

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 02/29/12 for the Period Ending 02/29/12

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
CIK	0001069308
Symbol	OPXA
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

**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 29, 2012

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 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 8.01 Other Events

On February 29, 2012, Opexa Therapeutics, Inc. (the “Company”) issued a press release announcing that it had entered into an agreement with Pharmaceutical Research Associates, Inc. (“PRA”) to provide contract research organization (CRO) services related to the design, implementation and management of the Company’s planned Phase IIb clinical trial program in secondary progressive multiple sclerosis, which it intends to commence upon securing the necessary resources to do so.

A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Press release issued by Opexa Therapeutics, Inc. on February 29, 2012.
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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, thereunto duly authorized.

Dated: February 29, 2012

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 issued by Opexa Therapeutics, Inc. on February 29, 2012.

Opexa Therapeutics Executes Strategic Service Agreement with Pharmaceutical Research Associates to Manage Clinical Trial

Opexa selects a leading Clinical Research Organization with demonstrated success managing clinical trials in subjects with Multiple Sclerosis

THE WOODLANDS, Texas--(BUSINESS WIRE)--February 29, 2012-- **Opexa Therapeutics, Inc. (NASDAQ: OPXA)**, a biotechnology company developing Tovaxin®, a novel T-cell therapy for multiple sclerosis (MS), announced today that the Company has executed an agreement with Pharmaceutical Research Associates, Inc. (PRA) to provide contract research organization (CRO) services to support Opexa's upcoming Phase IIb clinical trial for Tovaxin in patients with Secondary Progressive multiple sclerosis (SPMS).

"We undertook an extensive process to ensure that we found a CRO that could deliver on the unique challenges faced by clinical sites during an SPMS trial," commented Neil K. Warma, President and Chief Executive Officer of Opexa. "We are very pleased with the depth of PRA's experience along with their insights into the industry. We are confident that this collaboration with PRA's top-notch clinical management team will provide Opexa superior support to accumulate and report the data from this study in an efficient and cost effective manner. Our clinical trial plans are progressing well as we focus on securing the necessary resources and implementing the remaining operational steps that will allow us to start the trial."

Tami Klerr-Naivar, Senior Vice President, Business Development for PRA, commented, "PRA is pleased to support the upcoming planned Phase IIb clinical trial of Tovaxin. MS is a challenging indication for a clinical trial, and we believe that our demonstrated experience and success in over 300 neurologic indications will provide great value to Opexa in their effort to demonstrate the efficacy and safety of Tovaxin in patients with SPMS."

About Opexa

Opexa Therapeutics, Inc. is dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases such as multiple sclerosis (MS). The Company's leading therapy, Tovaxin®, a personalized cellular immunotherapy treatment, is in clinical development targeting both Secondary Progressive and Relapsing Remitting 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.

For more information, visit the Company's website at www.opexatherapeutics.com.

About Pharmaceutical Research Associates

PRA, a leading global CRO, has supported over 2,100 clinical trials in more than 80 countries on 6 continents through their global offices. PRA has broad experience in Central Nervous System studies, and over the past five years PRA has managed 16 MS studies in North America spanning Phases I, II and III clinical trials and is presently engaged in 11 ongoing MS studies. In a recent 2011 survey conducted by CenterWatch in which overall relationship quality between sites and CROs was measured, PRA ranked 4th out of 1,205 companies while scoring nearly 83% cumulative excellent and good ratings by industry participants in the survey. For more information, visit PRA's website at www.clearlypra.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 the development of the Company's product candidate, Tovaxin, 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: our 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), 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 and to undertake and complete any further clinical studies for Tovaxin, the success of our clinical trials, the efficacy of Tovaxin for any particular indication, such as Relapsing Remitting MS or Secondary Progressive MS, 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 that the Company may license or transfer, 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 our reports filed with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2011.

CONTACT:

Opexa Therapeutics, Inc.
Neil K. Warma, 281-775-0600
President & CEO
nwarma@opexatherapeutics.com

or

Investors:

Burns McClellan
Carney Noensie, 212-213-0006
cnoensie@burnsmc.com