

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 08/16/05 for the Period Ending 08/16/05

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
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CIK	0001069308
Symbol	OPXA
SIC Code	2834 - Pharmaceutical Preparations
Fiscal Year	12/31

PHARMAFRONTIERS CORP

FORM 8-K

(Unscheduled Material Events)

Filed 8/16/2005 For Period Ending 8/16/2005

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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 16, 2005

PharmaFrontiers Corp.

(Exact Name of Registrant as Specified in Its Charter)

Texas

(State or Other Jurisdiction of Incorporation)

000-25513

(Commission File Number)

76-0333165

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

2408 Timberloch Place, Suite B-7
The Woodlands, Texas

(Address of Principal Executive Offices)

77380

(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 15, 2005, Registrant filed its Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005. On August 16, 2005, 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 16, 2005

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.

PHARMAFRONTIERS CORP.

By: /s/ David B. McWilliams

David B. McWilliams, Chief Executive Officer

DATE: August 16, 2005

PharmaFrontiers Reports Second Quarter 2005 Financial Results; Provides Research Update

THE WOODLANDS, Texas--(BUSINESS WIRE)--Aug. 16, 2005--PharmaFrontiers Corp. (OTCBB:PFTR), a company involved in the development and commercialization of cell therapies, today provides an update on its research programs and future plans. In addition, the Company reports financial results for the three and six months ended June 30, 2005.

Highlights of the second quarter of 2005 (April through June) include:

- Positive interim results announced from two Phase I/II Multiple Sclerosis trials with Tovaxin(TM);
- Clinical Plans presented at the 19th Annual Meeting of the Centers of Multiple Sclerosis Centers in Orlando, Florida in June;
- INC Research, Inc., a global CRO, selected as development partner for Tovaxin;
- Financing of \$5.08 million completed;
- Four new members added to Scientific Advisory Board.

Research and Development

During the quarter, PharmaFrontiers announced interim results from its two Phase I/II trials for Multiple Sclerosis using its drug, Tovaxin. The studies indicated that the drug was safe and well-tolerated and also concluded that Myelin-Peptide Reactive T Cells (MRTCs) in patients with Multiple Sclerosis can be depleted by Tovaxin treatment. Multiple Sclerosis Impact Scale (MSIS) and Kurtzke Expanded Disability Status Scale (ECSS) clinical measures were improved.

Commenting on recent events, David B. McWilliams, chief executive officer of PharmaFrontiers, said, "Our Tovaxin program is progressing very well. Our interim data showed that the drug is well tolerated and demonstrated improvement in patients. We believe this is significant because Multiple Sclerosis is a disease for which current therapies are limited, and often cause extremely unpleasant side effects. New therapies with benign profiles like Tovaxin are urgently needed; this is supported by the fact that after our presentation at the Annual Meeting of the Centers of Multiple Sclerosis Centers in June, we had strong interest from 15 centers to participate in our trials. Our clinical development program is advancing as planned and we will be presenting our data at the 21st Congress of the European Committee/10th Annual Meeting of the Americas Committee for Treatment and Research in Multiple Sclerosis. The meeting will be held in Greece from September 28 through October 1, 2005. We then plan to begin our Phase IIb/III clinical trials in late 2005 or early 2006." Mr. McWilliams also described recent progress in PharmaFrontiers' stem cell program, which the Company believes may provide the basis for therapies to treat a variety of diseases and conditions such as diabetes and congestive heart failure. "We are currently in the process of refining our operations for maximum efficiency and productivity. We have cut our processing time from two to three weeks down to just seven to ten days. In addition, we are producing consistently high yields of stem cells from blood. We believe that we will produce 50 million stem cells per 500 mls of blood. Now that these operating efficiencies have been implemented, we plan to initiate animal studies shortly." During the quarter, the Company formed a strategic relationship with INC Research, Inc., a global contract research organization (CRO), to develop Tovaxin. INC Research specializes in diseases of the central nervous system.

To support and advise on its research efforts, during the quarter, PharmaFrontiers appointed four new members to its scientific advisory board. They are: Eliezer Huberman, Ph.D., director of Biological & Biotechnological Research at the Argonne National Laboratory and PharmaFrontiers' SAB chairman; Norman Barton, M.D., Ph.D., executive vice president and chief medical officer of CepTor Corporation; Daniel R. Marshak, Ph.D., senior vice president - research and development, and chief technology officer for Cambrex; and Shelly Heimfeld, Ph.D., director of the Stem Cell Program at Fred Hutchinson Cancer Research Center in Seattle, Washington. Dr. Jingwu Zhang, professor of Neurology and Immunology at Baylor College of Medicine and Scientific Director of the Baylor-Methodist Multiple Sclerosis Center in Houston continues to serve as a member of the SAB.

Financial Results

The Company's financial statements compare the three and six months ended June 30, 2005 with results from its inception through June 30, 2004.

The Company reported no revenue for the three and six months ended June 30, 2005 or in its comparative period. General and administrative expenses during the three and six months ended June 30, 2005 were \$2.7 million and \$4.3 million, respectively, compared with \$0.5 million and \$1.1 million during the same periods in 2004. The increase in general and administrative expenses is due primarily to the start-up of operations, which included the hiring of new personnel including employees and consulting fees to directors and scientific advisory board members. The increase in operations is also attributable to the acquisition of Opexa Pharmaceuticals and the assumption of its operations. Also included are professional fees including legal, accounting and other consulting services.

Research and development expense was \$.6 million and \$1.3 million for the three and six months of 2005, respectively, compared with no expenses for the same periods in 2004. The increase is primarily related to the acquisition of Opexa Pharmaceuticals and the assumption of its operations and research and development programs, including its ongoing Phase I/II clinical trial for Tovaxin as well as the beginning of the pre-clinical studies for the cardiac and diabetes stem cell therapies. Also included are professional fees incurred from consulting services and legal fees to secure and expand license patent claims.

Interest expense was \$4.5 million and \$5.9 million, respectively, for the three and six months ended June 30, 2005, compared with \$.12 million and \$.15 million during the same periods in 2004. The increase is mostly due to the amortization of the remaining discount under the beneficial

conversion feature of the Company's Bridge Notes and the accrued interest on the Bridge Notes that was converted into shares of Common Stock.

PharmaFrontiers had a net loss for the three and six months of 2005 of (\$7.7 million) and \$(11.5 million) or (\$0.70) and (\$1.08) per share (basic and diluted), compared with a net loss of (\$.7 million) and (\$1.2 million) or (0.11) or (\$.24) per share (basic and diluted) for the same periods in 2004.

The Company had cash of \$5.1 million on June 30, 2005, having completed a private placement of equity, which raised \$5.18 million during the quarter. Subsequent to the close of the quarter, the Company raised an additional \$.8 million through the sale of equity.

About PharmaFrontiers Corp.

PharmaFrontiers' strategy is to develop and commercialize cell therapies to treat several major disease areas such as cardiac and pancreatic conditions and Multiple Sclerosis. The company 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. PharmaFrontiers also owns patented and proprietary individualized cell therapies that are in FDA Phase I/II human dose ranging clinical trials to evaluate their safety and effectiveness in treating MS.

Safe Harbor Statement

This press release contains "forward-looking statements," including statements about PharmaFrontiers' 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 PharmaFrontiers' ability to obtain additional funding, develop its stem cell technologies, achieve its operational objectives, and obtain patent protection for its discoveries, that may cause PharmaFrontiers' actual results to be materially different from any future results expressed or implied by such forward-looking statements. PharmaFrontiers undertakes no obligation to update or revise any such forward-looking statements, whether as a result of new information, future events or otherwise.

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