

BIOCRYST PHARMACEUTICALS INC

Form 8-K

January 28, 2013

# **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: January 25, 2013**

## **BioCryst Pharmaceuticals, Inc.**

**(Exact Name of Registrant as Specified in Charter)**

**Delaware**  
**(State or other jurisdiction**

**of incorporation)**

**000-23186**  
**(Commission**

**File Number)**  
**4505 Emperor Blvd., Suite 200**

**Durham, North Carolina 27703**

**62-1413174**  
**(IRS Employer**

**Identification #)**

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(Address of Principal Executive Office)

(919) 859-1302

(Registrant's telephone number, including area code)

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 provisions (see General Instruction A.2 below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 210.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 8.01 Other Events.**

BioCryst has completed its analysis of results from a study of a low dose of BCX5191 in chimpanzees to characterize its efficacy against the hepatitis C virus (HCV). In response to regulatory feedback, this experiment was designed to determine if non-toxic doses of BCX5191 would have a potent antiviral effect. Preclinical toxicology studies in rats had previously established a no observed adverse effect level, or NOAEL, of 0.5 mg/kg/day BCX5191. In a preliminary experiment, uninfected chimpanzees were given a single 20 mg dose of BCX5191. The blood levels achieved with this dose were similar to those observed in rats at the NOAEL dose. Chimpanzees chronically infected with HCV were then dosed with 20mg/day BCX5191 for seven days and HCV RNA copies/mL measured daily. Following seven days of treatment at that dose, the viral load reduction observed in the animals was insufficient to justify continued development. As a consequence, BioCryst is terminating its BCX5191 preclinical program, and the Company does not intend to pursue the development of BCX5191 or backup compounds against HCV.

**BioCryst Forward-Looking Statements**

This Current Report contains forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause BioCryst's 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 HHS/BARDA may further condition, reduce or eliminate future funding of the peramivir program; that BioCryst or its licensees may not be able to enroll the required number of subjects in planned clinical trials of its product candidates and that such clinical trials may not be successfully completed; that the company or its licensees may not commence as expected additional human clinical trials with product candidates; that the FDA may require additional studies beyond the studies planned for product candidates or may not provide regulatory clearances which may result in delay of planned clinical trials, clinical hold with respect to such product candidate or the lack of market approval for such product candidate; that ongoing and future preclinical and clinical development may not have positive results; that the company or its licensees may not be able to continue future development of current and future development programs; that such development programs may never result in future product, license or royalty payments being received; that the companies may not be able to retain its current pharmaceutical and biotechnology partners for further development of its product candidates or may not reach favorable agreements with potential pharmaceutical and biotechnology partners for further development of product candidates; that its actual cash burn rate may not be consistent with its expectations; that 2013 operating expenses and cash usage will be within management's expected ranges. 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,

all of which identify important factors that could cause the actual results to differ materially from those contained in BioCryst's projections and forward-looking statements.

**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: January 25, 2013

**BioCryst Pharmaceuticals, Inc.**

By: /s/ Alane Barnes  
Alane Barnes  
General Counsel, Corporate Secretary