

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 06/21/07 for the Period Ending 06/21/07

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 21, 2007

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 Offices)

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))

Item 8.01. Other Events.

On June 21, 2007, Registrant reported positive top-line data from its open-label Phase I/II extension clinical trial of the investigational T-cell vaccine, Tovaxin(TM), 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 21, 2007

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/ David B. McWilliams

David B. McWilliams, Chief Executive
Officer

DATE: June 21, 2007

EXHIBIT INDEX

Exhibit No. -----	Description -----
99.1	Press release issued June 21, 2007

Opexa Therapeutics Reports Positive Top-line Data in Phase I/II Extension Trial with Tovaxin(TM) for Multiple Sclerosis

Effectiveness Shown in Relapsing Remitting Subjects Across Both Phase I/II Dose Escalation and Extension Trials

THE WOODLANDS, Texas--(BUSINESS WIRE)--June 21, 2007--Opexa Therapeutics, Inc. (NASDAQ:OPXA), a company involved in the development and commercialization of cell therapies, today announced positive top-line data in an open-label Phase I/II extension clinical trial of the investigational T-cell vaccine, Tovaxin(TM), for multiple sclerosis (MS). In this one-year, 8-subject extension clinical trial of relapsing remitting (RRMS) and secondary progressive (SPMS) subjects, Tovaxin therapy was shown to be safe and effective. The "per-protocol" analysis of Tovaxin therapy achieved a 92% reduction in annualized relapse rate (ARR) in subjects who received two treatment doses of 30 - 45 x 10(6) attenuated T-cells eight weeks apart and were monitored for an additional 44 weeks. Subjects in the extension study had previously been treated an average of 5.2+/-1.8 (1, 8; median 5.4) years earlier at Baylor College of Medicine under the direction of Jingwu Zhang, M.D., Ph.D with a T-cell vaccine developed from myelin basic protein (MBP) reactive T-cells. The safety profile revealed only injection site mild reactions and no severe adverse reactions related to T-cell vaccination.

Both Phase I/II clinical studies have demonstrated that T-cell vaccination depletes myelin reactive T-cells in peripheral blood. In the extension study patient population, the myelin reactive T-cell frequencies were reduced by 84% and 72% at 6 and 12 months on study, respectively. Reductions in myelin reactive T-cell frequencies in the dose escalation study were 76.7% and 64.8% at 6 and 12 months on study, respectively.

All subjects currently are enrolled in a retreatment extension study to collect longitudinal safety and effectiveness data.

Effectiveness data for the 13 RRMS subjects across the two Phase I/II trials showed an 80% reduction in ARR. The Expanded Disability Scoring Scale (EDSS) for the RRMS subjects for a 0.5 point effect was improved, unchanged and worsened by 64.3%, 21.4% and 14.3%, respectively. The EDSS for a 0.5 point sustained (no change over 3 months) effect was improved, unchanged and worsened by 42.9%, 42.9% and 14.2%, respectively. The EDSS for a 1.0 sustained effect was improved, unchanged and worsened by 28.6%, 57.1% and 14.3%, respectively.

Brian Loftus, M.D. of Bellaire Neurology, the Principal Investigator of these Tovaxin studies, commented, "This data, combined with prior data presented on myelin reactive T-cell frequencies and ARR reductions, laid the ground work for the placebo-controlled Tovaxin IIb clinical trial (TERMS). We have shown that myelin reactive T-cells can be identified and used to produce T-cell vaccine which effectively induces the depletion of an individual's autoreactive T-cells and results in positive clinical outcomes. I anticipate Tovaxin will usher in the age of personalized therapy for MS."

David McWilliams, president and chief executive officer of Opexa, said, "We are particularly encouraged by the data from this extension trial which indicates that subjects previously treated with T-cell vaccine can be safely and effectively retreated with Tovaxin. This outcome is important to our planned extension trial for subjects currently enrolled in our TERMS trial following the one year core study time period." In addition, the effectiveness data in RRMS subjects across the two Phase I/II trials indicate strongly positive outcomes in both ARR and EDSS improvements following Tovaxin therapy."

About TERMS

The Tovaxin Phase IIb clinical study will include 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. As of May 17, 2007, Opexa announced the completion of patient enrollment in a 150-patient Phase IIb safety and efficacy study (TERMS). All patients who complete the trial will be eligible to participate in an optional one-year extension study, in which they will receive Tovaxin under an open-label protocol. The open-label study is being planned under a different protocol that will be submitted to the FDA.

The TERMS study is being conducted at 36 U.S. sites to evaluate the safety and effectiveness of Tovaxin. The TERMS study is registered on the U.S. National Institutes of Health-sponsored website, www.clinicaltrials.gov, where pharmaceutical companies are required to register trials for medicines that will treat serious or life-threatening diseases or conditions. For more information, visit the TERMS website at www.tovaxin.com.

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(TM). The observed regulatory immune responses have been shown to collectively correlate with clinical improvement in treated patients.

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(TM), a T-cell therapy for multiple sclerosis is in a Phase IIb trial. 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.

Safe Harbor Statement

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, 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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