## 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: November 8, 2004

### **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)

provisions:		
<u> </u>	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)	
<u> </u>	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)	
<u> </u>	Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))	
<u> _ </u>	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))	

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following

#### Item 8.01 Other Events.

On November 8, 2004, Registrant issued a press release announcing the initiation of the clinical development of BCX-4208 for psoriasis. 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 November 8, 2004 entitled "BioCryst Pharmaceuticals Initiates Clinical Development of BCX-4208 for Psoriasis".

#### **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: November 8, 2004 BioCryst Pharmaceuticals, Inc.

By: /s/ Michael A. Darwin

Michael A. Darwin Chief Financial Officer and Chief Accounting Officer

#### EXHIBIT INDEX

Item Description



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#### FOR IMMEDIATE RELEASE

## BIOCRYST PHARMACEUTICALS INITIATES CLINICAL DEVELOPMENT OF BCX-4208 FOR PSORIASIS

- Second Generation PNP Inhibitor is More Potent and Has Longer Half-Life -

**Birmingham,** AL – **November 8, 2004** – BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) announced today that the first group of subjects has been dosed in a Phase I pharmacokinetic and safety study of BCX-4208, BioCryst's second-generation purine nucleoside phosphorylase (PNP) inhibitor, for the treatment of psoriasis. BCX-4208 is a potent PNP inhibitor that blocks activation of T-cells. The compound has a long half-life and suitable oral bioavailability in animals, which makes it an ideal candidate for chronic dosing in autoimmune diseases such as psoriasis. The trial is being conducted in the United States under an IND filed with the U.S. Food and Drug Administration (FDA) in August 2004.

This Phase I placebo-controlled trial is a dose-escalating study consisting of up to seven dose groups of healthy volunteers. Each dose group will include 12 subjects, 8 of whom will receive a single oral dose of BCX-4208, with the other 4 receiving a placebo. BioCryst plans to use the results of this trial to design a multi-dose Phase I trial in healthy volunteers, which will be conducted in early 2005. Assuming successful completion of Phase I, that trial will be immediately followed by a Phase II open-label trial in psoriasis patients.

"Entering the clinic with our second PNP product candidate is an important milestone for BioCryst," stated Dr. Charles E. Bugg, Chairman and CEO of BioCryst. "BCX-4208 is a more potent PNP inhibitor than our first product candidate, forodesine hydrochloride, has a longer half-life complexed to PNP, and has excellent oral bioavailability, making it an ideal drug candidate for chronic dosing in T-cell mediated autoimmune diseases. We are very excited about developing BCX-4208 as a treatment for psoriasis and other autoimmune conditions where an oral therapy would be advantageous and improve patient quality of life."

-more-

#### **About BioCryst**

BioCryst Pharmaceuticals, Inc. designs, optimizes and develops novel drugs that block key enzymes involved in cancer, cardiovascular and 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, forodesine hydrochloride (BCX-1777), an inhibitor of purine nucleoside phosphorylase (PNP), is currently in a Phase II trial for patients with T-cell malignancies and a Phase I trial with oral forodesine hydrochloride in CTCL. In addition, BioCryst plans to initiate a Phase I/II trial for B-cell acute lymphoblastic leukemia during the fourth quarter 2004. Forodesine hydrochloride has been granted 'Orphan Drug' status by the U.S. Food and Drug Administration for three indications: T-cell non-Hodgkin's lymphoma, including cutaneous T-cell lymphoma; chronic lymphocytic leukemia (CLL) and related leukemias including prolymphocytic leukemia, adult T-cell leukemia, and hairy cell leukemia; and for treatment of acute lymphoblastic leukemia (ALL). BioCryst's second-generation PNP inhibitor, BCX-4208 is currently in a Phase I study of healthy volunteers with the goal of initiating a Phase II study during 2005 in patients with psoriasis. In addition, BioCryst has several new enzyme targets in drug discovery including tissue factor/factor VIIa and hepatitis C polymerase. For more information about BioCryst, please visit the company's web site at www.biocryst.com.

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 forodesine hydrochloride or BCX-4208, that the Phase I trial of forodesine hydrochloride for treatment of patients with cutaneous T-cell lymphoma may not be successfully completed, that BioCryst may not commence as expected additional trials with forodesine hydrochloride and Phase II studies with BCX-4208, that forodesine hydrochloride, BCX-4208, or any of our other product candidates may not receive required regulatory clearances from the FDA, that Phase IIa clinical trials of forodesine hydrochloride may not show the drug is effective over the 6-week period, 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, that we may not be able to continue future development of forodesine hydrochloride, BCX-4208 or any of our other current development programs including tissue factor/factor VIIa and hepatitis C polymerase, that forodesine hydrochloride, 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 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.

Quarterly Reports on Form 10-Q, which identify important factors that could cause the actual results to differ materially from those contained in the projections or forward-looking statements.