

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 08/11/11 for the Period Ending 08/11/11

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

**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): August 11, 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) 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 obligations 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 August 11, 2011, Opexa Therapeutics, Inc. filed its Quarterly Report on Form 10-Q for the quarter ended June 30, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Opexa Therapeutics, Inc. on August 11, 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: August 11, 2011

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 August 11, 2011.

Opexa Therapeutics Reports Second Quarter 2011 Financial Results and Provides Corporate Update

THE WOODLANDS, Texas--(BUSINESS WIRE)--August 11, 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 June 30, 2011 and provided an overview of recent corporate developments.

Recent highlights include:

- Executed strategic agreements with the American Red Cross and the Blood Group Alliance, Inc. to provide blood collection services to support future clinical development of Tovaxin. In combination, the two groups provide Opexa with access to over 90% of the blood procurement centers in the United States;
- Met with Health Canada's Biologics and Genetics Therapies Directorate as part of the process to secure approval for Opexa to conduct a portion of future clinical development in Canada;
- Initiated the design and development of a proprietary Web-based system to manage patient and product flow throughout future clinical studies;
- Presented Tovaxin data at the 2011 American Academy of Neurology Meeting; and
- Continued work on operational and clinical plans for a pivotal trial in Relapsing Remitting MS (RRMS) as well as evaluating clinical development opportunities in Secondary Progressive MS (SPMS).

"We are pleased with our first half accomplishments and as we move into the second half of the year, we will continue to execute on a number of critical steps necessary for the execution of our next clinical study," commented Neil K. Warma, President and Chief Executive Officer of Opexa. "We are working to ensure that the various steps in the manufacturing process for Tovaxin are being effectively implemented prior to the next trial, recognizing that such process has been substantially modified and optimized to support late stage clinical development and potential commercialization. We are also working to ensure that clinical operations will be ready, including securing key clinical sites and obtaining advisory input on trial design."

"In the second quarter, we secured the American Red Cross and the Blood Group Alliance as partners for blood procurement in future clinical studies and possibly into potential commercialization," continued Mr. Warma. "These arrangements should simplify the patient experience with Tovaxin and improve efficiency. To further enhance efficiency, we are designing and building a proprietary Web-based system to manage patient recruitment, scheduling and product flow. During the second quarter, we also had a constructive meeting with the Canadian Health Authority which was critical for our ability to enroll patients as part of any future clinical trial in Canada where the incidence of MS is relatively high."

“While we continue to work on preparations for a pivotal Phase III clinical study in RRMS,” commented Mr. Warma, “we are also exploring trial designs for a potential Phase II clinical study in SPMS. Although any study is subject to our ability to secure the necessary funding, we believe that Tovaxin is well positioned in both RRMS and SPMS, which we believe distinguishes us from the majority of other MS drugs on the market or in development. As there are limited treatment options for patients with progressive forms of MS, the substantial unmet medical need has increased the urgency to develop new treatments for these patients and, subsequently, our interest in advancing Tovaxin in SPMS.”

“As of June 30, 2011, our cash and cash equivalents totaled approximately \$9.9 million and our current monthly burn rate was approximately \$470,000,” continued Mr. Warma. “At the current burn rate, we should have sufficient capital beyond 2011. Moving forward, we expect to maintain our focus on implementing operational steps in anticipation of continuing the clinical study of Tovaxin and working to secure the necessary resources to support such a study.”

Second Quarter Financial Results

Opexa reported no commercial revenues in the three and six months ended June 30, 2011 or in the comparable prior-year periods.

Research and development expenses were \$854,208 and \$1,539,369 for the three and six months ended June 30, 2011, respectively, compared with \$785,103 and \$1,568,637 for the three and six months ended June 30, 2010, respectively. The increase for the three months ended June 30, 2011 compared to the three months ended June 30, 2010 was due to increased staff associated with development activities and an increase in associated laboratory costs and supplies, and was partially offset by a decrease in the engagement of consultants.

General and administrative expenses for the three and six months ended June 30, 2011 were \$560,834 and \$1,152,892, respectively, compared with \$595,424 and \$1,079,849 for the three and six months ended June 30, 2010, respectively. The decrease for the three months ended June 30, 2011 compared to the three months ended June 30, 2010 was due to decreased legal fees, and was partially offset by an increase in business development expenses.

Depreciation and amortization expense for the three and six months ended June 30, 2011 was \$70,732 and \$100,366, respectively, compared with \$48,729 and \$98,375 for the three and six months ended June 30, 2010, respectively. The increase was due to an increase in depreciation for facility buildout costs incurred during the first half of 2011 and an increase in depreciation for laboratory and manufacturing equipment acquired during the first half of 2011, and was partially offset by the decrease in depreciation expense on certain assets that were disposed during 2010.

Interest expense for the three and six months ended June 30, 2011 was \$870 and \$2,005, respectively, compared with \$392,121 and \$497,196 for the three and six months ended June 30, 2010, respectively. The decrease in expense was primarily related to the amortized interest incurred during the first half of 2010 and the amortization of the remaining discount and deferred financing fees in conjunction with the June 23, 2010 conversion of the 10% Convertible Promissory Notes. Interest expense for the three and six months ended June 30, 2011 is related solely to the financing costs on insurance policies and the loan payable on an equipment line.

Opexa reported a net loss for the three months ended June 30, 2011 of \$1.49 million, or (\$0.06) per share, and a net loss for the six months ended June 30, 2011 of \$2.79 million, or (\$0.13) per share. For the same three month and six month periods ending June 30, 2010, Opexa reported a net loss of \$1.82 million, or (\$0.12) per share, and \$3.24 million, or (\$0.21) per share, respectively.

Cash and cash equivalents were \$9,876,675 as of June 30, 2011 compared to \$5,874,614 as of June 30, 2010.

Further details can be found in the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 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 a Phase III clinical trial with Tovaxin in RRMS following the completion of a Phase IIb clinical study in 150 patients with MS. Data from this clinical study show evidence that RRMS 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. In addition, Opexa is evaluating opportunities to advance Tovaxin through clinical development in SPMS, an area with high unmet medical need.

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," "exploring," "evaluating" 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 RRMS or SPMS, 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 June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Research and development	\$ 854,208	\$ 785,103	\$ 1,539,369	\$ 1,568,637
General and administrative	560,834	595,424	1,152,892	1,079,849
Depreciation and amortization	70,732	48,729	100,366	98,375
Operating loss	(1,485,774)	(1,429,256)	(2,792,627)	(2,746,861)
Interest income	260	395	471	580
Interest expense	(870)	(392,121)	(2,005)	(497,196)
Net loss	<u>\$ (1,486,384)</u>	<u>\$ (1,820,982)</u>	<u>\$ (2,794,161)</u>	<u>\$ (3,243,477)</u>
Basic and diluted loss per share	\$ (0.06)	\$ (0.12)	\$ (0.13)	\$ (0.21)
Weighted average shares outstanding	23,048,488	15,827,353	22,007,955	15,569,623

Selected Balance Sheet Data:

	June 30, 2011	June 30, 2010
Cash and cash equivalents	\$ 9,876,675	\$ 5,874,614
Other current assets	119,619	94,047
Fixed assets, net	930,141	851,535
Total assets	10,926,435	6,820,196
Total current liabilities	754,825	910,272
Total long term liabilities	-	-
Total stockholders' equity	10,171,610	5,909,924

CONTACT:

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