

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 11/13/06 for the Period Ending 11/13/06

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): **November 13, 2006**

Opexa Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

(Formerly PharmaFrontiers Corp.)

Texas

(State or Other Jurisdiction of Incorporation)

000-25513

(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))
-

Item 2.02. Results of Operations and Financial Condition.

On November 13, 2006 Registrant filed its Quarterly Report on Form 10-QSB for the quarter ended September 30, 2006. On November 13, 2006, 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 13, 2006

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, Chief Executive Officer

DATE: November 13, 2006

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued November 13, 2006



OPEXA THERAPEUTICS

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OPEXA REPORTS THIRD QUARTER FINANCIAL RESULTS

THE WOODLANDS, Texas (November 13, 2006) - Opexa Therapeutics, Inc. (NASDAQ:OPXA), a company involved in the development and commercialization of cell therapies, today reported financial results for the three and nine months ended September 30, 2006. Highlights of the third quarter of 2006 and recent weeks include:

- Commenced Phase IIb Multiple Sclerosis trial for Tovaxin™; first patient dosed
- Reported positive data from Phase I/II Tovaxin trial -- patients exhibited a relapse rate reduction of more than 90%
- Listed on NASDAQ Global Market
- Initiated animal studies to test whether the Company's proprietary adult human monocyte-derived pancreatic-like islet clusters are effective therapy for the diabetes mellitus indication.

David McWilliams, chief executive officer, stated, "We have achieved several crucial milestones during this quarter that greatly enhanced both our investor profile and our clinical program. We made our NASDAQ debut in September, which was a long-standing corporate goal. In addition, we treated the first multiple sclerosis patient with Tovaxin in our Phase IIb trial. The data we reported from our Phase I/II trial were outstanding and we hope to replicate the impressive reduction in relapse rate in our Phase IIb trial. We expect to announce results from this trial in the first half of 2008."

Third Quarter Financial Results

Opexa reported no revenues for the three months ended September 30, 2006 or in the comparable prior-year period. General and administrative expenses in the third quarter of 2006 were \$1,430,507, compared with \$2,324,228 in the third quarter of 2005. The decrease is due primarily to the decrease in non-cash stock-based compensation expense in the 2006 period. On January 1, 2006 Opexa adopted Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R"), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including stock options and restricted stock based on estimated fair values. The Company elected to adopt the modified prospective transition method as provided by SFAS 123R and, accordingly, prior-year results have not been restated.

Research and development expenses were \$2,113,878 in the 2006 third quarter, compared with \$622,311 in the 2005 third quarter. The increase primarily was related to the initiation of the Phase IIb clinical trial, and a higher allocation of facilities and overhead costs to research and development due to increased development activities.

Interest expense was \$278 in the third quarter of 2006, compared with \$1,385,234 in the prior year. Interest expense in the 2005 quarter was due to notes payable that were then outstanding, which subsequently were converted into equity in June 2005, resulting in acceleration of the amortization of the discount related to the notes.

Interest income was \$259,141 in the third quarter of 2006, compared with \$31,565 in the prior year. The increase was due to the investment of the cash proceeds from the April 2006 offering in cash equivalent investments.

The Company recognized a gain on derivative instruments of \$2,418,078 in the quarter. This gain was a result of the net unrealized (non-cash) change in the fair value of derivative instrument liabilities related to certain warrants.

Opexa reported a net loss for the third quarter of 2006 of \$1,331,557, or \$0.20 per share, compared with a net loss for the third quarter of 2005 of \$4,726,848 or \$2.31 per share. The decrease in net loss primarily was due to the decrease in non-cash stock-based compensation expense and interest expense and the gain on derivative instruments.

The Company had cash and cash equivalents of \$17,327,320 as of September 30, 2006, compared with \$2,560,666 as of December 31, 2005. In April 2006 the Company raised approximately \$23.0 million in gross proceeds through a private placement of units to institutional and other accredited investors.

Year-to-Date Financial Results

Opexa reported no revenues in the nine months ended September 30, 2006 or in the comparable prior-year period. General and administrative expenses for the first nine months of 2006 were \$5,676,221, compared with \$5,789,973 for the first nine months of 2005. The decrease is due primarily to the decrease in non-cash stock-based compensation expense in the 2006 period.

