

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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Industry	Biotechnology & Drugs
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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 13, 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On January 20, 2009 the company announced several changes in its senior management. On January 13, 2009, Jim C. Williams, chief operating officer notified Opexa Therapeutics, Inc. that he will retire effective February 13, 2009. Dr. Williams has agreed to continue to serve Opexa in a consulting capacity during the transition. Donna Rill currently Vice President of Operations was promoted to Senior Vice President of Operations effective immediately. To further support the ongoing discussions and advance the clinical development of Tovaxin®, Dawn McGuire, M.D., a board-certified neurologist with experience in all phases of drug and biologic development for multiple sclerosis and a member of Opexa's Clinical Advisory Board, has agreed to increase her advisory role to the company and guide clinical development of Tovaxin.

The Company issued a press release announcing Ms. Rill's promotion, Dr. McGuire's increased advisory role and Dr. William's retirement plans and other corporate and partnering updates. A copy of this press release is furnished as Exhibit 99.1 to this Current Report.

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: January 20, 2009

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued January 20, 2009

Opexa Provides Update on Various Corporate Developments

THE WOODLANDS, Texas--(BUSINESS WIRE)--January 20, 2009--Opexa Therapeutics, Inc. (NASDAQ:OPXA), a company dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases such as multiple sclerosis (MS) and diabetes, today announced an update on corporate activities. Since providing additional data analysis for its TERMS Phase IIB clinical trial in October, Opexa has been actively engaged in discussions to partner Tovaxin®, its lead therapy and novel treatment for MS, as it positions itself for pivotal trials and future commercialization. Additionally, partnering discussions have been initiated and are advancing with Opexa's stem cell therapy to treat Type 1 and Type 2 diabetes.

To further support the ongoing discussions and advance the clinical development of Tovaxin, Dawn McGuire, M.D., a member of Opexa's Clinical Advisory Board, has agreed to increase her advisory role to the company and guide clinical development of Tovaxin. Dr. McGuire, a board-certified neurologist, has experience in all phases of drug and biologic development for multiple sclerosis. While Vice President of Clinical Research and Medical Affairs at Elan Pharmaceuticals, she was the development team leader for Tysabri.

"Tovaxin offers the potential for immunomodulatory treatment that is exquisitely individualized for a complex disease that manifests in a highly individual manner. Early results with Tovaxin suggest reduction not only in relapse rates but also in global neuronal loss among patients with the most active disease. I see great promise here," commented Dr. McGuire.

In other management news, Opexa has promoted Donna Rill to Senior Vice President of Operations. She will continue to oversee the production and manufacturing of all cell therapy programs and will focus on the upcoming end of Phase II meeting with the FDA and the scale up of operations to support future Tovaxin trials in North America and Europe. Dr. Jim Williams, Chief Operating Officer, will retire from the company, effective February 13, 2009 after several years of overseeing the clinical development of Tovaxin. He will remain available in a consulting capacity to assist with any transition.

"With possibly the safest therapy for MS demonstrated to date and some very encouraging efficacy data in clinically relevant relapse rates and disability scores, we are pleased with the level of discussions we are having with potential partners," commented Neil K. Warma, President and CEO of Opexa Therapeutics, Inc. "We are extremely fortunate to have someone of Dr. McGuire's experience to further advise on our clinical development strategy and steward the clinical development of Tovaxin. Her substantial knowledge and experience in MS, having overseen the early development of Tysabri will certainly contribute very favorably to our development program and partnering discussions. We are grateful to Jim for having contributed immensely to the development of Tovaxin to date and for overseeing the management of the first-in-class TERMS IIB study and we are pleased he will remain a consultant to the company as we continue forward with our clinical strategy."

As previously disclosed Opexa streamlined its operations in late November 2008 to better manage its current expenses, reduce its cash burn and extend its available runway. As partnership discussions continue to advance, the company will pursue a number of strategic alternatives including the raising of additional capital to allow it the time to further pursue and negotiate a partnership for Tovaxin in MS and/or its adult stem cell program in diabetes.

