

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 08/14/06 for the Period Ending 08/14/06

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.

FORM 8-K (Current report filing)

Filed 8/14/2006 For Period Ending 8/14/2006

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Telephone	(281) 272-9331
CIK	0001069308
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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): August 14, 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)

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))

Item 8.01. Other Events.

On August 14, 2006 Registrant filed its Quarterly Report on Form 10-QSB for the quarter ended June 30, 2006. On August 14, 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:

Exhibit No. -----	Description -----
99.1	Press release issued August 14, 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: August 14, 2006

EXHIBIT INDEX

Exhibit No. -----	Description -----
99.1	Press release issued August 14, 2006

Opexa Reports Second Quarter Financial Results

THE WOODLANDS, Texas--(BUSINESS WIRE)--Aug. 14, 2006--Opexa Therapeutics, Inc. (OTCBB:OPXA), a company involved in the development and commercialization of cell therapies, today reported financial results for the three and six months ended June 30, 2006. Highlights of the second quarter of 2006 include:

- Changed corporate name to Opexa Therapeutics, Inc., and OTC/BB trading symbol to "OPXA"
- Raised gross proceeds of \$23 million in a private placement
- Effected a 1-for-10 reverse stock split in preparation for application to Nasdaq for a listing
- Initiated Phase IIb clinical trial with Tovaxin(TM) for the treatment of multiple sclerosis (MS)
- Named Lynne Hohlfeld as chief financial officer
- Appointed Michael S. Richmond, Gregory H. Bailey, M.D., David Hung, M.D. and Scott B. Seaman to the board of directors

Commenting on the quarter, David B. McWilliams, chief executive officer of Opexa, stated, "This has been a very dynamic and rewarding time for Opexa. We implemented an important capital restructuring and name change during the quarter, and completed a \$23 million financing that provides the financial underpinnings for our Phase IIb trial with Tovaxin and funds our other business activities. We also strengthened our corporate governance with the addition of four new directors, each of whom brings a valuable skill set and perspective to Opexa." He added, "On the clinical front, we achieved a very significant milestone with the initiation of our randomized, placebo-controlled Phase IIb trial to evaluate the effectiveness of our T cell-based therapeutic vaccine, Tovaxin, for treating MS. We believe that Tovaxin attacks the underlying cause of MS and has advantages over existing treatments for the disease, including lower relapse rates, quick onset of action, minimal side effects, less frequent injections and reduced patient fatigue."

Second Quarter Financial Results

Opexa reported no revenues for the three months ended June 30, 2006 or in the comparable prior-year period. General and administrative expenses in the second quarter of 2006 were \$3,169,832, compared with \$2,677,941 in the second quarter of 2005. The increase primarily is due to the increase in 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 \$1,554,912 in the 2006 second quarter, compared with \$611,212 in the 2005 second 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 \$184 in the second quarter of 2006, compared with \$4,450,955 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.

The Company recognized a loss on derivative instruments of \$3,532,348 in the quarter. This loss 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 second quarter of 2006 of \$8,475,868, or \$1.40 per share, compared with a net loss for the second quarter of 2005 of \$7,747,740, or \$6.99 per share. The increase in net loss primarily was due to stock-based compensation expense and loss on derivative instruments, offset in part by the decrease in interest expense.

The Company had cash and cash equivalents of \$19,931,542 as of June 30, 2006, compared with \$2,560,666 million as of December 31, 2005. In April 2006 the Company raised approximately \$23 million in gross proceeds through a private placement of units to institutional and other accredited investors.

During the quarter, Lynne Hohlfeld, CPA, was named chief financial officer of Opexa, and Michael S. Richmond, Gregory H. Bailey, M.D., David Hung, M.D., and Scott B. Seaman were appointed to the Company's board of directors.

Year-to-Date Financial Results

Opexa reported no revenues in the six months ended June 30, 2006 or in the comparable prior-year period. General and administrative expenses for the first half of 2006 were \$4,245,714, compared with \$3,465,745 for the first half of 2005.

Opexa reported a net loss for the first half of 2006 of \$10,446,178, or \$2.57 per share, compared with a net loss for the first half of 2005 of \$11,495,046, or \$10.78 per share. The decrease in net loss primarily is due to the decrease in interest expense, partially offset by stock-based compensation expense and the loss on derivative instruments.

