
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: August 9, 2005

BioCryst Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or other jurisdiction
of incorporation)

000-23186
(Commission
File Number)

62-1413174
(IRS Employer
Identification #)

2190 Parkway Lake Drive, Birmingham, Alabama 35244
(Address of Principal Executive Office)

(205) 444-4600
(Registrant's telephone number, including area code)

Item 8.01 Other Events.

On August 9, 2005, Registrant issued a press release announcing the initiation of a Phase I pharmacokinetic clinical trial with intravenous/oral Fodosine™ in healthy volunteers. The press release is being filed as Exhibit 99.1 to this Current Report on Form 8-K.

Neither the filing of any press release as an exhibit to this Current Report on Form 8-K nor the inclusion in such press release of a reference to Registrant's Internet address shall, under any circumstances, be deemed to incorporate the information available at such Internet address into this Current Report on Form 8-K. The information available at Registrant's Internet address is not part of this Current Report on Form 8-K or any other report filed by Registrant with the Securities and Exchange Commission.

Item 9.01 Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated August 9, 2005 entitled "BioCryst Advances Lead Product Program; Initiates Intravenous/Oral Pharmacokinetic Clinical Trial of Fodosine™ in Healthy Volunteers to Support Pivotal Trial".

EXHIBIT INDEX

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99.1	Press release dated August 9, 2005 entitled "BioCryst Advances Lead Product Program; Initiates Intravenous/Oral Pharmacokinetic Clinical Trial of Fodosine™ in Healthy Volunteers to Support Pivotal Trial".



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FOR IMMEDIATE RELEASE

**BIOCRYST ADVANCES LEAD PRODUCT PROGRAM; INITIATES INTRAVENOUS/ORAL
 PHARMACOKINETIC CLINICAL TRIAL OF FODOSINE™ IN HEALTHY VOLUNTEERS TO SUPPORT
 PIVOTAL TRIAL**

Birmingham, Alabama – August 9, 2005 – BioCryst Pharmaceuticals, Inc. (Nasdaq NM: BCRX) today announced that it has initiated a Phase I pharmacokinetic study of Fodosine™ (forodesine hydrochloride), the company’s lead anti-cancer compound, to evaluate the bioavailability and effect of food on oral versus intravenous formulations in healthy volunteers. Fodosine™ is a transition state purine nucleoside phosphorylase (PNP) inhibitor, which functions by blocking the DNA synthesis machinery of the body’s T-cells. The small molecule drug is being developed for treatment of T-cell mediated cancers, and has been designated an “Orphan Drug” for several indications, including T-cell leukemia, cutaneous T-cell lymphoma (CTCL), chronic lymphocytic leukemia (CLL) and acute lymphoblastic leukemia (ALL).

This single-center, randomized Phase I study is scheduled to enroll up to 18 healthy subjects and is expected to last approximately 21 days. The trial is being conducted under fed and fast conditions, to evaluate and compare the safety, tolerability, and bioavailability of orally administered Fodosine™ versus intravenously administered Fodosine™.

The trial is a single dose, three-period crossover study. Each subject will receive three study treatments with one treatment administered on Day 1 of each of the three consecutive dosing periods. The treatments to be used are:

Treatment A:	oral, 300 mg (three 100 mg capsules) of Fodosine™, fasting
Treatment B:	oral, 300 mg (three 100 mg capsules) of Fodosine™, fed
Treatment C:	intravenous infusion, 40 mg/m ² of Fodosine™ (100 mL), fasting

Results of the Phase I trial will assist in facilitating design of a proposed Phase IIb “pivotal” clinical program in patients with T-cell leukemia, using a combination of intravenous and oral formulations of Fodosine™.

“We believe this Phase I study will contribute meaningfully to the design of our pivotal Phase IIb trial by confirming the drug relationships we have observed in earlier pharmacokinetic studies,” stated Dr. Charles E. Bugg, Chairman and CEO of BioCryst. “Additionally, we are encouraged by the FDA’s approval of Fodosine™’s use in healthy volunteers, which we believe is further validation of the compound’s safety profile.”

