

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
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): February 7, 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) 775-0600

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 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))
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Item 2.02. Results of Operations and Financial Condition.

On February 7, 2011, Opexa Therapeutics, Inc. (the “**Company**”) filed a preliminary prospectus supplement with the Securities and Exchange Commission (the “**Preliminary Prospectus**”) with respect to a proposed underwritten public offering of units consisting of shares of its common stock and common stock purchase warrants as described below under Item 8.01 under the heading “Proposed Public Offering.” In the Preliminary Prospectus, the Company disclosed the following information with respect to the Company’s financial results for the fiscal year ended December 31, 2010:

“As of December 31, 2010, we had cash and cash equivalents of \$3,812,535. During January 2011, we sold an aggregate of 384,759 shares of our common stock for gross proceeds of \$1,077,111 under an “at the market” continuous offering program pursuant to a prospectus supplement dated May 17, 2010. Our current burn rate, which is in the absence of any clinical trial as well as significant activities in preparation for such a trial, is approximately \$380,000 per month. If we do not commence a clinical trial using our own resources, or undertake substantial activities in preparation for such a trial, we believe we have sufficient liquidity before receiving any proceeds from this offering to support our operations through 2011.”

Item 8.01. Other Events.***Proposed Public Offering***

On February 7, 2011, the Company announced that it is offering to sell, subject to market conditions, units consisting of shares of its common stock and common stock purchase warrants in an underwritten public offering. A copy of the press release is attached as Exhibit 99.1 to this report and is incorporated by reference herein.

The Company is offering to sell these shares pursuant to a shelf registration statement on Form S-3, as amended (Registration No. 333-163108), declared effective by the Securities and Exchange Commission on November 23, 2009.

Updated Company Disclosure

The Company is filing information for the purpose of updating the description of its business from that described under the heading and subheadings, “Item 1. Business—Overview,” “—T-Cell Therapy,” “—Other Opportunities” and “—Stem Cell Therapy” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2009 filed with the SEC on March 5, 2010. The updated Company disclosure is attached as Exhibit 99.2 to this report 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 issued by Opexa Therapeutics, Inc. on February 7, 2011.
99.2	Updated Company disclosure.

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: February 7, 2011

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President & Chief Executive Officer

EXHIBIT INDEX

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OPEXA THERAPEUTICS

Company Contact:

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Neil K. Warma
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**Opexa Therapeutics, Inc. Announces
Proposed Public Offering of Common Stock and Warrants**

THE WOODLANDS, Texas (February 7, 2011) – Opexa Therapeutics, Inc. (NASDAQ: OPXA), a company developing a novel T-cell therapy for multiple sclerosis (MS), today announced that is offering to sell shares of its common stock and common stock purchase warrants in an underwritten public offering. All of the shares in the offering are to be sold by Opexa. The offering is subject to market conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

Lazard Capital Markets LLC is acting as sole book-running manager in the offering.

Opexa intends to use the proceeds from this offering for general corporate purposes (including working capital and operational purposes) and to prepare for and proceed toward the initiation of a pivotal Phase III clinical study in the United States of Tovaxin in relapsing remitting MS.

The offering is made pursuant to the shelf registration statement on Form S-3 that was filed by Opexa with the Securities and Exchange Commission (SEC) and declared effective by the SEC on November 23, 2009. A preliminary prospectus supplement relating to and describing the terms of the offering will be filed with the SEC and will be available on the SEC's web site at <http://www.sec.gov>. Copies of the preliminary prospectus supplement relating to these securities may also be obtained from the offices of Lazard Capital Markets LLC at 30 Rockefeller Plaza, 60th Floor, New York, NY, 10020 or via telephone at (800) 542-0970. This press release does not constitute an offer to sell or the solicitation of an offer to buy these securities, nor will there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale is not permitted.

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 IIb clinical study with Tovaxin in 150 patients with MS. Data from this clinical study show evidence that relapsing remitting 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 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 the Company’s expectations regarding the completion, timing and size of the proposed public offering, 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 and the satisfaction of customary closing conditions related to the proposed public offering, the Company’s capital position, the ability of the Company to enter into and benefit from a partnering arrangement for 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 program and to undertake and complete the pivotal Phase III study in the United States for Tovaxin in RRMS, 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 of this prospectus supplement. We assume no obligation or undertaking to update or revise any forward-looking statements contained herein to reflect any changes in our 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 our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the SEC, and in the preliminary prospectus supplement related to the proposed offering to be filed with the SEC.

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Our Business

We are a biopharmaceutical company developing personalized cellular therapies with the potential to treat major illnesses, including multiple sclerosis (MS). These therapies are based on our proprietary T-cell technology. Information related to our product candidates is preliminary and investigative. Our product candidates are not approved by the Food and Drug Administration (FDA).

