OPEXA THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

Filed 08/06/10 for the Period Ending 08/06/10

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
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Symbol	OPXA
SIC Code	2834 - Pharmaceutical Preparations
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): August 6, 2010

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 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 6, 2010, Opexa Therapeutics, Inc. filed its Quarterly Report on Form 10-Q for the quarter ended June 30, 2010 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 August 6, 2010

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 6, 2010

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 August 6, 2010.

Exhibit 99.1

Opexa Therapeutics Reports Second Quarter 2010 Financial Results

THE WOODLANDS, Texas--(BUSINESS WIRE)--August 6, 2010--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, 2010 and provided an update on its corporate developments.

Recent highlights include:

- Implementation of process improvements and optimization of manufacturing process to support late stage clinical trials and regulatory requirements;
- Preparation for clinical studies and positioning for future FDA interactions;
- Enlisting the support of worldwide thought leaders in MS, neurology, and immunology for newly reconstituted SAB.

“Having put in place a world class management team in the first few months of this year, we have been leveraging this expertise to further advance the Tovaxin program in both the clinical development and manufacturing functions,” commented Neil K. Warma, President and Chief Executive Officer of Opexa. “Additionally we have recently formed a new and very experienced Scientific Advisory Board to support the team and assist with the development efforts. The group is comprised of some of the most renowned MS leaders in North America and Europe and we are thrilled that they have agreed to work with us to advance Tovaxin. Our focus in 2010 has remained true to our plan to optimize the manufacturing process and develop the clinical plans to support late stage development of Tovaxin in MS. Over the remainder of the year, we aim to complete planned experiments for process improvements and develop clinical study protocols in advance of meeting with the FDA. Discussions with potential partners are also continuing.”

“As of the end of the second quarter, June 30, 2010, our cash and cash equivalents totaled approximately $6 million and our monthly burn rate for the quarter was approximately $380,000. We continue to remain diligent in the utilization of cash resources and despite the planned increase in clinical and manufacturing activities this quarter, I am pleased with the returns we are seeing with relatively limited expenditures. At the current burn rate, we have sufficient capital beyond 2010,” commented Mr. Warma.

Second Quarter Financial Results

Opexa reported no revenues in the three months ended June 30, 2010 or in the comparable prior-year period.

Research and development expenses were $785,103 and $1,568,637 for the three and six months ended June 30, 2010, respectively, compared with $425,701 and $1,163,482 for the three and six months ended June 30, 2009, respectively. The increase in expenses was primarily related to an increase in personnel and the initiation of key experiments, and was partially offset by a decrease in stock compensation expense.

General and administrative expenses for the three and six months ended June 30, 2010 were $595,424 and $1,079,849, respectively, compared with $411,675 and $807,990 for the three and six months ended June 30, 2009, respectively. The increase in expense is due to an increase in professional service fees, and was partially offset by a decrease in stock compensation expense.

Opexa reported a net loss for the three months ended June 30, 2010 of $1.82 million, or ($0.12) per share, and a net loss for the six months ended June 30, 2010 of $3.24 million, or ($0.21) per share. For the same three and six month period ending June 30, 2009, Opexa reported a net loss of $0.9 million, or ($0.07) per share, and $2.5 million, or ($0.20) per share, respectively.

Cash and cash equivalents were $5,874,614 as of June 30, 2010 compared to $827,004 as of June 30, 2009.

Further details can be found in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010.

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 multiple sclerosis (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 completed its 150 patient ***Tovaxin for Early Relapsing Multiple Sclerosis*** (TERMS) Phase 2b clinical study in late 2008 which was one of the first clinical studies investigating an autologous T-cell therapy in MS patients. Data from this clinical study show evidence that Relapsing Remitting MS (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.

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: market conditions, 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), 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 programs, 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 the reports filed with the Securities and Exchange Commission.

OPEXA THERAPEUTICS, INC.
(a development stage company)

Statements of Expenses Data:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	**2009**	**2010**	**2009**
Research and development	$ 785,103	$ 425,701	$ 1,568,637	1,163,482
General and administrative	595,424	411,675	1,079,849	807,990
Depreciation and amortization	48,729	53,706	98,375	111,084
Operating loss	(1,429,256)	(891,082)	(2,746,861)	(2,082,556)
Interest income	395	385	580	1,494
Other income and expense, net	-	-	-	-
Gain (loss) on derivative instruments	-	74,206	-	(366,774)
Interest expense	(392,121)	(47,007)	(497,196)	(52,628)
Net loss	$ (1,820,982)	$ (863,498)	$ (3,243,477)	$ (2,500,464)
Basic and diluted loss per share	$ (0.12)	$ (0.07)	$ (0.21)	$ (0.20)
Weighted average shares outstanding	15,827,353	12,245,858	15,569,623	12,245,858

Selected Balance Sheet Data:

	June 30, 2010	June 30, 2009
Cash and cash equivalents	$ 5,874,614	$ 827,004
Other current assets	94,047	226,982
Fixed assets, net	851,535	1,055,447
Total assets	6,820,196	2,109,433
Total current liabilities	910,272	856,189
Total long term liabilities	-	1,906,670
Total stockholders' equity	5,909,924	202,763

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