About BioCryst

BioCryst Pharmaceuticals, Inc. designs, optimizes and develops novel drugs that block key enzymes involved in cancer, cardiovascular diseases, autoimmune diseases, and viral infections. BioCryst integrates the necessary disciplines of biology, crystallography, medicinal chemistry and computer modeling to effectively use structure-based drug design to discover and develop small molecule pharmaceuticals.

BioCryst's lead product candidate, Fodosine™, is a transition-state analog inhibitor of the target enzyme purine nucleoside phosphorylase (PNP). The drug is currently in a Phase IIa trial for patients with T-cell leukemia, a Phase I trial with an oral formulation in cutaneous T-cell lymphoma (CTCL), a Phase I/II trial in B-cell acute lymphoblastic leukemia and a Phase I pharmacokinetic trial in healthy volunteers. Results of the Phase IIa and the Phase I pharmacokinetic trial will assist in the design of a planned combination IV and oral Phase IIb pivotal clinical trial in patients with T-cell leukemia. BioCryst also plans to initiate a Phase II trial in chronic lymphocytic leukemia (CLL) during 2005. Fodosine™ has been granted Orphan Drug status by the U.S. Food and Drug Administration for three indications: T-cell non-Hodgkin's lymphoma, including CTCL; CLL and related leukemias including T-cell prolymphocytic leukemia, adult T-cell leukemia, and hairy cell leukemia; and for treatment of acute lymphoblastic leukemia (ALL). Additionally the FDA has granted "fast track" status to the development of Fodosine™ for the treatment of relapsed or refractory T-cell leukemia. A Phase I study with BioCryst's second-generation PNP inhibitor, BCX-4208, was recently completed in healthy volunteers. A Phase Ib multi-dose study with BCX-4208 commenced in August 2005, with the goal of initiating a Phase II study in patients with psoriasis in late 2005 or early 2006. In addition, BioCryst has other enzyme targets in drug discovery including hepatitis C polymerase and tissue factor/factor VIIa. For more information about BioCryst, please visit the company's web site at www.biocryst.com.

Forward-looking statements

These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Some of the factors that could affect the forward-looking statements contained herein include that we may not be able to enroll the required number of subjects in clinical trials of Fodosine™ or BCX-4208, that each of the Phase IIa trial for patients with T-cell leukemia, Phase I trial of BCX-4208, Phase I trial of Fodosine™ for treatment of patients with cutaneous T-cell lymphoma and the Phase I pharmacokinetic study of Fodosine™ may not be successfully completed, that BioCryst may not commence as expected additional trials with Fodosine™ and with BCX-4208, that Fodosine™, BCX-4208, or any of our other product candidates may not receive required regulatory clearances from the FDA, that Phase IIa clinical trials of Fodosine™ may not show the drug is effective over the 6-week period, that ongoing and future clinical trials may not have positive results, that we may not be able to obtain a Special Protocol Assessment or otherwise be able to complete successfully the Phase IIb trial that is currently planned to be pivotal, that we may not be able to continue future development of Fodosine™, BCX-4208 or any of our other current development programs including tissue factor/factor VIIa and hepatitis C polymerase, that Fodosine™, BCX-4208 or our other development programs may never result in future product, license or royalty payments being received by BioCryst, that BioCryst may not reach favorable agreements with potential pharmaceutical and biotech partners for further development of its product candidates, that BioCryst may not have sufficient cash to continue funding the development, manufacturing, marketing or distribution of its products and that additional funding, if necessary, may not be available at all or on terms acceptable to BioCryst. Please refer to the documents BioCryst files periodically with the Securities and Exchange Commission, specifically BioCryst's most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and current reports on Form 8-K, which identify important factors that could cause the actual results to differ materially from those contained in the projections or forward-looking statements.

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