Our lead product candidate, Tovaxin®, is a personalized T-cell therapeutic vaccine licensed from Baylor College of Medicine, which is in clinical development for the treatment of MS.

Opexa was incorporated in Texas in March 1991. Our principal executive offices are located at 2635 Technology Forest Blvd., The Woodlands, Texas 77381, and our telephone number is (281) 775-0600.

T-Cell Therapy and Tovaxin®

Tovaxin ® is a novel T-cell immunotherapy positioned to enter Phase III clinical development for the treatment of relapsing remitting MS (RR-MS). It is a personalized therapy that is specifically tailored to each patient's disease profile. Tovaxin is manufactured using our proprietary method for the production of a patient-specific T-cell immunotherapy, which encompasses the collection of blood from the MS patient, isolation of peripheral blood mononuclear cells, generation of an autologous pool of myelin-reactive T-cells raised against selected peptides from myelin basic protein, myelin oligodendrocyte glycoprotein and proteolipid protein, and the return of these expanded, irradiated T-cells back to the patient. These attenuated T-cells are reintroduced into the patient via subcutaneous injection to trigger a therapeutic immune system response.

Summary of TERMS Phase IIb Clinical Trial Data

Tovaxin for Early Relapsing Multiple Sclerosis (TERMS) was a Phase IIb clinical study of Tovaxin in RR-MS patients. Although the study did not show statistical significance in its primary endpoint (the cumulative number of gadolinium-enhanced brain lesions using MRI scans summed at various points in the study), the study showed compelling evidence of efficacy in various clinical and other MRI endpoints.

The TERMS study was a multi-center, randomized, double blind, placebo-controlled trial in 150 patients with RR-MS or high risk Clinically Isolated Syndrome. Patients received a total of five subcutaneous injections at weeks 0, 4, 8, 12 and 24. Key results from the TERMS trial include:

- In the modified intent to treat patient population (n=142), the annualized relapse rate (ARR) for Tovaxin-treated patients was 0.214 as compared to 0.339 for placebo-treated patients, which represented a 37% decrease in ARR for Tovaxin as compared to placebo in the general population;

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- In a prospective group of patients with more active disease (ARR>1, n=50), Tovaxin demonstrated a 55% reduction in ARR as compared to placebo, and a 73% reduction in relapse rate was observed in Tovaxin patients in this population compared to placebo during the 24 week period following the administration of the full course of treatment;
 - In a retrospective analysis in patients naïve to previous disease modifying treatment (*i.e.*, patients who had not previously used any drugs other than steroids to treat their disease), the results showed that patients, when treated with Tovaxin, had a 64% reduction in ARR versus placebo (p=0.046, n=70).

Tovaxin has demonstrated a favorable side effect profile throughout the clinical development program. In four clinical trials to date, including the Phase IIb TERMS trial, there have been no serious adverse events associated with Tovaxin treatment. The most common side effect is mild to moderate irritation at the site of injection, which is typically resolved in 24 hours. We believe the favorable safety profile of Tovaxin is a key differentiator when compared to marketed or other developmental MS drugs.

T-Cell Therapy Regulatory Status

In late 2010, we completed face-to-face discussions with the U.S. Food and Drug Administration (FDA) regarding our planned development program for Tovaxin. Based on positive feedback from the FDA, we believe that we are now positioned from a regulatory perspective to advance with a pivotal Phase III clinical study of Tovaxin in MS, subject to securing the appropriate financing to conduct such a study. We are in the process of completing necessary preparations to be able to initiate such a study.

Our recent discussions with the FDA consisted of two separate meetings to review both the complete Tovaxin manufacturing process as well as the prospective clinical trial plan for Tovaxin. The first meeting focused on the improvements and modifications we have 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, we 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 III clinical trial, although additional supporting data is expected to be submitted to the FDA prior to initiating such a study.

The second meeting was an "end of Phase II" clinical meeting in which we presented our rationale and trial design for a Phase III pivotal study with Tovaxin in RR-MS patients. The FDA concurred in general with our proposed clinical trial protocol, including the patient population, end points, patient numbers and overall trial design. The FDA also offered several recommendations to further enhance such a Phase III trial.

Other Opportunities

Our proprietary T-cell technology has enabled us to develop intellectual property and a comprehensive sample database that may enable discovery of novel biomarkers and other relevant peptides to be used to treat MS patients.

Stem Cell Therapy

In 2009, Novartis Pharmaceuticals acquired our stem cell technology platform, which had been in early preclinical development, and took over all future responsibilities and opportunities for this technology, although we retain an option on certain manufacturing rights. As part of the transaction, we were paid an upfront fee of \$3 million and a milestone payment of \$500,000 for certain technology transfer activities. We remain eligible to receive a second technology transfer milestone fee in addition to potential clinical and commercial milestones and royalty payments from the sale of any products resulting from the use of the technology. However, there can be no assurance that we will receive any future payments in respect of the stem cell technology.