliams, president and chief executive officer of Opexa Therapeutics, stated, "I am pleased by the steady progress of the trial and the recommendation of the DSMB. We have delivered all Tovaxin doses to patients in the study and now look forward to presenting 52-week topline results of the TERMS Phase IIb study in September. McWilliams continued, "with this report, we are aggressively moving forward with our regulatory plans and furthering our discussion with potential strategic development partners."

About TERMS Descriptive Analysis

The descriptive analysis provided to the DSMB included clinical laboratory results, adverse events, vital signs and physical examination data as well as the cumulative number of gadolinium-enhancing lesions on T1-weighted MRI scans, the cumulative number of new gadolinium-enhancing lesions, the change in T2-weighted lesion volume, and annualized relapse rates. Disease progression, as measured by changes in disability scores using the industry-standard Kurtzke Expanded Disability Status Scale (EDSS) along with other select qualitative/quantitative MS-specific instruments, was also assessed.

About TERMS

The Tovaxin Phase IIb clinical study includes 150 patients in a multicenter, randomized, double blind, placebo-controlled trial designed primarily to evaluate the efficacy, safety and tolerability of the Tovaxin T-Cell vaccination with clinically isolated syndrome (CIS) and relapsing-remitting MS (RR-MS) patients. A total of 100 patients will receive Tovaxin, while 50 will receive placebo. The study is designed as a two-arm, 52-week, parallel-group study, whereby patients will be given five subcutaneous injections at 0, 4, 8, 12 and 24 weeks. The analyses will be performed at the end of the 52-week study to assess the safety and efficacy of Tovaxin. The primary efficacy variable is the cumulative number of gadolinium-enhancing lesions on T1-weighted MRI scans summed over the Week 28, 36, 44, and 52 MRIs. The secondary efficacy variables are the cumulative number of new gadolinium-enhancing lesions at Weeks 28-52, the change in T2-weighted lesion volume, and the annualized relapse rate.

About T-cell Vaccination

For a T-cell vaccine to be effective, it should be able to induce T-cell cytotoxic and/or regulatory immune responses against the pathogenic T-cells. Studies of T-cell vaccine have indicated that T-cell vaccination with peripheral blood-derived autologous myelin-peptide selected T-cells in multiple sclerosis patients 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 correlate with clinical improvement in some patients treated in earlier clinical studies.

About Opexa Therapeutics

Opexa Therapeutics develops and commercializes cell therapies to treat autoimmune diseases such as MS, 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, 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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