

OPEXA THERAPEUTICS, INC.

FORM 8-K

(Current report filing)

Filed 05/13/08 for the Period Ending 05/13/08

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
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 13, 2008**

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

(I.R.S. Employer Identification No.)

**2635 N. Crescent Ridge Drive
The Woodlands, Texas**

(Address of Principal Executive Office)

77381

(Zip Code)

Registrant's telephone number, including area code: **(281) 272-9331**

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 (see General Instruction A.2 below) :

- 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 13, 2008 Registrant filed its Quarterly Report on Form 10-Q for the quarter ended March 31, 2008. On March 13, 2008, Registrant announced its results of operations in a press release. A copy of the press release announcing the results is filed as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(c) Exhibit 99.1

The following exhibit is to be filed as part of this 8-K:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued May 13, 2008

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 hereto duly authorized.

OPEXA THERAPEUTICS, INC.

By: /s/ DAVID B. MCWILLIAMS
David B. McWilliams
President and Chief Executive Officer

DATE: May 13, 2008

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued May 13, 2008

Opexa Therapeutics Reports First Quarter 2008 Financial Results and Updates on Tovaxin[®] Phase IIb Study

THE WOODLANDS, Texas--(BUSINESS WIRE)-- **Opexa Therapeutics, Inc.** (NASDAQ:OPXA), a company involved in the development and commercialization of cell therapies, today reported financial results for the quarter ended March 31, 2008 and provided an update on its progress.

Recent Highlights include:

- Completed a public equity financing with gross proceeds of \$7.6 million in February;
- Completed dosing in the Tovaxin IIb clinical trial with topline results expected in September 2008;
- Recommendation received from the Data Safety Monitoring Board (DSMB) from its review of the mid-study descriptive analysis to continue the study as scheduled;
- Positive results of Phase I/II studies of Tovaxin for multiple sclerosis (MS), with a greater than 90% reduction in annualized relapse rate in subjects as compared to their average prior two years was presented by the principal investigator, Brian Loftus, M.D. at the American Academy of Neurology annual meeting in April.

David McWilliams, chief executive officer of Opexa, commented, “The Phase IIb trial continues to be executed according to our plan and the level of dropouts has remained low. To date only 150 patient visits remain of the approximately 2,500 total visits comprising the trial. We look forward to reporting topline results on our primary endpoints in September. McWilliams continued, “We are also encouraged by the strong interest in the open label extension study for Tovaxin offered to all participants completing the Phase IIb study. Over 90% of patients who have completed the one-year TERMS study to date have elected to enroll in the extension study.”

First Quarter Financial Results

Opexa reported no revenues for the three months ended March 31, 2008 or in the comparable prior-year period.

Research and development expenses were approximately \$2.4 million in the first quarter of 2008, compared with approximately \$3.2 million in the first quarter of 2007. The decrease was primarily related to the initial enrollment and start-up costs of the Phase IIb clinical trial for Tovaxin recorded in 2007 and a reduction in stock compensation expense. We expect our research and development expense to increase as we continue to invest in the development of our technology.

General and administrative expenses were approximately \$0.7 million in the first quarter of 2008, compared with approximately \$0.8 million in the first quarter of 2007. The decline is primarily due to a decrease in stock compensation expense, professional service fees and overhead expenses. The Company expects future general and administrative expenses to be higher as it prepares for commercialization of its products.

Opexa reported a net loss for the first quarter of 2008 of approximately \$3.1 million or \$0.37 per share, compared with a net loss for the first quarter of 2007 of approximately \$4.0 million or \$0.59 per share. The decrease in net loss primarily was due to the initial enrollment and start-up costs of the Phase IIb trial for Tovaxin recorded in 2007 and a reduction in stock-based compensation expense.

The Company had cash and cash equivalents of approximately \$6.3 million as of March 31, 2008, compared with approximately \$2.6 million as of December 31, 2007. The March 31, 2008 quarter-end cash balance included gross proceeds of approximately \$7.6 million raised from the February 19, 2008 public offering.

About Opexa Therapeutics

Opexa Therapeutics develops and commercializes cell therapies to treat autoimmune diseases such as MS, rheumatoid arthritis, and diabetes. The Company is focused on autologous cellular therapy applications of its proprietary T-cell and stem cell therapies. The Company's lead product, Tovaxin, a T-cell therapy for multiple sclerosis is in Phase IIb trials. The Company holds the exclusive worldwide license for adult multipotent stem cells derived from mononuclear cells of peripheral blood. The technology allows large quantities of monocyte derived stem cells to be produced efficiently for use in autologous therapy, thus circumventing the threat of rejection. The Company is in preclinical development for diabetes mellitus. 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," including statements about Opexa Therapeutics' growth and future operating results, discovery and development of products, strategic alliances and intellectual property, as well as other matters that are not historical facts or information. These forward-looking statements are based on management's current assumptions and expectations and involve risks, uncertainties and other important factors, specifically including those relating to Opexa Therapeutics' ability to obtain additional funding, develop its stem cell technologies, obtain FDA approval for its therapeutic products, achieve its operational objectives, and obtain patent protection for its discoveries, that may cause Opexa Therapeutics' actual results to be materially different from any future results expressed or implied by such forward-looking statements. Opexa Therapeutics undertakes no obligation to update or revise any such forward-looking statements, whether as a result of new information, future events or otherwise.

OPEXA THERAPEUTICS, INC.
(a development stage company)
Financial Highlights
(Unaudited)

Statements of Expenses Data:

	Three Months Ended	
	March 31,	
	2008	2007
Research and development	\$ 2,373,936	\$ 3,247,466
General and administrative	709,517	849,786
Depreciation	58,277	48,831
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Operating loss	(3,141,730)	(4,146,083)
Interest income	37,709	178,823
Other income and expense, net	8,317	—
Interest expense	(6,326)	(2,453)
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Net loss	\$ (3,102,030)	\$ (3,969,713)
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Basic and diluted loss per share	\$ (0.37)	\$ (0.59)
Weighted average shares outstanding	8,312,169	6,696,784

Selected Balance Sheet Data:

	March 31,	December 31,
	2008	2007
Cash and cash equivalents	\$ 6,325,990	\$ 2,645,482
Other current assets	176,381	355,266
Fixed assets (net)	1,321,310	1,370,647
Total assets	7,823,681	4,371,395
Total current liabilities	1,862,773	2,075,354
Total long term liabilities	147,274	162,456
Total stockholders' equity	5,813,634	2,133,585

CONTACT:

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