

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 05/15/07 for the Period Ending 05/14/07

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

OPEXA THERAPEUTICS, INC.

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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 14, 2007



Opexa Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Texas

(State or Other Jurisdiction of Incorporation)

001-33004

(Commission File Number)

2635 N. Crescent Ridge Drive

The Woodlands, Texas

(Address of Principal Executive Offices)

76-0333165

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

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 14, 2007 Registrant filed its Quarterly Report on Form 10-QSB for the quarter ended March 31, 2007. On May 15, 2007, Registrant announced its results of operations in a press release. A copy of the press release is attached as Exhibit 99.1.

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 15, 2007

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/ David B. McWilliams
David B. McWilliams
President and Chief Executive Officer

DATE: May 14, 2007

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued May 15, 2007



OPEXA THERAPEUTICS

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Opexa Reports First Quarter 2007 Results

THE WOODLANDS, Texas (May 15, 2007) - 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, 2007 and provided an update on its progress.

Highlights of the first quarter of 2007 and recent weeks include:

- Positive top-line data from Phase I/II dose escalation trial with Tovaxin™ for multiple sclerosis
- Opexa announces two scientific presentations to be delivered in June on progress of development of monocyte-derived pancreatic islet cells for diabetes

David McWilliams, chief executive officer of Opexa, commented, "As our Phase I/II clinical trial for Tovaxin (TERMS study) progressed nicely during the quarter, we were also very pleased to announce additional news concerning clinical and scientific data, which helps support our broad, evidence-based development plan for our autologous personalized therapies. We reached a key milestone when we announced that data from our 10-patient Phase I/II dose escalation study of Tovaxin was positive and showed a statistically significant reduction in annualized relapse rate as compared to baseline. Furthermore, there were no safety issues reported. In addition, we continue to generate impressive data from our monocyte-derived stem cell program, which we are delivering at prestigious scientific forums. These comprise important steps to fulfilling our objective to submit an Investigational New Drug (IND) application with the U.S. Food and Drug Administration for this stem cell therapy. "

Year-to-Date Financial Results

Opexa reported no revenues in the three months ended March 31, 2007 or in the comparable prior-year period. General and administrative expenses for the three months ended March 31, 2007 were \$849,786, compared to \$1,075,882 for the three months ended March 31, 2006. The decrease in G&A expenses was due to a combination of factors, including a decrease in stock compensation expenses, professional service fees and overhead expenses. The Company anticipates increases in general and administrative expenses as it continues to develop and prepare for commercialization of its technology.

Research and development expenses were \$3,247,466 for the three months ended March 31, 2007, compared to \$738,450 for the three months ended March 31, 2006. The increase in R&D expenses was primarily due to the costs of conducting the Phase IIb clinical trial for Tovaxin and research and development in support of pre-clinical diabetes stem cell therapies.

Interest income was \$178,823 for the three months ended March 31, 2007, compared to \$19,621 for the three months ended March 31, 2006. The increase was due to the investment of the cash proceeds from the April 2006 equity offering in short term and cash equivalent investments.

Interest expense was \$2,453 for the three months ended March 31, 2007, compared to \$429 for the three months ended March 31, 2006.

Opexa reported a net loss for the three months ended March 31, 2007 of \$4,381,988 or (\$0.65) per share, compared with a net loss for the three months ended March 31, 2006 of \$1,970,310, or (\$0.95) per share. The increase in net loss was primarily due to the costs associated with the Phase IIb clinical trial for Tovaxin.

Cash and cash equivalents and investments in marketable securities were \$12,060,839 as of March 31, 2007. This compares with \$14,972,010 as of December 31, 2006.

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.

Safe Harbor Statement

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, 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.

Tables to Follow

OPEXA THERAPEUTICS, INC.
(a development stage company)
BALANCE SHEETS
(unaudited)

	March 31,	December 31,
	<u>2007</u>	<u>2006</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 12,060,839	\$ 12,019,914
Investment in marketable securities	—	2,952,096
Other current assets	<u>782,037</u>	<u>472,881</u>
Total current assets	12,842,876	15,444,891
Intangible assets, net accumulated amortization of \$3,945,843 and \$3,533,569, respectively	24,310,928	24,723,203
Property & equipment, net accumulated depreciation of \$444,115 and \$395,284, respectively	<u>1,373,764</u>	<u>1,361,377</u>
Total assets	<u><u>\$ 38,527,568</u></u>	<u><u>\$ 41,529,471</u></u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,105,273	\$ 868,862
Stock payable	112,440	112,440
Accrued expenses	506,302	135,069
Note payable	1,500,000	1,500,000
Current maturity of long term debt	29,337	14,080
Derivative liability	<u>—</u>	<u>6,656,677</u>
Total current liabilities	3,253,352	9,287,128
Long term liabilities:		
Loan payable	<u>130,034</u>	<u>96,242</u>
Total liabilities	<u>3,383,386</u>	<u>9,383,370</u>
Commitments and contingencies	—	—
Stockholders' equity:		
Convertible preferred stock, no par value, 10,000,000 shares authorized, none issued and outstanding	—	—
Common stock, \$0.50 par value, 100,000,000 shares authorized, 6,696,784 shares issued and outstanding	3,348,351	3,348,351
Additional paid in capital	74,500,068	63,118,180
Deficit accumulated during the development stage	<u>(42,704,237)</u>	<u>(34,320,430)</u>
Total stockholders' equity	<u>35,144,182</u>	<u>32,146,101</u>
Total liabilities and stockholders' equity	<u><u>\$ 38,527,568</u></u>	<u><u>\$ 41,529,471</u></u>

OPEXA THERAPEUTICS, INC.
(a development stage company)
STATEMENTS OF EXPENSES
Three months ended March 31, 2007 and 2006 and the
Period from January 22, 2003 (Inception) to March 31, 2007
(unaudited)

	<u>2007</u>	<u>2006</u>	<u>Inception through March 31, 2007</u>
Research and development	\$ 3,247,466	\$ 738,450	\$ 15,676,375
General and administrative	849,786	1,075,882	15,056,255
Depreciation and amortization	461,106	432,333	4,279,929
Loss on disposal of assets	<u>-</u>	<u>362</u>	<u>482,309</u>
Operating loss	(4,558,358)	(2,247,027)	(35,494,868)
Interest income	178,823	19,621	955,044
Other income	-	3,385	77,003
Gain (loss) on derivative liability	-	254,140	-
Interest expense	<u>(2,453)</u>	<u>(429)</u>	<u>(8,241,416)</u>
Net loss	<u>\$ (4,381,988)</u>	<u>\$ (1,970,310)</u>	<u>\$ (42,704,237)</u>
Basic and diluted loss per share	\$ (0.65)	\$ (0.95)	N/A
Weighted average shares outstanding	6,696,784	2,065,430	N/A