# 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) January 25, 2005

#### 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)

# Item 8.01. Other Events.

On January 25, 2005, 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 January 25, 2005 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.

# **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/ Carrie E. Carlander

Name: Carrie E. Carlander

Title: Chief Financial Officer, Vice President, Finance, and Treasurer

January 26, 2005

# EXHIBIT INDEX

**Exhibit** 

<u>Description</u>
Press Release of the Company dated January 25, 2005. 99.1

# ENDPOINTS MET IN FIRST STAGE OF ADVENTRX COFACTOR PHASE II METASTATIC COLORECTAL CANCER STUDY

**Patient Enrollment Completed in Phase II Study** 

SAN DIEGO - January 25, 2005 - ADVENTRX Pharmaceuticals, Inc. (Amex: ANX) today announced that the primary endpoint for response rate and the secondary endpoint for safety were met in the first stage of its Simon two-stage design Phase II trial using CoFactor™ to modulate the effect of 5-fluorouracil (5-FU) in patients with metastatic colorectal cancer. The Company further announced that patient enrollment is complete in this Phase II study. The Company currently expects to announce a complete summary of study results in the second quarter of this year.

The Phase II study, entitled "COFU: a multi-center Phase II clinical trial to evaluate the safety and efficacy of weekly treatment with CoFactor' and 5fluorouracil in patients with metastatic colorectal carcinoma," is an open-label, single-arm study to evaluate safety, tumor response, time-to-tumor progression and overall survival in metastatic colorectal cancer patients treated with CoFactor and 5-FU. A total of 50 patients were recruited for this trial.

"We are pleased with our clinical progress and we currently plan to report summary clinical results from the entire Phase II trial this spring," said Cellia Habita, M.D., Ph.D., ADVENTRX senior vice president of clinical and medical affairs. "We initiated this trial on the strength of earlier Phase I/II results that demonstrated CoFactor administered with 5-FU appeared to show improvement of objective response and time-to-tumor progression and reduced toxic side effects in colorectal, pancreatic, gastric and breast cancers."

"We are encouraged that the first stage of the Phase II clinical trial met both the primary and secondary endpoints," said Evan M. Levine, ADVENTRX president and chief executive officer. "Meeting our stage I endpoints and completing patient enrollment mark additional important milestones in our efforts to move CoFactor through the clinical process. We are currently in the process of applying for additional clinical studies with CoFactor administered in combination with other regimens in metastatic colorectal, advanced pancreatic, and late stage gastric cancers with the goal of filing an NDA in late 2007."

ADVENTRX presently intends to file for clearance in the first quarter of 2005 in both the US and European Union to begin randomized controlled multicenter metastatic colorectal cancer trials with CoFactor and 5-FU as a first-line therapy. The Company also currently intends to file in the EU in the second quarter of 2005 to begin a clinical trial in patients with advanced pancreatic cancer. In October 2004, the Company was granted orphan drug status for CoFactor for the treatment of pancreatic cancer in the US and EU.

#### **About CoFactor**

CoFactor (5.10-methylenetetrahydrofolate) is a biomodulator designed for use with 5-FU, a widely used cancer drug. CoFactor was designed to deliver the active form of folate, allowing 5-FU to work more effectively to kill cancer cells. In previous Phase II trials in Europe, CoFactor was administered to cancer patients 20 minutes before intravenous administration of 5-FU and demonstrated clinical benefit in metastatic colorectal, pancreatic, gastric and breast cancer patients.

#### About ADVENTRX

ADVENTRX Pharmaceuticals, Inc. is a biopharmaceutical research and development company with a business strategy 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. Additional information about ADVENTRX is available at 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 the receipt of necessary approvals from the FDA 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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