

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): January 5, 2011

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
(IRS Employer Identification No.)

2635 Technology Forest Blvd., The Woodlands, Texas
(Address of principal executive offices)

77381
(Zip Code)

Registrant's telephone number, including area code: **(281) 272-9331**

N/A

(Former name or former address, if changed since last report)

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:

- ☐ 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 Events.

On January 5, 2011, Opexa Therapeutics, Inc. (the “ **Company** ”) issued a press release regarding the results of its recent meetings with the U.S. Food and Drug Administration regarding the development path for Tovaxin®, the Company’s product in clinical development for the treatment of multiple sclerosis (MS).

A copy of the press release issued by the Company is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release distributed by Opexa Therapeutics, Inc. on January 5, 2011.

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, thereunto duly authorized.

Dated: January 5, 2011

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President & Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release distributed by Opexa Therapeutics, Inc. on January 5, 2011.

Opexa Completes Successful Meetings with FDA to Pursue Phase 3 Clinical Study for Tovaxin® in Multiple Sclerosis

Company's face-to-face meetings with FDA focus on optimized manufacturing process and clinical trial protocol for Phase 3

THE WOODLANDS, Texas--(BUSINESS WIRE)--January 5, 2011--Opexa Therapeutics, Inc. (NASDAQ:OPXA), a leading cell therapy company developing Tovaxin[®] for multiple sclerosis (MS), today announced the successful completion of two separate meetings with the U.S. Food and Drug Administration (FDA) regarding the Company's planned development program for Tovaxin. Based on positive feedback from the FDA, Opexa believes it is now positioned from a regulatory perspective to advance with a pivotal Phase 3 clinical study of Tovaxin in MS. The Company is in the process of completing necessary preparations to be able to initiate such a study.

"We are very pleased with the outcome of our two recent FDA meetings regarding Tovaxin, the first ever personalized T-cell therapy for MS patients, as we believe we now have a well defined path forward for Phase 3 clinical studies," commented Neil K. Warma, President and Chief Executive Officer of Opexa. "Importantly, we believe the outcome of these meetings will contribute positively to our ongoing discussions with potential development partners due to the importance of the FDA's feedback, as well as our ability to secure the necessary resources for the continued development of Tovaxin. We remain motivated to again treat patients in a clinical setting as we continue to believe Tovaxin is the most promising therapy in development for MS."

"Tovaxin has shown promise throughout its clinical development and I am pleased that Opexa is prepared from a regulatory perspective to move forward with pivotal trials," commented Clyde Markowitz, M.D., director of the Multiple Sclerosis Center at the University of Pennsylvania, professor of neurology at the University of Pennsylvania School of Medicine in Philadelphia and member of Opexa's scientific advisory board. "As a clinical investigator in Opexa's last clinical trial with Tovaxin and having treated several of my patients in this clinical setting, I am particularly impressed with its excellent safety profile. Based on my clinical experience, I am excited that Opexa is preparing to conduct Phase 3 trials with Tovaxin to advance the therapy closer to the market and those MS patients in need of improved therapies."

Opexa's recent discussions with the FDA consisted of two separate *End of Phase 2* meetings to review both the complete Tovaxin manufacturing process, as well as the going-forward clinical trial plan for Tovaxin. The first face-to-face meeting focused on the improvements and modifications Opexa has incorporated into Tovaxin's manufacturing and CMC (Chemistry, Manufacturing and Control) process in an effort to improve efficiency, reduce overall costs and implement commercial stage requirements. As part of this meeting, Opexa presented data and details supporting an optimized manufacturing process, including a transition to fewer process steps, comparability plans and complete reagent profiles. The FDA agreed that the optimized Tovaxin manufacturing process would meet the requirements for a pivotal Phase 3 clinical trial. Additional supporting data is expected to be submitted to the FDA prior to initiating such a study.

The second meeting was a face-to-face *End of Phase 2* clinical meeting in which Opexa presented its rationale and trial design for a Phase 3 pivotal study with Tovaxin in Relapsing Remitting-MS (RR-MS) patients. The FDA concurred with Opexa regarding its proposed clinical trial protocol including the patient population, end points, patient numbers and trial design. The FDA also offered several recommendations to further enhance a Phase 3 trial. The Phase 3 clinical trial protocol presented to the FDA was based, in part, on a recently conducted analysis of data from the previous Phase 2b TERMS trial in a sub-population of patients that were naïve to disease modifying agents (*i.e.*, patients who had not previously used any drugs other than steroids to treat their disease). The analysis produced encouraging results which showed that these patients, when treated with Tovaxin, had a 64% reduction in annualized relapse rate versus placebo ($p=0.046$, $n=70$). This statistically significant efficacy result, coupled with the superior safety profile of Tovaxin, was highlighted during the FDA meeting to emphasize what the Company believes to be a promising benefit-to-risk profile for Tovaxin.

“The positive outcome of these meetings with the FDA and the fact that we were able to complete these meetings during 2010 is the result of hard work by a focused and talented Opexa team,” said Mr. Warma. “In the months leading up to these meetings, we worked on significantly improving the efficiency of the process used to manufacture Tovaxin and have taken critical steps to move closer to a commercial ready process. Additionally, we analyzed the clinical data from all previous Tovaxin studies to determine what we believe is an optimal trial design to support our Phase 3 program and spent substantial time obtaining expert advice and guidance from our scientific advisory board. Moving forward we are focused on implementing the necessary steps to advance toward a Phase 3 clinical trial, continuing discussions with potential development partners for Tovaxin and attempting to secure appropriate financing. We remain committed to the further development of Tovaxin.”

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 therapy, Tovaxin®, is a personalized cellular immunotherapy treatment that is in clinical development for 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 has completed a Phase 2b clinical study with Tovaxin in 150 patients with MS. Data from this clinical study show evidence that RR-MS patients treated with Tovaxin saw overall clinical and disability benefits over the placebo group, including a clinically relevant decrease in the Annualized Relapse Rate (ARR), and improvement in disability score (EDSS), as well as an excellent safety profile with no serious adverse events related to Tovaxin treatment.

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 words “expects,” “believes,” “anticipates,” “estimates,” “may,” “could,” “intends,” and similar expressions are intended to identify forward-looking statements. 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 payments, returns, royalties, 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: market conditions, our capital position, the ability of the Company to enter into and benefit from a partnering arrangement and/or to raise sufficient and necessary financing to further develop the Company's product candidate, Tovaxin, on reasonably satisfactory terms (if at all), and our dependence (if partnered) on the resources and abilities of any partner for the further development of Tovaxin, 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 (including for Tovaxin), the risk of litigation regarding our intellectual property rights, the success of third party development and commercialization efforts with respect to products covered by intellectual property rights transferred by the Company, our limited manufacturing capabilities, our dependence on third-party manufacturers, 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. These forward-looking statements speak only as of the date made. We assume no obligation or undertaking to update any forward-looking statements to reflect any changes in expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make in the reports filed with the Securities and Exchange Commission.

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