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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) **November 2, 2004**

**ADVENTRX Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation)

**001-32157**

(Commission File Number)

**84-1318182**

(IRS Employer Identification No.)

**6725 Mesa Ridge Road, Suite 100  
San Diego, California 92121**

(Address of principal executive offices) (Zip Code)

**(858) 552-0866**

(Company's telephone number, including area code)

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Item 8.01. Other Events.

On November 2, 2004, the Company announced certain developments regarding its CoFactor Phase II trial and current plans regarding certain regulatory filings.

The press release issued by the Company on November 2, 2004 with respect to these matters is included with this report as an exhibit.

Item 9.01. Financial Statements and Exhibits.

- (c) The exhibit list required by this item is incorporated by reference to the Exhibit Index filed as part of this report.
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## 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.

**ADVENTRX Pharmaceuticals, Inc.**

**By:** /s/ Steven M. Plumb

**Name:** Steven M. Plumb

**Title:** Chief Financial Officer

November 3, 2004

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EXHIBIT INDEX

Exhibit      Description

99.1            Press Release of the Company dated November 2, 2004.

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## FDA Clears CoFactor™ to Begin Second Stage of Phase II Clinical Trial for Metastatic Colorectal Cancer

**SAN DIEGO - November 2, 2004** - ADVENTRX Pharmaceuticals, Inc. (Amex: ANX) today announced that it has been granted allowance by the Food and Drug Administration (FDA) to begin recruiting patients for the second stage of its Phase II trial using CoFactor™ to modulate the effect of 5-fluorouracil (5-FU) for metastatic colorectal cancer. The Company reported available clinical data to the FDA related to the 23 initial patients recruited as part of the Simon Two-Stage trial design. Based on this submission, the FDA granted the Company authorization to proceed to the second stage of the study and enroll an additional 25 patients.

The Phase II trial of CoFactor is an open-label single arm study to evaluate safety, tumor response, time-to-tumor-progression and overall survival in patients treated with CoFactor and 5-FU. Eligible patients for this study have surgically incurable, metastatic colon or rectal adenocarcinoma, and no prior chemotherapy for metastatic disease.

“We are extremely pleased to receive the go-ahead from the FDA to advance CoFactor to the second stage of the Phase II clinical trial,” said Celia Habita, M.D., Ph.D., Vice President of Clinical and Medical Affairs for ADVENTRX. “At this rate, we currently anticipate completing total patient enrollment by the end of 2004 and reporting results in the spring.”

The Company currently plans to file in 2004 in the European Union and in 2005 in the US for clearance to begin randomized controlled Phase II multicenter metastatic colorectal cancer trials. In addition, the Company currently intends to file with the FDA and the European Medicines Agency (EMA) in the first quarter of 2005 to begin trials for treatment of patients with advanced pancreatic cancer in both the US and EU. In October 2004, the FDA and EMA each granted the Company orphan drug status for CoFactor for the treatment of pancreatic cancer in the US and EU, respectively.

### **About CoFactor**

CoFactor (5,10-methylenetetrahydrofolate) is a biomodulator designed for use with 5-FU, a commonly used cancer drug. CoFactor is the active metabolite of leucovorin that bypasses the chemical pathway required by leucovorin to deliver the correct form of folate to cancer cells, allowing 5-FU to work more effectively. In previous Phase II trials in Europe, CoFactor was administered to metastatic colorectal cancer patients 20 minutes before intravenous administration of 5-FU. In these European trials, CoFactor improved survival and time-to-tumor-progression while lowering toxicity in metastatic colorectal cancer patients.

### **About ADVENTRX**

ADVENTRX Pharmaceuticals, Inc. is a biopharmaceutical research and development company whose business strategy is to commercialize leading edge medical research through licensing agreements with prominent universities and research institutions. The Company focuses on cancer and antiviral research to launch products that either extend the usefulness of current therapies or replace marginal therapies with new approaches to treatment. More information on ADVENTRX can be found on [www.adventrx.com](http://www.adventrx.com).

### **Forward Looking Statement**

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Such statements are made based on management's current expectations and beliefs. Actual results may vary from those currently anticipated based upon a number of factors, including uncertainties inherent in the drug development process, the timing and success of clinical trials, the validity of research results, and

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the receipt of necessary approvals from the United States Food and Drug Administration and other regulatory agencies. The Company undertakes no obligation to release publicly any revisions, which may be made to reflect events or circumstances after the date hereof.

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