OPEXA THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

Filed 06/03/05 for the Period Ending 06/03/05

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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 6/3/2005 For Period Ending 6/3/2005

Address	2408 TIMBERLOCH PLACE, SUITE B-7
	THE WOODLANDS, Texas 77380
Telephone	(281)272-9331
CIK	0001069308
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): June 3, 2005

PharmaFrontiers Corp.
(Exact Name of Registrant as Specified in Its Charter)

Texas		
(State or Other Jurisdiction of Incorporation)		
000-25513		76-0333165
(Commission File Number)		(I.R.S. Employer Identification No.)
2408 Timberloch Place, Suite B-7 The Woodlands, Texas		77380
(Address of Principal Executive Offices)		(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 June 3, 2005, Registrant announced interim results of two Phase I/II clinical trials for Multiple Sclerosis 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 exhibits are to be filed as part of this 8-K:

Exhibit No.	Description
99.1	Press release issued June 3, 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 McWilliams
David McWilliams, Chief Executive Officer

DATE: June 3, 2005

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued June 3, 2005.

Exhibit 99.1

PharmaFrontiers Announces Positive Interim Results of Two Phase I/II Clinical Trials for Multiple Sclerosis

THE WOODLANDS, Texas--(BUSINESS WIRE)--June 3, 2005--PharmaFrontiers Corp. (OTCBB:PFTR), a company involved in the development and commercialization of cell therapies, announced that interim results of Tovaxin(TM) in two Multiple Sclerosis (MS) Phase I/II open-label studies indicated that it was safe and well tolerated, and patients showed positive responses. All patients enrolled in the studies had received prior standard of care therapy for MS and were in the relapsing remitting or secondary progressive stages of MS.

Tovaxin(TM) is a trivalent formulation of attenuated myelin-peptide reactive T cells (MRTCs), which are derived from peripheral blood and produced ex vivo as myelin basic protein (MBP), proteolipid protein (PLP) and myelin oligodendrocyte glycoprotein (MOG) reactive T cells.

An interim analysis of a Phase I/II dose-escalation study of six evaluable patients, half of whom received a low dose (six to nine million MRTCs) and the other half received a mid dose (30-45 million MRTCs) during the six-month evaluable period, indicated that the Tovaxin(TM) therapy reduces peripheral blood MRTC levels in concert with improvements in disability scores Kurtzke Expanded Disability Status Scale (EDSS) as well as in disability neurological assessments for psychological scores Multiple Sclerosis 29 point Impact Scale (MSIS-29). The exacerbation rate over the previous two years for the patients was 1.18 per year. Only one treated patient reported an exacerbation during the six-month evaluable period in this study. All of the related adverse events were mild or moderate in severity.

An interim analysis of a Phase I/II extension study of nine evaluable patients, who received two doses (30-45 million MRTCs) during the six-month evaluable period, indicated a mean percent reduction in MRTCs observed at three and six months for all three categories of MRTCs. A statistically significant percent (greater than minus 60%) reduction in PLP T cells was observed at three and six months. There was a percentage reduction (greater than or equal to minus 21%) in MBP and MOG T cells at three and six months. Percentage reductions in the EDSS and MSIS-29 physiological scores from baseline were observed at the three and six-month follow-up visits. The exacerbation rate over the previous two years for the patients was 0.85 per year. There were no exacerbations during the six-month evaluable period in this study. The most common adverse event was injection site pain, reported by four patients. Adverse events reported by two patients included muscle weakness, abnormal vision, anorexia, pharyngitis / nasopharyngitis, neuropathy and paresthesia. All of the related adverse events were mild or moderate in severity.

"We are very encouraged by these preliminary MRTC levels, which demonstrated a dose response and large mean percentage reductions from baseline at follow-up visits during the six-month period," said David B. McWilliams, chief executive officer of PharmaFrontiers. "Accordingly, we plan on beginning our Phase IIb/III clinical trials by the end of 2005 or early 2006." The Company's preliminary results and clinical development plans will be discussed at a June 4 luncheon at the 19th Annual Meeting of the Consortium of Multiple Sclerosis Centers in Orlando, FL.

"These data, combined with the strong safety profile of Tovaxin(TM), should be welcome news to all MS patients and their families, especially in light of disappointing product news of this past year," Mr. McWilliams added.

About PharmaFrontiers Corporation

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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End of Filing