

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 04/15/05 for the Period Ending 04/15/05

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 4/15/2005 For Period Ending 4/15/2005

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): April 15, 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 April 15, 2005, Registrant filed its Annual Report on Form 10-KSB for the fiscal year ended December 31, 2004 and 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 exhibits are to be filed as part of this 8-K:

Exhibit No. -----	Description -----
99.1	Press release issued April 15, 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: April 15, 2005

EXHIBIT INDEX

Exhibit No. -----	Description -----
99.1	Press release issued April 15, 2005.

PharmaFrontiers Provides Update, Financial Results

THE WOODLANDS, Texas--(BUSINESS WIRE)--April 15, 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 12 months ended December 31, 2004.

Research and Development

"We began our journey as a public company during May 2004 with the completion of a reverse merger into a public shell, and strengthened our pipeline of potential therapies for the treatment of several debilitating diseases," said David B. McWilliams, president and chief executive officer of PharmaFrontiers.

In November 2004, the Company acquired Opexa Pharmaceuticals, which held the rights to Tovaxin(TM), a novel autologous therapeutic T cell treatment for multiple sclerosis. Tovaxin(TM) has considerable potential because it attacks the underlying cause of MS rather than just addressing its symptoms. Rights to Tovaxin(TM) originally were obtained under an exclusive, worldwide license from the Baylor College of Medicine in Houston, Texas.

Tovaxin is currently being studied in two Phase I/II clinical trials. Patients have been enrolled in the first trial, which is an extension study of patients previously treated with a first-generation formulation of the therapy. These patients showed clinical benefit in an earlier T cell therapy study conducted at Baylor College of Medicine and are now being examined to determine if they can be safely and effectively re-treated with a second-generation T cell therapy. The first cohort of ten patients have received two-doses of the new formulation of Tovaxin. PharmaFrontiers anticipates that six-month results evaluating safety, tolerability and efficacy will be available in the third quarter of 2005.

The second Phase I/II clinical trial is a dose-escalating study with Tovaxin. The study is designed to evaluate safety, tolerability and efficacy in at least 9 but not more than 15 patients. Six patients have completed the initial four-dose injection schedule; the first group of three patients received a low-dosage level, the second group of three patients received a mid-dosage level and a third group of three is to receive a high-dosage level. One-year clinical results for the low and mid dose groups are expected to be available by the third quarter of 2005.

"We believe that Tovaxin has advantages over existing treatments for multiple sclerosis, which afflicts 400,000 individuals in the U.S. alone," continued Mr. McWilliams. "This is true 'designer medicine', because we make use of an individual's own T cells to manufacture the therapy. Tovaxin seems easier to tolerate, has the potential to place the disease into remission, and possibly reverse the effects. We are looking forward to submitting data from these trials to the U.S. Food and Drug Administration by the end of 2005 to request approval to begin a pivotal Phase IIb study."

PharmaFrontiers continues to advance its pre-clinical research in stem cell technology for the treatment of heart failure and Type I diabetes. Its technology, licensed through its relationship with Argonne National Laboratories from the University of Chicago, permits the creation of adult pluripotent stem cells from monocytes isolated from patients' own blood.

"Our stem cell technology avoids the emotional issues connected with embryonic stem cell research, while from a clinical perspective our technology is inexpensive, it is easy to obtain, and it avoids the rejection associated with transplants, " Mr. McWilliams went on to say. "We hope to be able to initiate human tests of our cardiac and diabetes stem cell therapy some time in 2006. We also recognize the potential use of our technology platform in the treatment of a host of additional diseases, including macular degeneration, stroke and Parkinson's disease."

Financial results

The company reported no revenue for 12 months ended December 31, 2004. General and administrative expenses were \$3.1 million, reflecting the start-up of the company and hiring of key employees. Research and development expenses for the year ended December 31, 2004 were \$0.6 million for PharmaFrontiers. On a pro forma basis for the combined companies, research and development expenses for the year ended December 31, 2004 were \$2.4 million, mainly reflecting the costs of the Phase I/II clinical trials for Tovaxin and pre-clinical cardiac and diabetes stem cell research. Net loss was \$4.6 million in 2004, or \$0.73 cents per basic and diluted share. The company had cash of \$0.9 million at December 31, 2004. Subsequent to the end of the year, PharmaFrontiers completed the second tranche of a total \$6.1 million interim financing in the form of convertible notes, with \$4.5 million closing in February of 2005.

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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