

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 08/14/08 for the Period Ending 08/14/08

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): **August 14, 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 obligations 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 August 14, 2008 Registrant filed its Quarterly Report on Form 10-Q for the quarter ended June 30, 2008. On August 14, 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 August 14, 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 hereunto duly authorized.

OPEXA THERAPEUTICS, INC.

By: /s/ Lynne Hohlfeld
Lynne Hohlfeld
Chief Financial Officer

DATE: August 14, 2008

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued August 14, 2008

Opexa Therapeutics Reports Second Quarter 2008 Financial Results and Recent Corporate Highlights

Conference Call Scheduled for August 19, 2008, at 4:00 p.m. Eastern Time

THE WOODLANDS, Texas--(BUSINESS WIRE)--Opexa Therapeutics, Inc. (NASDAQ:OPXA), a company developing novel cell therapies for multiple sclerosis (MS), today reported financial results for the quarter ended June 30, 2008, and provided an update on its recent accomplishments.

Second Quarter 2008 Highlights:

- Hiring of new president and chief executive officer, Neil Warma
- Reported two year data on Tovaxin Phase I/II open label studies in patients with multiple sclerosis:
 - 73% of patients remained relapse free after two years
 - 86% demonstrated no worsening of disease (27% of these showed an improvement)
 - 82% decrease in annualized relapse rate (ARR)
 - No serious adverse events based on five subcutaneous injections/year
- Received positive recommendation from the TERMS Data and Safety Monitoring Board (DSMB) to continue the trial unmodified after a regularly scheduled DSMB meeting
- Delivered poster presentation demonstrating further characterization of monocyte-derived islet cell technology for diabetes at the annual meeting of the International Society for Stem Cell Research

Recent highlights (subsequent to quarter end):

- Completed a private placement financing with total gross proceeds of approximately \$3 million
 - Continued significant progress towards completion of the Phase IIb TERMS trial with Tovaxin in patients with multiple sclerosis; on track to communicate top line results in September 2008
-

“The second quarter of this year finished strongly as we continued to make progress with our Tovaxin Phase IIb trial,” commented Neil K. Warma, president and chief executive officer of Opexa. “We remain on track to complete treatment of the study’s final patient later this month and look forward to reporting top-line data from the study in September. We believe that Tovaxin is well positioned at this stage of its development based on its favorable safety profile and encouraging efficacy data demonstrated thus far and may address certain patient compliance issues with a treatment regimen of five subcutaneous injections per year. Additionally, the close of our recent financing prior to the announcement of the Tovaxin Phase IIb data demonstrated validation from sophisticated investors and further strengthened the company’s operations.”

Second Quarter Financial Results

Opexa reported no revenues for the three months ended June 30, 2008, or in the comparable prior-year period.

Research and development expenses were approximately \$2.3 million in the second quarter of 2008, compared with approximately \$3.7 million in the second 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. 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 \$1.3 million in the second quarter of 2008, compared with approximately \$0.9 million in the second quarter of 2007. The increase in expenses is primarily due to an increase in stock compensation expense in the current period. 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 second quarter of 2008 of approximately \$3.6 million or \$0.36 per share, compared with a net loss for the second quarter of 2007 of approximately \$4.5 million or \$0.67 per share.

The company had cash and cash equivalents of approximately \$3.5 million as of June 30, 2008, compared with approximately \$2.6 million as of December 31, 2007. The June 30, 2008 quarter-end cash balance included gross proceeds of approximately \$7.6 million from the February 19, 2008 public offering, but does not include proceeds from the private financing completed earlier this week.

Year-to-Date Financial Results

Opexa reported no revenues in the six months ended June 30, 2008 or in the comparable prior-year period.

Research and development expenses were approximately \$4.7 million for the six months ended June 30, 2008, compared to approximately \$7.0 million for the six months ended June 30, 2007. The decrease in R&D expenses was primarily due 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 in 2008.

General and administrative expenses for the six months ended June 30, 2008 were approximately \$2.0 million, compared to \$1.7 million for the six months ended June 30, 2007. The increase in G&A expenses was primarily due to an increase in stock compensation expense. The company anticipates increases in general and administrative expenses as it continues to develop and prepare for commercialization of its technology.

Opexa reported a net loss for the six months ended June 30, 2008 of approximately \$6.7 or \$0.73 per share, compared with a net loss for the six months ended June 30, 2007 of approximately \$8.5 million or \$1.26 per share.

Conference Call Information

Opexa will host a conference call on Tuesday, August 19, 2008, at 4:00 p.m. Eastern Time, to discuss the company's second quarter results and clinical development progress.

The call may be accessed either through the call-in number below or through the audio webcast. The dial-in number for the call is: (612) 288-0340.

This call is being webcast and can be accessed through the Investors page on Opexa's website at www.opexatherapeutics.com and will be available through September 18, 2008.

Additionally, a replay of the call will be available until Tuesday, August 26, 2008, at 11:59 p.m. Eastern Time. The call replay can be accessed by calling:

U.S.: (800) 475-6701
International: (320) 365-3844
Access Code: 956411

About Opexa Therapeutics

Opexa Therapeutics develops and commercializes cell therapies to treat autoimmune diseases such as multiple sclerosis (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 is Tovaxin, a T-cell therapy for MS which is in Phase IIb trials. The Company holds an 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 the preclinical stages of the development of insulin-producing monocyte-derived islets as a replacement therapy 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 June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Research & development	\$ 2,331,592	\$ 3,712,208	\$ 4,705,528	\$ 6,959,674
General and Administrative	1,298,180	865,744	2,007,697	1,715,530
Depreciation	58,793	50,096	117,070	98,925
Loss on disposal of assets	116	4,034	116	4,034
Operating loss	(3,688,681)	(4,632,082)	(6,830,411)	(8,778,163)
Interest Income	31,495	141,971	69,204	320,794
Other income and expense, net	26,584	—	34,901	—
Interest expense	(4,694)	(3,691)	(11,020)	(6,144)
Net loss	<u>\$ (3,635,296)</u>	<u>\$ (4,493,802)</u>	<u>\$ (6,737,326)</u>	<u>\$ (8,463,513)</u>
Basic and diluted loss per share	\$ (0.36)	\$ (0.67)	\$ (0.73)	\$ (1.26)
Weighted average shares outstanding	10,235,223	6,696,784	9,273,485	6,696,784

Selected Balance Sheet Data:

	June 30, 2008	December 31, 2007
Cash and cash equivalents	\$ 3,493,781	\$ 2,645,482
Other current assets	363,533	355,266
Fixed assets (net)	1,284,731	1,370,647
Total assets	5,142,045	4,371,395
Total current liabilities	1,784,169	2,075,354
Total long term liabilities	131,847	162,456
Total stockholders' equity	3,226,029	2,133,585

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