# 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: June 20, 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 June 20, 2005, Registrant issued a press release announcing FDA approval of fast track status for Fodosine<sup>TM</sup> in the treatment of relapsed or refractory T-cell leukemia. 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.

Exhibit No.	Description
99.1	Press release dated June 20, 2005 entitled "BioCryst Receives FDA Fast Track Status for Fodosine™ in the Treatment of
	Relapsed or Refractory T-cell Leukemia".

## **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: June 20, 2005	BIOCRYST PHARMAC	EUTICALS, INC.
	By:	/s/ MICHAEL A. DARWIN

Michael A. Darwin Chief Financial Officer and Chief Accounting Officer

## EXHIBIT INDEX

Item	Description
99.1	Press release dated June 20, 2005 entitled "BioCryst Receives FDA Fast Track Status for Fodosine™ in the Treatment of Relapsed or Refractory T-cell Leukemia".



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

# BIOCRYST RECEIVES FDA FAST TRACK STATUS FOR FODOSINE™ IN THE TREATMENT OF RELAPSED OR REFRACTORY T-CELL LEUKEMIA

**Birmingham, Alabama – June 20, 2005** - BioCryst Pharmaceuticals, Inc. (Nasdaq NM: BCRX) today announced that the U.S. Food and Drug Administration (FDA) has granted "fast track" status to the development of Fodosine<sup>TM</sup> (forodesine hydrochloride), for the treatment of relapsed or refractory T-cell leukemia. Fodosine<sup>TM</sup> is a transition state analog inhibitor with especially strong binding to the target enzyme. Currently being studied in a Phase IIa clinical trial, Fodosine<sup>TM</sup> is BioCryst's lead product candidate.

The fast track programs of the FDA are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The FDA informed BioCryst that it granted fast track designation for the following reasons:

- 1. Because of the life-threatening nature of the disease
- 2. Based on clinical responses observed in clinical studies

"This decision of the FDA underpins our confidence in Fodosine™ as an effective therapy for the treatment of T-cell leukemia. The next step is to take Fodosine™ into a pivotal study where we will test its ability to halt disease progression in patients who have failed standard treatment regimens," stated Charles E. Bugg, Ph.D., Chairman and Chief Executive Officer of BioCryst.

Fodosine<sup>™</sup>, BioCryst's lead product candidate, 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 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<sup>™</sup> 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).

#### 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 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. A Phase I multi-dose study with BCX-4208 will follow, with the goal of initiating a Phase II study during 2005 in patients with psoriasis. 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<sup>TM</sup> 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  $^{\text{TM}}$  and with BCX-4208, that Fodosine  $^{\text{TM}}$ , 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<sup>TM</sup> 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  $Fodosine^{\text{TM}}, BCX-4208 \ or \ any \ of \ our \ other \ current \ development \ programs \ including \ tissue \ factor/factor \ VIIa \ and \ hepatitis \ C \ polymerase, \ that \ Fodosine^{\text{TM}}, BCX-4208 \ or \ any \ of \ our \ other \ current \ development \ programs \ including \ tissue \ factor/factor \ VIIa \ and \ hepatitis \ C \ polymerase, \ that \ Fodosine^{\text{TM}}, BCX-4208 \ or \ any \ of \ our \ other \ current \ development \ programs \ including \ tissue \ factor/factor \ VIIa \ and \ hepatitis \ C \ polymerase, \ that \ Fodosine^{\text{TM}}, BCX-4208 \ or \ any \ of \ our \ other \ ot$ 4208 or our other development programs may never result in future product, license or royalty payments being received by BioCryst, 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.