

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 04/24/09 for the Period Ending 04/20/09

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
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SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
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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): **April 20, 2009**



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 obligations 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 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On April 20, 2009, the Company announced that it had received a letter from NASDAQ stating that the Company did not comply with Listing Rule 5550(b)(1) relating to stockholders' equity. Management is working on a plan that it will submit to NASDAQ outlining the manner in which the company plans to regain compliance. The plan will include the recently completed first tranche of financing completed on April 14, 2009, together with additional planned development and financing milestones. A copy of this press release is furnished as Exhibit 99.1 to this Current Report.

Item 8.01 Other Event.

On April 24, 2009, the Company announced that data from its Phase I/II dose escalation study has been recently published in the May 2009 edition of the "Journal of Clinical Immunology". A copy of this press release is furnished as Exhibit 99.1 to this Current Report.

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>
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99.1	Press release issued April 24, 2009
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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

Chief Executive Officer

DATE: April 23, 2009

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued April 24, 2009

Opexa Publication of Tovaxin® Clinical Data in *Journal of Clinical Immunology*

Tovaxin Phase I/II dose escalation study published in leading journal

THE WOODLANDS, Texas--(BUSINESS WIRE)--April 24, 2009-- **Opexa Therapeutics, Inc.** (NASDAQ: OPXA), a company developing a novel T-cell therapy for multiple sclerosis (MS) and a stem cell therapy for diabetes, today announced that data from its Phase I/II dose escalation study has been recently published in the May 2009 edition of the prestigious *Journal of Clinical Immunology*. Encouraging data from this clinical study paved the way for the larger Phase IIb TERMS trial that was completed in late 2008.

This small dose finding study of Tovaxin®, Opexa's T cell vaccine in development for MS, enrolled patients with relapsing-remitting MS or secondary progressive MS who had failed or were intolerant of currently approved MS therapies. The study was designed to find a safe and effective Tovaxin dose.

Tovaxin immunization resulted in rapid depletion of circulating myelin-reactive T cells (MRTC), with an observed dose-response effect. A safe and effective dose was identified for further clinical trials, associated with reductions in MRTC ranging from 92% at week 5 to 65% at week 52. Clinically, using the per-protocol criteria for MS relapses, a statistically significant reduction in relapse rate (85%, $p < 0.05$) was seen among the 10 evaluable patients, and a 63% reduction was demonstrated in the modified intent-to-treat population.

The MRI lesions were stable and there was an improving trend in disability as measured by the expanded disability status scale (EDSS) and patients' physical score as measured by the Multiple Sclerosis Impact Scale (MSIS-29), following the second injection. The mid-dose was selected for further clinical development studies because of the rapid depletion of peripheral blood MRTC and a trend towards an improvement in clinical outcomes following immunization. The most common vaccine-associated adverse events were injection site reactions, all of which were mild and resolved rapidly.

"These early results support the further development of Tovaxin as a highly promising and well tolerated treatment for multiple sclerosis. Demonstration of substantial reduction in MRTCs was associated with an indication of clinical benefit," commented Dawn McGuire M.D., a board certified neurologist and a member of Opexa's Clinical Advisory Board. "Importantly, Opexa was able to define a safe and effective dose during the Phase I/II studies, which has since been confirmed in the recently completed larger Phase IIb TERMS trial and will be used in future planned trials."

The vaccine was prepared by using two peptides from each of three myelin proteins: myelin basic protein (MBP), myelin oligodendrocyte glycoprotein (MOG) and proteolipid protein (PLP). The peptides were used to identify and expand patient-specific myelin-reactive T cells for vaccine preparation. Vaccine was administered at four scheduled intervals over 20 weeks, with immunologic, clinical and MRI follow-up to 52 weeks.

Opexa continues to pursue the clinical development of Tovaxin which has demonstrated remarkable safety and promising efficacy in three clinical studies to date. The publication reference is:

B. Loftus, B. Newsom, M. Montgomery, K. Von Gynz-Rekowski, M. Riser, S. Inman, P. Garces, D. Rill, J. Zhang, J.C. Williams. Autologous attenuated T-cell vaccine (Tovaxin®) dose escalation in multiple sclerosis relapsing-remitting and secondary progressive patients nonresponsive to approved immunomodulatory therapies, *Clinical Immunology* 131 202-215, 2009.

In other company news, Opexa received notification from NASDAQ on April 20, 2009 stating that the Company is not in compliance with the shareholder's equity requirements for continued listing set forth in Marketplace Rule 5550(b)(1). The Company is developing a plan to be submitted to NASDAQ outlining the manner in which the company plans to regain compliance. It is anticipated that the plan will include the recently completed first tranche of financing that was disclosed in the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on April 16, 2009, together with additional planned development and financing milestones.

About Tovaxin

Tovaxin is an individualized cellular immunotherapy treatment in Phase IIb clinical development for multiple sclerosis (MS). Tovaxin is derived from T-cells isolated from peripheral blood, expanded *ex vivo*, and reintroduced into the patients via subcutaneous injections. This process triggers a potent immune response against specific subsets of autoreactive T-cells known to attack myelin and, thereby, reduces the risk of relapse over time.

Opexa completed the 150 patient landmark ***Tovaxin for Early Relapsing Multiple Sclerosis*** (TERMS) Phase IIb clinical study in late 2008 which was one of the first clinical studies investigating an autologous T-cell therapy in MS patients. Data from this clinical study show compelling evidence that Relapsing Remitting MS (RRMS) patients treated with Tovaxin saw overall clinical, MRI, and immunological benefits over the placebo group, including statistical significance for decrease in the Annualized Relapse Rate (ARR), improvement in disability score (EDSS), and improvement in quality of life measures (MSQLI), as well as an excellent safety profile with no serious adverse events related to Tovaxin treatment.

About Opexa

Opexa Therapeutics, Inc. is 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 and diabetes. The Company's therapies are based on proprietary, autologous T-cell and stem cell technologies.

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.

CONTACT:

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