

---

**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 Ib clinical trial with oral BCX-4208 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 Initiates BCX-4208 Oral Phase Ib Clinical Trial in Healthy Volunteers".

## 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.

Dated: August 9, 2005

BIOCRIST PHARMACEUTICALS, INC.

By: /s/ MICHAEL A. DARWIN

---

**Michael A. Darwin**  
**Chief Financial Officer and Chief**  
**Accounting Officer**

## EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated August 9, 2005 entitled "BioCryst Initiates BCX-4208 Oral Phase Ib Clinical Trial in Healthy Volunteers".



BIOCRYST PHARMACEUTICALS, INC.  
 2190 PARKWAY LAKE DRIVE  
 BIRMINGHAM, AL 35244  
 205-444-4600 205-444-4640 FAX  
 www.biocryst.com

Contact:  
 BioCryst Pharmaceuticals, Inc.  
 Jonathan M. Nugent  
 V.P. Corporate Communications  
 (205)444-4633

**FOR IMMEDIATE RELEASE**

**BIOCRYST INITIATES BCX-4208 ORAL PHASE Ib CLINICAL TRIAL  
 IN HEALTHY VOLUNTEERS**

**Birmingham, Alabama – August 9, 2005** – BioCryst Pharmaceuticals, Inc. (Nasdaq NM: BCRX) today announced that it has initiated a Phase Ib trial of BCX-4208, the company's second generation, transition-state analog inhibitor of purine nucleoside phosphorylase (PNP). Being conducted in healthy volunteers, the trial is designed to evaluate the safety, tolerability, and pharmacokinetics of multiple oral doses of BCX-4208.

The single-center study is being conducted as a randomized, double-blind, placebo-controlled, dose-escalating trial consisting of three dose groups. Groups of 10 subjects (eight on active drug, two on placebo) will receive 0.5 mg/kg, 1.5 mg/kg or 2.5 mg/kg oral doses of BCX-4208 once daily for seven days. All doses will be administered two hours prior to breakfast after an overnight fast. The study is scheduled to enroll 30 healthy adult subjects. Assuming successful completion of this trial, the company plans to initiate a Phase II clinical trial in psoriasis patients.

"The initiation of this trial underscores our ongoing commitment to advancing BCX-4208," stated Dr. Charles E. Bugg, Chairman and CEO of BioCryst. "We plan to use information from this trial as part of a robust data package that will support our efforts to rapidly advance BCX-4208 into Phase II trials, initially in psoriasis with the option of expanding into additional autoimmune indications."

**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 and a combination IV and oral 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. Additionally Fodosine™ is currently being studied in a Phase I trial with an oral formulation in cutaneous T-cell lymphoma (CTCL). BioCryst also plans to initiate a Phase I/II trial in B-cell acute lymphoblastic leukemia and 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. The Phase Ib trial announced today will be conducted 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](http://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 and the Phase I trial of Fodosine™ for treatment of patients with cutaneous T-cell lymphoma 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.

# # #