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OPEXA THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

Filed 05/06/11 for the Period Ending 05/06/11

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

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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): May 6, 2011

OPEXA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Texas	**001-33004**	**76-0333165**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2635 Technology Forest Blvd., The Woodlands, Texas	**77381**
(Address of principal executive offices)	(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))

Item 2.02 Results of Operations and Financial Condition

On May 6, 2011, Opexa Therapeutics, Inc. filed its Quarterly Report on Form 10-Q for the quarter ended March 31, 2011 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

Exhibit No.	Description
99.1	Press Release issued by Opexa Therapeutics, Inc. on May 6, 2011.

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 6, 2011

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma
Neil K. Warma
President & Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by Opexa Therapeutics, Inc. on May 6, 2011.

Exhibit 99.1

Opexa Therapeutics Reports First Quarter 2011 Financial Results

THE WOODLANDS, Texas--(BUSINESS WIRE)--May 6, 2011--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, 2011 and provided an update on its corporate developments.

Recent highlights include:

- Closing an underwritten public offering of $8.5 million gross proceeds, providing necessary funding to continue preparations for a planned Phase III clinical trial;
- Presenting clinical data on Tovaxin during a poster session at the 63 rd annual American Academy of Neurology (AAN) conference, highlighting important efficacy data in a subpopulation of patients that had previously not been exposed to or taken any drugs for the treatment of their MS; and
- Presenting Opexa's progress in the ongoing clinical development program for Tovaxin at the 13 th annual BIO CEO & Investor Conference in New York and the 6 th annual Cell Therapy Conference in Beijing.

"We have maintained an active pace over the past several months in preparation for our Phase III clinical trial and are making good progress on a number of fronts," commented Neil K. Warma, President and Chief Executive Officer of Opexa. "We are using the proceeds from our recent financing to ramp up our efforts in preparation for the trial. The funds will be directed, in part, over the next several months to increasing our headcount to an appropriate level to manage future studies and executing necessary manufacturing and clinical steps in advance of initiating the trial. The presentation of the efficacy data was well received at AAN, and after reviewing recent data from other MS developmental drugs, we continue to believe Tovaxin is very well positioned to be a leading therapy in the treatment of MS. Tovaxin's potent efficacy and excellent safety profile, coupled with the fact that Tovaxin is newly manufactured each year to match each patient's evolving disease profile, is generating strong interest among patients and physicians."

"As of the end of the first quarter, March 31, 2011, our cash and cash equivalents totaled approximately $11.4 million and our monthly burn rate for the quarter was approximately $425,000. At the current burn rate, we should have sufficient capital beyond 2011, and we are focused on raising the necessary funds to commence our planned Phase III clinical trial either through a potential Tovaxin partnership or additional capital raise," commented Mr. Warma.

First Quarter Financial Results

Opexa reported no commercial revenues in the three months ended March 31, 2011 or in the comparable prior-year period.

Research and development expenses were $685,161 for the three months ended March 31, 2011, compared with $783,534 for the three months ended March 31, 2010. The decrease in expenses was primarily related to a decrease in the engagement of consultants, a decrease in the procurement and use of supplies in our laboratory, a reduction of stock compensation expense, and the reduction of employee recruitment expenses, and was partially offset by an increase in headcount in preparation for increased development activities.

General and administrative expenses for the three months ended March 31, 2011 were $592,058 compared with $484,425 for the three months ended March 31, 2010. The increase in expenses is due to an increase in stock compensation expense to employees and an increase in business development activities, and was partially offset by a decrease in legal expenses.

Opexa reported a net loss for the three months ended March 31, 2011 of $1,307,777, or ($0.06) per share, compared with a net loss for the three months ended March 31, 2010 of $1,422,495, or ($0.09) per share.

Cash, cash equivalents and investments in marketable securities were $11,427,985 as of March 31, 2011 compared to $7,092,036 as of March 31, 2010.

Further details can be found in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2011.

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 late stage 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 is preparing for Phase III clinical trials with Tovaxin following the completion of a Phase IIb clinical study 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 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: 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 a pivotal Phase III clinical study for Tovaxin, 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 our reports filed with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2010.

OPEXA THERAPEUTICS, INC.
(a development stage company)

Statements of Expenses Data:

	Three Months Ended March 31,	
	2011	**2010**
Research and development	$ 685,161	$ 783,534
General and administrative	592,058	484,425
Depreciation and amortization	29,634	49,646
Operating loss	(1,306,853)	(1,317,605)
Interest income	211	185
Interest expense	(1,135)	(105,075)
Net loss	$ (1,307,777)	$ (1,422,495)
Basic and diluted loss per share	$ (0.06)	$ (0.09)
Weighted average shares outstanding	20,955,860	15,523,710

Selected Balance Sheet Data:

	2011	**2010**
Cash and cash equivalents	$ 11,427,985	$ 7,092,036
Other current assets	113,774	199,117
Fixed assets, net	980,358	900,264
Total assets	12,522,117	8,191,417
Total current liabilities	1,060,526	901,158
Total long term liabilities	-	1,175,282
Total stockholders' equity	11,461,591	6,114,977

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