

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 11/05/07 for the Period Ending 11/02/07

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
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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): November 2, 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)

76-0333165

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

2635 N. Crescent Ridge Drive

The Woodlands, Texas

(Address of Principal Executive Offices)

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 November 2, 2007 Registrant filed its Quarterly Report on Form 10-QSB for the quarter ended September 30, 2007. On November 5, 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 November 5, 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: November 2, 2007

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued November 5, 2007



OPEXA THERAPEUTICS

Company Contact:

Opexa Therapeutics, Inc.

Lynne Hohlfeld

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Opexa Reports Third Quarter 2007 Financial Results

THE WOODLANDS, Texas (Nov. 5, 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 September 30, 2007 and provided an update on its progress.

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

- All 150 patients have received their first vaccine dose in the five dose vaccine series of the Phase IIb trial with Tovaxin® for multiple sclerosis.
- The Data Safety Monitoring Board of the Tovaxin Phase IIb study has met three times and reported no safety issues and recommends continuing the trial as planned.
- Lorin Jeffry (Jeff) Randall joined its board of directors, bringing the number of directors to six. Mr. Randall will also serve as a member of the audit committee.
- Named Dawn McGuire, M.D., to its Clinical Advisory Board (CAB) for multiple sclerosis (MS).

David McWilliams, chief executive officer of Opexa commented, “We continue to make good progress in the clinical development of Tovaxin. At the end of August, we completed the initial vaccination of all 150 subjects enrolled in the Tovaxin Phase IIb trial. This is an important milestone because it establishes August 2008 as the date for the last subject to be evaluated for safety and efficacy. In addition, in the third quarter, we completed the third meeting of the data safety monitoring board with no safety issues relative to the subjects in the trial.

In the third quarter, we also strengthened both the board of directors and the Tovaxin clinical advisory board. Jeff Randall joined the board of directors in August. Jeff has a strong financial track record with several companies in the biotech industry and we look forward to taking advantage of his background and experience to move the company forward. Likewise, Dawn McGuire joined the Tovaxin clinical advisory board in September. Dr. McGuire is board certified in neurology and psychiatry and has important hands on experience in the development of multiple sclerosis drugs.”

Third Quarter Financial Results

Opexa reported no revenues for the three months ended September 30, 2007 or in the comparable prior-year period. General and administrative expenses were \$842,079 in the third quarter of 2007, compared with \$1,430,507 in the third quarter of 2006. 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.

Research and development expenses were \$3,189,256 in the third quarter of 2007, compared with \$2,113,878 in the third quarter of 2006. The increase primarily was related to the costs of the Phase IIb clinical trial for Tovaxin and stock compensation expense recorded in 2007.

Opexa reported a net loss for the third quarter of 2007 of \$3,924,641, or \$0.59 per share, compared with a net loss for the third quarter of 2006 of \$1,331,557 or \$0.20 per share. The increase in net loss primarily was due to the costs related to the Phase IIb trial for Tovaxin and the loss on impairment of intangible assets offset in part by a reduction in stock-based compensation expense and gain on extinguishment of liability.

The Company had cash and cash equivalents of \$5,844,299 as of September 30, 2007, compared with \$12,019,914 as of December 31, 2006.

Year-to-Date Financial Results

Opexa reported no revenues in the nine months ended September 30, 2007 or in the comparable prior-year period. General and administrative expenses for the nine months ended September 30, 2007 were \$2,557,609, compared to \$5,676,221 for the nine months ended September 30, 2006. The decrease in G&A expenses was primarily due to a decrease in stock compensation expense, 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 \$10,148,930 for the nine months ended September 30, 2007, compared to \$4,407,240 for the nine months ended September 30, 2006. The increase in R&D expenses was primarily due to the costs of conducting the Phase IIb clinical trial for Tovaxin, research and development in support of pre-clinical diabetes stem cell therapies and stock compensation expense recorded in 2007.

Opexa reported a net loss for the nine months ended September 30, 2007 of \$13,212,705 or (\$1.97) per share, compared with a net loss for the nine months ended September 30, 2006 of \$11,777,735, or (\$2.38) per share. The increase in net loss was primarily due to the costs related to the Phase IIb trial for Tovaxin and the loss on impairment of intangible assets offset in part by a reduction in stock-based compensation expense, gain on extinguishment of liability and loss on derivative instruments.

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)
STATEMENTS OF EXPENSES
Three and Nine Months ended September 30, 2007 and 2006 and the
Period from January 22, 2003 (Inception) to September 30, 2007
(unaudited)

	Three Months Ended September 30, 2007	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2007	Nine Months Ended September 30, 2006	Inception through September 30, 2007
Research and development	\$ 3,189,256	\$ 2,113,878	\$ 10,148,930	\$ 4,407,240	\$ 22,577,839
General and administrative	842,079	1,430,507	2,557,609	5,676,221	16,764,078
Depreciation and amortization	463,630	462,098	1,387,106	1,354,873	5,205,929
Loss on impairment of intangible asset	1,139,677	-	1,139,677	-	1,139,677
Loss on disposal of assets	-	2,015	4,034	2,377	486,343
Operating loss	<u>(5,634,642)</u>	<u>(4,008,498)</u>	<u>(15,237,356)</u>	<u>(11,440,711)</u>	<u>(46,173,866)</u>
Interest income	102,292	259,141	423,086	477,547	1,199,307
Other income	-	-	-	46,450	77,003
Gain on extinguishment of debt	1,612,440	-	1,612,440	-	1,612,440
Gain (loss) on derivative liability	-	2,418,078	-	(860,130)	-
Interest expense	(4,731)	(278)	(10,875)	(891)	(8,249,838)
Net loss	<u><u>\$ (3,924,641)</u></u>	<u><u>\$ (1,331,557)</u></u>	<u><u>\$ (13,212,705)</u></u>	<u><u>\$ (11,777,735)</u></u>	<u><u>\$ (51,534,954)</u></u>
Basic and diluted loss per share	\$ (0.59)	\$ (0.20)	\$ (1.97)	\$ (2.38)	N/A
Weighted average shares outstanding	6,696,784	6,696,784	6,696,784	4,950,862	N/A

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

	<u>September 30, 2007</u>	<u>December 31, 2006</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,844,299	\$ 12,019,914
Investment in marketable securities	-	2,952,096
Other current assets	<u>385,717</u>	<u>472,881</u>
Total current assets	6,230,016	15,444,891
Intangible assets, net accumulated amortization of \$4,771,303 and \$3,533,568, respectively	22,345,791	24,723,203
Property & equipment, net accumulated depreciation of \$532,585 and \$395,284, respectively	<u>1,355,753</u>	<u>1,361,377</u>
Total assets	<u><u>\$ 29,931,560</u></u>	<u><u>\$ 41,529,471</u></u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,226,879	\$ 868,862
Stock payable	-	112,440
Accrued expenses	791,134	135,069
Note payable	-	1,500,000
Current maturity of loan payable	59,224	14,080
Derivative liability	<u>-</u>	<u>6,656,677</u>
Total current liabilities	2,077,237	9,287,128
Long term liabilities:		
Loan payable	<u>177,339</u>	<u>96,242</u>
Total liabilities	<u><u>2,254,576</u></u>	<u><u>9,383,370</u></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	75,863,587	63,118,180
Deficit accumulated during the development stage	<u>(51,534,954)</u>	<u>(34,320,430)</u>
Total stockholders' equity	<u>27,676,984</u>	<u>32,146,101</u>
Total liabilities and stockholders' equity	<u><u>\$ 29,931,560</u></u>	<u><u>\$ 41,529,471</u></u>

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