FORM 8-K

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PHARMOS CORP

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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 12, 2004

PHARMOS CORPORATION
(Exact name of Registrant as Specified in its Charter)

Nevada	0-11550	36-3207413
(State or Other Jurisdiction of Incorporation)	(Commission file Number)	(IRS Employer Identification No.)

99 Wood Avenue South, Suite 311, Iselin, New Jersey	08830
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code (732) 452-9556

Item 5. Other Events

On August 12, 2004, Pharmos Corporation ("Pharmos") issued a press release announcing that the U.S. Food and Drug Administration granted orphan drug designation to Pharmos' lead product candidate, dexanabinol, a neuroprotective agent that Pharmos is developing to treat severe traumatic brain injury.

A copy of Pharmos' press release is attached as Exhibit 99.1 and is incorporated herein by reference.

Item 7. Financial Statements and Exhibits

(c)

Exhibits.

99.1 Press Release dated August 12, 2004.

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 on this 12th day of August, 2004.

PHARMOS CORPORATION

By: /s/ James A. Meer

Name: James A. Meer
Title: Vice President,
Chief Financial Officer

EXHIBIT 99.1

[PHARMOS CORPORATION LOGO]
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FOR IMMEDIATE RELEASE

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Pharmos Receives FDA Orphan Drug Designation for Dexanabinol
Prospect of Marketing Exclusivity Benefits Commercialization Strategy

Iselin, NJ, August 12, 2004 - Pharmos Corporation (Nasdaq: PARS) today announced the U.S. Food and Drug Administration (FDA) granted orphan drug designation to the Company's lead product candidate, dexanabinol, a neuroprotective agent that the Company is developing to treat severe traumatic brain injury (TBI). Dexanabinol is currently being tested in a pivotal Phase III trial for this indication. Results of the trial, which completed enrollment (861 patients) in March 2004, are expected to be announced around the end of this year.

The FDA Office of Orphan Products Development (OOPD) administers provisions of the Orphan Drug Act (http://www.fda.gov/orphan/oda.htm) that provide incentives for companies and individuals to develop drug products that treat conditions affecting 200,000 or fewer patients annually in the U.S. and that provide a significant therapeutic advantage over existing treatments. A major benefit of orphan drug designation is the provision of seven years of market exclusivity in the U.S. to the first sponsor that obtains marketing approval in the designated indication. The designation also provides for tax credits relating to research conducted to generate data required for marketing approval, reduced filing fees and preferential pre-filing regulatory guidance.

"We are pleased to be awarded orphan designation for dexanabinol to treat this serious condition for which there is no FDA-approved product," said Haim Aviv, Ph.D., Chairman and CEO. "In addition to benefiting the regulatory submission process, orphan designation provides market exclusivity that adds one more layer of protection beyond our robust intellectual property position for dexanabinol in the treatment of severe TBI."

About TBI

TBI is a leading cause of death and disability in the young adult population, due primarily to automobile accidents, and in the elderly due to falls. According to the CDC, annually within the U.S. there are about 1.5 million head injuries which lead to roughly a quarter million hospital admissions, a number 20 times greater than hospitalizations due to spinal cord injury. TBI is the cause of nearly 52,000 deaths and approximately 80,000 cases of severe long-term disability each year. About 2% of the U.S. population is living with disabilities resulting from TBI which leads to an annual societal burden of over $50 billion (http://www.cdc.gov/node.do/id/0900f3ec8000dbdc). If dexanabinol achieves marketing approval, the Company believes that it will be a high-value

product because amelioration of the high morbidity associated with this condition would have major benefit both to patients' quality of life and to society's financial burden.

About Pharmos

Pharmos discovers, develops, and commercializes novel therapeutics to treat a range of indications, in particular neurological and inflammation-based disorders. The Company's first neuroprotective product is dexanabinol, a tricyclic dextrocannabinoid, currently undergoing clinical testing as a treatment for TBI and as a preventive agent against post-surgical cognitive impairment. Other dextrocannabinoid compounds and CB2-selective receptor agonist compounds from Pharmos' proprietary synthetic

cannabinoid library are being studied in pre-clinical programs targeting stroke, pain, multiple sclerosis and other disorders.

Statements made in this press release related to the business outlook and future financial performance of the Company, to the prospective market penetration of its drug products, to the development and commercialization of the Company's pipeline products and to the Company's expectations in connection with any future event, condition, performance or other matter, are forward-looking and are made pursuant to the safe harbor provisions of the Securities Litigation Reform Act of 1995. Such statements involve risks and uncertainties which may cause results to differ materially from those set forth in these statements. Additional economic, competitive, governmental, technological, marketing and other factors identified in Pharmos' filings with the Securities and Exchange Commission could affect such results.