

OPEXA THERAPEUTICS, INC.

FORM 8-K

(Current report filing)

Filed 03/18/08 for the Period Ending 03/18/08

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
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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): **March 18, 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 March 18, 2008 Registrant filed its Annual Report on Form 10-K for the fiscal year ended December 31, 2007. On March 18, 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 March 18, 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/ DAVID B. MCWILLIAMS
David B. McWilliams
President and Chief Executive Officer

DATE: March 18, 2008

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued March 18, 2008

Opexa Therapeutics Reports Year End 2007 Financial Results

Conference Call Scheduled for March 25th at 4:00 p.m. Eastern Time

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 year ended December 31, 2007 and provided an update on its progress.

Recent Highlights include:

- Completed dosing in the Tovaxin® I Ib clinical trial with expected topline results 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;
- 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; and
- Progress was made in our adult monocyte-derived stem cell program. Preclinical animal studies using pancreatic endocrine cell clusters known as monocyte-derived islets (MDIs) demonstrated that MDIs generated from monocyte-derived stem cells (MDSCs) function in a glucose responsive manner when transplanted into diabetic animals.

David McWilliams, chief executive officer of Opexa, commented, “We have made progress in advancing our clinical program for Tovaxin for the treatment of MS. I am pleased at how efficiently we have managed this trial. The high interest among MS patients in a potentially paradigm shifting therapy encouraged rapid enrollment and resulted in excellent patient compliance. We look forward to reporting topline results in September. McWilliams continued, “In addition, we are encouraged by the preclinical results in our stem cell program to treat Type I and Type II diabetes and believe it provides another significant opportunity for us.”

“On the financial front, the public financing we recently completed provides adequate cash to fund operations into early fourth quarter of 2008 which supports the completion of our Phase I Ib trial,” McWilliams added.

Year Ended December 31, 2007 Financial Results

Opexa reported no revenues in the year ended December 31, 2007 or in the comparable prior-year period.

Research and development expenses were \$13,071,856 for 2007, compared with \$7,850,373 for 2006. The increase was primarily due to the costs of the Phase IIb clinical trial for Tovaxin and an increase in stock compensation expense recorded in 2007.

General and administrative expenses for 2007 were \$3,418,306 compared with \$5,461,047 for 2006. The decrease was due to a combination of factors including a decrease in stock compensation expenses, professional service fees and overhead expenses in 2007.

Interest expense was \$16,103 for 2007, compared with \$984 for 2006. The increase in interest expense was primarily due to a loan payable consisting of an equipment line.

Interest income was \$477,605 for 2007, compared with \$688,299 for 2006. The decrease was due to the reduction in cash balances that were available for investment in cash equivalent investments.

Gain on derivative liability was \$-0- for 2007, compared with a gain of \$104,978 for 2006.

Gain on Extinguishment of Debt was \$1,612,440 for 2007, compared with a gain of \$-0- for 2006.

Opexa reported a net loss for the year ended December 31, 2007 of \$14,667,367, or (\$2.19) per share, compared with a net loss for the year ended December 31, 2006 of \$12,649,170, or (\$2.35) per share.

Cash and cash equivalents and investments in marketable securities were \$2,645,482 as of December 31, 2007 compared to \$14,972,010 as of December 31, 2006. The 2006 year-end cash balance included gross proceeds of \$23.0 million raised through the sale of the Company's common stock.

Conference Call Information

Opexa will host a conference call on Tuesday, March 25 at 4:00 p.m. ET, to discuss 2007 financial results, the 2008 operating plan and an update of the clinical development programs. You may access the call either through the call-in number below or through the audio webcast. The access number for the call is:

Number: (612) 332-0418

Passcode: 915804

This call is being webcast and can be accessed through the Investors page on Opexa's web site at www.opexatherapeutics.com and will be available on the Company's web site through April 25, 2008.

Additionally, a replay of the call will be available until Tuesday, April 1, 2008 at 11:59 p.m. ET. The call replay can be accessed by calling:

Domestic Number: Access Code: (800) 475-6701

International Number: Access Code: (320) 365-3844

Passcode: 915804

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)
STATEMENTS OF EXPENSES

	Twelve Months Ended December 31,	
	2007	2006
Research and development	\$ 13,071,856	\$ 7,850,373
General and administrative	3,418,306	5,461,047
Depreciation	232,955	174,117
Loss on disposal of assets	13,192	2,376
Operating loss	(16,736,309)	(13,487,913)
Interest income	477,605	688,299
Other income and expense, net	(5,000)	46,450
Gain on derivative liability	—	104,978
Gain on extinguishment of debt	1,612,440	—
Interest expense	(16,103)	(984)
Net loss	\$ (14,667,367)	\$ (12,649,170)
Basic and diluted loss per share	\$ (2.19)	\$ (2.35)
Weighted average shares outstanding	6,696,784	5,390,910

Selected Balance Sheet Data:

	2007	2006
Cash, cash equivalents and investments	\$ 2,645,482	\$ 14,972,010
Other current assets	355,266	472,881
Fixed assets (net)	1,370,647	1,361,377
Total assets	4,371,395	16,806,268
Total current liabilities	2,075,354	9,287,128
Total long term liabilities	162,456	96,242
Total stockholders' equity	2,133,585	7,422,898

CONTACT:

Opexa Therapeutics, Inc.
Lynne Hohlfeld, 281-719-3421
lhohlfeld@opexatherapeutics.com