**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) **May 13, 2005**

**ADVENTRX Pharmaceuticals, Inc.**
(Exact name of registrant as specified in its charter)

**Delaware**
(State or other jurisdiction of incorporation)

| **001-32157** | **84-1318182** |
|---|---|
| (Commission File Number) | (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 2.02. Results of Operations and Financial Condition.

On May 13, 2005, the Company announced its 2005 First Quarter Financial Results.

The press release issued by the Company on May 13, 2005 with respect to this matter is included with this report as an exhibit.

Item 8.01. Other Events.

On May 13, 2005, the Company announced preliminary Phase II trial results with CoFactor™ in metastatic colorectal cancer.

The press release issued by the Company on May 13, 2005 with respect to this matter is included with this report as an exhibit.

Item 9.01. Financial Statements and Exhibits.

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
May 13, 2005

EXHIBIT INDEX

| Exhibit | Description |
| --- | --- |
| 99.1 | Press Release of the Company dated May 13, 2005. |
| 99.2 | Press Release of the Company dated May 13, 2005. |

**Exhibit 99.1**

**ADVENTRX ANNOUNCES 2005 FIRST QUARTER FINANCIAL RESULTS**

**SAN DIEGO - May 13, 2005 -** ADVENTRX Pharmaceuticals, Inc. (Amex: ANX) today announced financial results for the three months ended March 31, 2005.

For the first quarter of 2005, ADVENTRX reported a net loss of $2.8 million, or $0.05 per share, compared with a net loss of $710,000, or $0.02 per share, for the first quarter of 2004.

“Building on our ability to demonstrate clinical benefit in colorectal and pancreatic cancers, we are moving Co-Factor™ into late-stage trials for both these indications. This year we have received approvals to initiate a US Phase III pivotal trial and a European Union Phase IIb international trial both in metastatic colorectal cancer,” said Evan M. Levine, ADVENTRX president and chief executive officer. “Later in the current quarter, we plan to file for European clearance to initiate a Phase III pivotal trial in pancreatic cancer. We expect to be enrolling patients in all three late-stage CoFactor trials by year end.”

***First Quarter Financial Review***

Research and development (R&D) expenses for the first quarter of 2005 were $1.7 million, compared with $296,000 for the first quarter of 2004. The increase in R&D expenses for the 2005 first quarter was due primarily to clinical expenses associated with the Company’s ongoing Phase II CoFactor trial. General and administrative expenses for the 2005 first quarter were $1.2 million, compared with $414,000 for the same period in 2004. This increase was due primarily to the hiring of additional personnel in the finance and marketing, and business development departments; increased directors and officers insurance premiums; increased legal fees; payments for settlements of certain disputes; and increased expenses associated with business development activities.

ADVENTRX reported cash and cash equivalents of approximately $10.5 million as of March 31, 2005, compared with $13.0 million as of December 31, 2004. This decrease was due primarily to the use of cash to fund R&D and general and administrative expenses.

**About CoFactor**

CoFactor (ANX-510) is a folate-based biomodulator drug developed to enhance the activity of the widely used cancer chemotherapeutic (5-FU). Clinical data from previous clinical trials in Europe have demonstrated clinical benefit and improved overall median survival in patients with advanced tumors, including colorectal, pancreatic and breast. In comparison to leucovorin, CoFactor creates more stable binding of the active form of 5-FU, FdUMP, to the target enzyme, thymidylate synthase (TS). CoFactor bypasses the chemical pathway required by leucovorin to deliver the active form of folate, allowing 5-FU to work more effectively. This improves 5-FU performance and lowers toxicity. ADVENTRX is the exclusive licensee of this compound. More information on CoFactor can be found at http://www.adventrx.com/products/antic_cofactor.htm.