Data from the TERMS Phase IIb clinical study with Tovaxin in MS demonstrated the following:

- **Promising Efficacy** – The Annualized Relapse Rate (ARR) for the prospective group of patients with a greater level of disease burden was 0.28 relapses per patient per year. Remarkably, the ARR for this group dropped to 0.07 after the full course of treatment was administered. Additionally, this group showed a statistically significant improvement in disability ($p=0.045$) and a substantial improvement in brain atrophy when treated with Tovaxin.
- **Excellent Safety** - There were no serious adverse events (SAEs) associated with Tovaxin treatment in the TERMS study. This is consistent with the previous clinical trials with Tovaxin, all of which showed no SAEs associated with Tovaxin treatment. This is an especially critical finding given the recent serious side effect occurrences associated with certain marketed and developmental MS products and the ongoing regulatory focus on risk/benefit relationships.
- **Ease of Administration** - Patient compliance may be improved with Tovaxin's treatment regimen of five subcutaneous injections per year.
- **Epitope data** - An analysis of the immunology data collected from several thousand patient samples is yielding valuable information on MS biomarkers and Tovaxin mechanism of action. Tovaxin appears to reduce myelin peptide reactivity and reduce the risk of relapse over time.

About Tovaxin for MS

Tovaxin is an individualized T-cell therapeutic vaccine that consists of attenuated patient-specific myelin-reactive T-cells against peptides of proteins from Myelin basic protein (MBP), Myelin oligodendrocyte glycoprotein (MOG) and Proteolipid protein (PLP) or combinations thereof. Tovaxin's dual mechanism of action combats the demyelination of the nerve fibers in the central nervous system, the underlying cause of MS. Clinical results have demonstrated that Tovaxin produces the following therapeutic effects:

- Anti-idiotypic effect - Induces an immune response that depletes and regulates the circulating pathogenic myelin-reactive T-cells that attack the myelin sheath of nerve fibers.
- Anti-ergotypic effect - Rebalances the overall immune system by causing a shift from pathogenic inflammatory T-cells to anti-inflammatory T-cells.

Tovaxin is manufactured in Opexa's in-house cGMP facility.

About the TERMS Study

The TERMS study was a Phase IIb multi-center, randomized, double blind, placebo-controlled trial in 150 patients with Relapsing-Remitting Multiple Sclerosis or high risk Clinically Isolated Syndrome. The study involved 2:1 randomization with 100 patients receiving Tovaxin and 50 receiving placebo. According to the study protocol, patients received a total of five subcutaneous injections at weeks 0, 4, 8, 12 and 24. The primary efficacy endpoint of the TERMS trial was the cumulative number of gadolinium-enhanced brain lesions (CELs) using MRI scans summed over weeks 28, 36, 44 and 52. The trial's secondary efficacy endpoints included annualized relapse rate (ARR), new CELs at weeks 28 through 52 and T2-weighted lesion volume compared to baseline.

About Opexa's Stem Cell program for diabetes

The autologous adult stem cell research platform at Opexa Therapeutics has been focused on the development of monocyte derived stem cells (MDSC) which are converted to monocyte derived pancreatic-like islets (MDI) as a potential therapeutic transplantation product for the treatment of Type 1 and Type 2 diabetes. A proprietary *in vitro* process has been developed to derive MDSC from blood monocytes, expand them *ex vivo*, and then convert them to MDI for transplantation into the hepatic main portal vein of diabetic patients. Opexa has demonstrated that the MDSC are multipotent stem cells that may be cultured under defined conditions to convert them into several cellular lineages. The MDSCs have specific time-dependent expression of markers that distinguish them from other stem cells. MDSCs have the capacity to differentiate towards hematopoietic, epithelial, endothelial, endocrine and neuronal cells. Currently, Opexa's main focus is the development of MDSC technology as a platform for the *ex vivo* generation of MDI for potential application in autologous transplantation cell therapy for diabetes mellitus patients.

About Opexa

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 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.

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