Research and development expenses were \$4,407,240 for the first nine months of 2006, compared with \$1,877,787 for the first nine months of 2005. The increase primarily was related to the initiation of the Phase IIB clinical trial, and a higher allocation of facilities and overhead costs to research and development due to increased development activities.

Interest expense was \$891 for the first nine months of 2006, compared with \$7,323,573 for the first nine months of 2005. Interest expense in the 2005 period was due to notes payable that were then outstanding, which subsequently were converted into equity in June 2005 resulting in acceleration of the amortization of the discount related to the notes.

Interest income was \$477,547 for the first nine months of 2006, compared with \$50,474 for the first nine months of 2005. The increase was due to the investment of the cash proceeds from the April 2006 offering in cash equivalent investments.

Opexa reported a net loss for the first nine months of 2006 of \$11,777,735, or \$2.38 per share, compared with a net loss for the first nine months of 2005 of \$16,221,894, or \$11.61 per share. The decrease in net loss primarily is due to the decrease in non-cash stock-based compensation expense and interest expense and the gain 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 type 1 diabetes. For more information, visit the Opexa Therapeutics website at www.opexatherapeutics.com.

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)
(formerly PharmaFrontiers Corp.)
CONSOLIDATED BALANCE SHEETS
(unaudited)

	September 30,	December 31,
	2006	2005
Assets		
Current assets:		
Cash and cash equivalents	\$ 17,327,320	\$ 2,560,666
Other current assets	519,221	182,524
Total current assets	17,846,541	2,743,190
Intangible assets, net of \$3,121,293 and \$1,888,891 of accumulated amortization	25,135,478	26,130,441
Property & equipment, net of \$343,635 and \$256,082 of accumulated depreciation	1,281,446	479,996
Other assets	-	388,210
Total assets	<u>\$ 44,263,465</u>	<u>\$ 29,741,837</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,070,577	\$ 689,467
Stock payable	112,440	-
Accrued expenses	202,890	240,309
Note payable	1,500,000	1,500,000
Derivative liability	7,621,785	6,761,655
Total current liabilities	10,507,692	9,191,431
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 and 2,061,955 shares issued and outstanding	3,348,351	1,030,977
Additional paid in capital	62,449,180	39,783,452
Deficit accumulated during the development stage	(32,041,758)	(20,264,023)
Total stockholders' equity	33,755,773	20,550,406
Total liabilities and stockholders' equity	<u>\$ 44,263,465</u>	<u>\$ 29,741,837</u>

OPEXA THERAPEUTICS, INC.
(a development stage company)
(formerly PharmaFrontiers Corp.)
CONSOLIDATED STATEMENTS OF EXPENSES
Three and Nine Months ended September 30, 2006 and 2005 and the
Period from January 22, 2003 (Inception) to September 30, 2006
(unaudited)

	Three Months Ended September 30, 2006	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2006	Nine Months Ended September 30, 2005	Inception through September 30, 2006
General and administrative	\$ 1,430,507	\$ 2,324,228	\$ 5,676,221	\$ 5,789,973	\$ 6,879,734
Depreciation and amortization	462,098	438,598	1,354,873	1,302,642	3,354,901
Research and development	2,113,878	622,311	4,407,240	1,877,787	16,765,127
Loss on disposal of assets	2,015	-	2,377	-	482,309
Operating loss	(4,008,498)	(3,385,137)	(11,440,711)	(8,970,402)	(27,482,071)
Interest income	259,141	31,565	477,547	50,474	565,469
Other income	-	11,958	46,450	21,903	77,003
Gain (loss) on derivative liability	2,418,078	-	(860,130)	-	3,036,711
Interest expense	(278)	(1,385,234)	(891)	(7,323,573)	(8,238,870)
Other expense	-	-	-	(296)	-
Net loss	<u>\$ (1,331,557)</u>	<u>\$ (4,726,848)</u>	<u>\$ (11,777,735)</u>	<u>\$ (16,221,894)</u>	<u>\$ (32,041,758)</u>
Basic and diluted loss per share	\$ (0.20)	\$ (2.31)	\$ (2.38)	\$ (11.61)	N/A
Weighted average shares outstanding	6,696,784	2,048,283	4,950,862	1,397,332	N/A

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