**About ADVENTRX**

ADVENTRX Pharmaceuticals is a biopharmaceutical research and development company focused on introducing new technologies for anticancer and antiviral treatments that improve the performance and safety of existing drugs and address significant problems such as drug metabolism, toxicity, bioavailability or resistance. More information can be found on the Company's Web site 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. For a discussion of such risks and uncertainties, which could cause actual results to differ from those contained in the forward-looking statements, see "Risk Factors" in the Company's last annual report on Form 10-KSB, as well as other reports that the Company files from time to time with the Securities and Exchange Commission. All forward-looking statements are qualified in their entirety by this cautionary statement. The Company undertakes no obligation to release publicly any revisions, which may be made to reflect events or circumstances after the date hereof.*

**Contact:**
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858-552-0866

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**Lippert Heilshorn & Associates**
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[Tables to Follow]

**ADVENTRX PHARMACEUTICALS, INC.**
(Formerly Biokeys Pharmaceuticals, Inc.)
(A Development Stage Enterprise)
Condensed Consolidated Statements of Operations
(unaudited)

| | Three months ended March 31, | |
|---|---|---|
| | **2005** | **2004** |
| Net sales | $ — | $ — |
| Cost of goods sold | — | — |
| Gross margin | — | — |
| Grant revenue | — | — |
| Interest income | 37,322 | 3,346 |
| | 37,322 | 3,346 |
| Operating expenses: | | |
| Research and development | 1,704,797 | 296,375 |
| General and administrative | 1,150,033 | 414,382 |
| Depreciation and amortization | 27,126 | 3,052 |
| Impairment loss – write off of goodwill | — | — |
| Interest expense | 300 | — |
| Equity in loss of investee | — | — |
| Total operating expenses | 2,882,256 | 713,809 |
| Loss before cumulative effect of change in accounting principle | (2,844,934) | (710,463) |
| Cumulative effect of change in accounting principle | — | — |
| Net loss | (2,844,934) | (710,463) |
| Preferred stock dividends | — | — |
| Net loss applicable to common stock | $ (2,844,934) | $ (710,463) |
| Loss per common share – basic and diluted | $ (.05) | $ (.02) |

**ADVENTRX PHARMACEUTICALS, INC.**
(Formerly Biokeys Pharmaceuticals, Inc.)
(A Development Stage Enterprise)
Condensed Consolidated Balance Sheets

| | March,31 2005 (unaudited) | December,31 2004 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 10,532,678 | $ 13,032,263 |
| Accrued interest income | — | 10,808 |
| Prepaid expenses | 54,881 | 115,144 |
| Other current assets | 27,392 | — |
| Assets available for sale | — | 108,000 |
| Total current assets | 10,614,951 | 13,266,215 |
| Property and equipment, net | 290,482 | 285,304 |
| Other assets | 53,012 | 57,268 |
| Total assets | $ 10,958,445 | $ 13,608,787 |
| **Liabilities and Shareholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 970,324 | $ 532,327 |
| Accrued liabilities | 102,392 | 628,754 |
| Accrued salary and related taxes | 88,796 | 57,315 |
| Total current liabilities | 1,161,512 | 1,218,396 |
| Commitments and contingencies | | |
| Shareholders' equity: | | |
| Common stock, $0.001 par value. Authorized 100,000,000 shares; | | |
| issued 54,037,987 shares in 2005 and 53,834,237 shares in 2004 | 54,039 | 53,835 |
| Additional paid-in capital | 47,804,769 | 47,553,497 |
| Deficit accumulated during the development stage | (38,027,128) | (35,182,194) |
| Treasury stock: 23,165 shares at cost | (34,747) | (34,747) |
| Total shareholders' equity | 9,796,933 | 12,390,391 |
| Total liabilities and shareholders' equity | $ 10,958,445 | $ 13,608,787 |

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**Exhibit 99.2**

**ADVENTRX REPORTS POSITIVE PRELIMINARY PHASE II TRIAL RESULTS WITH COFACTOR IN METASTATIC COLORECTAL CANCER**

**DATA SHOW INCREASED RESPONSE RATE AND NO GRADE 3/4 GASTROINTESTINAL OR HEMATOLOGICAL TOXICITY**

**SAN DIEGO - May 13, 2005 -** ADVENTRX Pharmaceuticals, Inc. (Amex: ANX) today announced a 63% overall clinical benefit and a 38% objective response rate in measurable patients treated with CoFactor™ and 5-fluorouracil (5-FU) as a first-line treatment of metastatic colorectal cancer in its Phase II trial. Furthermore, patients enrolled in this trial have exhibited no grade 3 or 4 gastrointestinal or hematological toxicities as determined in accordance with the National Cancer Institute's Common Terminology Criteria for Adverse Events grading system. Patients continue to be followed for time-to-tumor progression and overall survival. Of the 50 patients enrolled in the trial, 48 are available for tumor response assessment and 44 have been evaluated for tumor response as of May 13. ADVENTRX currently plans to announce response data on all patients in June at the World Congress on Gastrointestinal Cancer in Barcelona, Spain and final results, including time-to-tumor-progression and early survival, from this trial in the fourth quarter of this year.

