

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 05/11/12 for the Period Ending 05/11/12

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): May 11, 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 2.02 Results of Operations and Financial Condition

On May 11, 2012, Opexa Therapeutics, Inc. filed its Quarterly Report on Form 10-Q for the quarter ended March 31, 2012 and announced its results of operations in a press release. A copy of the press release announcing the results is furnished 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 issued by Opexa Therapeutics, Inc. on May 11, 2012

The information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities under that Section, nor be deemed to be incorporated by reference into the filings of the registrant under the Securities Act of 1933.

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: May 11, 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 May 11, 2012.

Opexa Therapeutics Reports First Quarter 2012 Financial Results and Provides Corporate Update

THE WOODLANDS, Texas--(BUSINESS WIRE)--May 11, 2012--Opexa Therapeutics, Inc. (NASDAQ:OPXA), a company developing Tovaxin®, a novel T-cell therapy for multiple sclerosis (MS), today reported financial results for the quarter ended March 31, 2012 and provided an update on recent corporate developments.

Corporate development highlights include:

- Submission to the FDA for final review of the protocol for a Phase IIb clinical trial for Tovaxin in patients with Secondary Progressive MS (SPMS) and, after receiving no additional comments from the FDA, being positioned to proceed with the trial from a regulatory perspective;
- Conducting a kick-off meeting with prospective clinical trial investigators at the 64th Annual American Academy of Neurology (AAN) meeting to review patient enrollment practices and the planned clinical trial details and protocol;
- Executing an agreement with Pharmaceutical Research Associates, Inc. (PRA) to provide contract research organization (CRO) services to support the planned clinical trial;
- Advancing preparations with numerous clinical trial sites; and
- Strengthening our overall cell therapy expertise, including key hires in Manufacturing and Quality Control.

“We are progressing favorably in the planning and preparations for a clinical trial in Secondary Progressive MS patients,” commented Neil K. Warma, President and Chief Executive Officer of Opexa. “The clinical trial protocol was submitted to the FDA for final review and we received no additional comments from them. This is a key milestone for us, providing us with the necessary regulatory positioning to advance with the trial preparations and discussions with potential trial sites. Operationally, we believe we remain on track to initiate the trial in the coming months as the team continues to work diligently to finalize preparations. In order to initiate the trial, we will need to secure additional financing, either through a potential partnership or additional capital raise, and this continues to be an important focus for us.”

“The meeting we recently held with clinical trial investigators at the annual American Academy of Neurology conference was well attended and included some of the most influential MS opinion leaders participating in the discussions related to our clinical trial design and enrollment criteria. We are anticipating strong enrollment once we are able to begin the trial, driven by the support of the clinicians and a strong desire from patients to participate. SPMS is understood to be a very serious medical condition coupled with the fact that patients have limited treatment options. We hope that Tovaxin can eventually develop into a treatment of choice, not only for SPMS but for all MS patients.”

“As of the end of the first quarter, our cash and cash equivalents totaled approximately \$4.7 million and our monthly burn rate for the quarter was approximately \$810,000, inclusive of increased cash expenditures to support preparations for the initiation of the planned Phase IIb clinical study in North America.”

First Quarter Financial Results

Opexa reported no commercial revenues in the three months ended March 31, 2012 or in the comparable prior-year period.

Research and development expenses were \$1,490,097 for the three months ended March 31, 2012, compared with \$685,161 for the three months ended March 31, 2011. The increase in expenses was primarily related to an increase in the procurement and use of laboratory reagents and supplies, and increases in professional service fees, employee personnel costs, facility costs and non-cash stock compensation expense.

General and administrative expenses for the three months ended March 31, 2012 were \$816,196, compared with \$592,058 for the three months ended March 31, 2011. The increase in expense is due to increases in business development activities, legal expenses, employee compensation expense and non-cash stock compensation expense.

Depreciation and amortization expenses were \$67,355 for the three months ended March 31, 2012, compared to \$29,634 for the three months ended March 31, 2011. The increase in expense is due to increases in depreciation for facility build-out costs, and increases in depreciation for laboratory, manufacturing and information technology equipment acquired during 2011 and 2012.

Opexa reported a net loss for the three months ended March 31, 2012 of \$2,373,999, or \$0.10 per share, compared with a net loss for the three months ended March 31, 2011 of \$1,307,777, or \$0.06 per share.

Cash and cash equivalents were \$4,677,956 as of March 31, 2012, compared to \$11,427,985 as of March 31, 2011.

Further details can be found in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012.

About Opexa

Opexa Therapeutics, Inc. is dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases such as MS. The Company's leading T-cell therapy is a personalized cellular immunotherapy treatment that is in late stage clinical development targeting both SPMS and Relapsing Remitting MS. The T-cell therapy 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 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," "hope," "anticipates," "estimates," "may," "could," "intends," "exploring," "evaluating," "progressing" 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 for 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.

OPEXA THERAPEUTICS, INC.
(a development stage company)

Statements of Expenses Data:

	Three Months Ended March 31,	
	2012	2011
Research and development	\$ 1,490,097	\$ 685,161
General and administrative	816,196	592,058
Depreciation and amortization	67,355	29,634
Operating loss	(2,373,648)	(1,306,853)
Interest income	136	211
Interest expense	(487)	(1,135)
Net loss	\$ (2,373,999)	\$ (1,307,777)
Basic and diluted loss per share	\$ (0.10)	\$ (0.06)
Weighted average shares outstanding	23,048,488	20,955,860

Selected Balance Sheet Data:

	2012	2011
Cash and cash equivalents	\$ 4,677,956	\$ 11,427,985
Other current assets	1,005,756	113,774
Fixed assets, net	1,390,674	980,358
Total assets	7,074,386	12,522,117
Total current liabilities	2,047,601	1,060,526
Total long term liabilities	-	-
Total stockholders' equity	5,026,785	11,461,591

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