About Opexa Therapeutics

Opexa Therapeutics develops and commercializes cell therapies to treat several major disease areas such as MS, rheumatoid arthritis, pancreatic and cardiac conditions. Opexa has exclusive license from Baylor College of Medicine for individualized cell therapies and has initiated a Phase IIb clinical trial to evaluate effectiveness in treating MS. The Company holds the exclusive worldwide license for an autologous T cell vaccine for rheumatoid arthritis from the Shanghai Institutes for Biological Sciences, Chinese Academy of Sciences of the People's Republic of China. Opexa also holds the exclusive worldwide license from the University of Chicago, through its prime contractor relationship with Argonne National Laboratory, for patents relating to the use of adult pluripotent stem cells derived from patients' own circulating blood. 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.

OPEXA THERAPEUTICS, INC.

(formerly PharmaFrontiers Corp.)

(a development stage company)

CONSOLIDATED BALANCE SHEETS

(unaudited)

	June 30, 2006	December 31, 2005
	-----	-----
Assets		
Current assets:		
Cash and cash equivalents	\$19,931,542	\$2,560,666
Other current assets	514,596	182,524
	-----	-----
Total current assets	20,446,138	2,743,190
	-----	-----
Intangible assets, net of \$2,709,019 and \$1,888,891 of accumulated amortization	25,547,752	26,130,441
Property & equipment, net of \$327,897 and \$256,082 of accumulated depreciation	1,262,048	479,996
Other assets	-	388,210
	-----	-----
Total assets	\$47,255,938	\$29,741,837
	=====	=====
Liabilities and Stockholder's Equity		
Current liabilities:		
Accounts payable	\$682,841	\$689,467
Stock payable	112,440	-
Accrued expenses	643,088	240,309
Note payable	1,500,000	1,500,000
Derivative liability	10,039,863	6,761,655
	-----	-----
Total current liabilities	12,978,232	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	61,639,556	39,783,452
Deficit accumulated during the development stage	(30,710,201)	(20,264,023)
	-----	-----
Total stockholders' equity	34,277,706	20,550,406

Total liabilities and stockholders' equity	\$47,255,938	\$29,741,837
	=====	=====

OPEXA THERAPEUTICS, INC.
(a development stage company)

CONSOLIDATED STATEMENTS OF EXPENSES

Three and Six Months ended June 30, 2006 and 2005 and the Period from January 22, 2003 (Inception) to June 30, 2006

(unaudited)

	Three Months Ended June 30, 2006	Three Months Ended June 30, 2005
General and administrative	\$3,169,832	\$2,677,941
Depreciation and amortization	460,442	26,816
Research and development	1,554,912	611,212
Loss on disposal of assets	-	-
Operating loss	(5,185,186)	(3,315,969)
Interest income	198,785	11,979
Other income	43,065	7,501
Gain (loss) on derivative liability	(3,532,348)	-
Interest expense	(184)	(4,450,955)
Other expense	-	(296)
Net loss	\$(8,475,868)	\$(7,747,740)
Basic and diluted loss per share	\$(1.40)	\$(6.99)
Weighted average shares outstanding	6,039,561	1,108,215

	Six Months Ended June 30, 2006	Six Months Ended June 30, 2005	Inception through June 30, 2006
General and administrative	\$4,245,714	\$3,465,745	\$5,449,227
Depreciation and amortization	892,775	864,044	2,892,803
Research and development	2,293,362	1,255,476	14,651,249
Loss on disposal of assets	362	-	480,294
Operating loss	(7,432,213)	(5,585,265)	(23,473,573)
Interest income	218,406	18,909	306,328
Other income	46,450	9,945	77,003
Gain (loss) on derivative liability	(3,278,208)	-	618,633
Interest expense	(613)	(5,938,339)	(8,238,592)
Other expense	-	(296)	-
Net loss	\$(10,446,178)	\$(11,495,046)	\$(30,710,201)
Basic and diluted loss per share	\$(2.57)	\$(10.78)	N/A
Weighted average shares outstanding	4,063,473	1,066,461	N/A

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