"To date our Phase II trial with CoFactor and 5-FU has demonstrated objective response rates of 38%. This is more than double the rate of 11-17% historically observed in clinical trials treating metastatic colorectal cancer patients with leucovorin and 5-FU, but with none of the typical grade 3 or 4 toxicities" said Evan M. Levine, president and CEO for ADVENTRX. "These results suggest that CoFactor increases the potency of 5-FU, while lowering toxicity compared with 5-FU/leucovorin treatment regimens. Based in part on these and earlier positive Phase II CoFactor data, we have received clearance under a Special Protocol Assessment (SPA) from the US Food and Drug Administration to begin a Phase III pivotal trial and clearance in the United Kingdom to begin an international Phase IIb trial using CoFactor and 5-FU as a first line combination therapy in metastatic colorectal cancer. We plan to initiate both of these trials this year."

The Phase II clinical trial is an open label, single arm Simon 2 stage study design to assess the safety and efficacy of CoFactor plus 5-FU as a first line treatment of metastatic colorectal cancer. CoFactor is ADVENTRX's biomodulator designed to enhance the effects of the widely used cancer drug, 5-FU.

Available objective response data from the Phase II trial showed 38% or 18 patients responded to treatment with CoFactor and 5-FU, surpassing the trial's response rate objective of 25%. To date, 12 patients have exhibited stable disease and 14 have progressive disease. World Health Organization criteria were used to define response as follows: complete response is a complete disappearance of the tumor; partial response is at least a 50% reduction in total tumor size; stable disease is less than a 50% reduction in total tumor size; and progressive disease is at least a 25% increase in tumor size at the end of the treatment cycle, as measured by CT or MRI scans. Objective response is defined as all patients having complete or partial responses, whose tumor measurements are confirmed by MRI or CT scan by repeat assessment performed no less than four weeks after the criteria for response is first met. The primary endpoint for the study, objective response, was evaluated at the completion of two cycles at week 16 with the exception of those patients that progressed as established by radiological assessment at the end of the first cycle (eight weeks). Clinical benefit is defined as tumor response or stable disease following study therapy. Other efficacy endpoints still being evaluated are time-to-tumor-progression and overall survival.

Safety data is available for all 50 patients. The clinical trial's treatment regimen of CoFactor plus 5-FU (COFU) was well tolerated, with no grade 3 or 4 gastrointestinal or hematological toxicities reported to date. The most common adverse events (AEs) were diarrhea, nausea and vomiting, none of which were grade 3 or 4. There was one additional adverse event, a single case of grade 3 watery eye.

Selected preliminary results of ADVENTRX's Phase II trial were published in the American Society of Clinical Oncology (ASCO) 2005 Annual Meeting Proceedings (abstract #3692). This abstract is available via ADVENTRX's Web site at www.adventrx.com.

ADVENTRX recently received clearance in the US under an SPA to begin a Phase III pivotal study of CoFactor in metastatic colorectal cancer. The Company also received clearance in the United Kingdom to begin an international Phase IIb trial with CoFactor and 5-FU in metastatic colorectal cancer. The Company plans to file in the first half of this year for clearance to initiate an EU-based Phase III CoFactor study in pancreatic cancer.

**About the Phase II COFU trial**
Patients enrolled in this trial are age 18 and older with ECOG 0-2 and measurable metastatic colorectal cancer, with or without adjuvant 5-FU/leucovorin, irinotecan, or oxaliplatin, but no prior chemotherapy for metastatic disease. Patients may receive more than two cycles each consisting of CoFactor 60 mg/$m^2$ and 5-FU 450 mg/$m^2$ (weekly IV bolus) for six consecutive weeks, followed by a 14 day rest period, which is defined as a cycle. Pre-established response criteria are greater than four responders of 23 patients for stage one, and greater than 12 responders of 48 patients for the full trial. The median age of patients was 65.5 (range 42-86), and mean number of doses was 10.2 (range 1-24). The clinical response is evaluated at the completion of two consecutive cycles. The trial is being conducted in the US and Europe under a US investigational new drug application (IND).

**About CoFactor**
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