BIOCRYST PHARMACEUTICALS INC
Form 8-K
November 27, 2012

UNITED STATES

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 (Date of earliest event reported): November 20, 2012

BioCryst Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**000-23186**	**62-1413174**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4505 Emperor Blvd., Suite 200

Durham, North Carolina 27703

(Address of Principal Executive Offices)

(919) 859-1302

(Registrant s telephone number, including area code)

(Former Name or Former Address, if Changed Since Last Report)

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

On November 20, 2012, BioCryst Pharmaceuticals, Inc. (the Company) had a teleconference with the U.S. Food and Drug Administration (FDA) regarding the Investigational New Drug (IND) application for BCX4161. During the call, FDA informed the Company that they were applying GMP manufacturing standards to the process of compounding BCX4161 capsules at the clinical site to be used for oral dosing studies. As a consequence, the BCX4161 IND has been placed on clinical hold. The practice of compounding drug product at clinical sites is not uncommon in Phase 1 studies. BioCryst had proposed to administer hard gel capsules containing formulated drug solution compounded at the clinical site.

The FDA will provide a letter within 30 days outlining the reasons for the clinical hold and the information required to have the hold removed. The Company had previously guided the initiation of Phase 1 testing in the United States before the end of 2012. The Company now estimates that Phase 1 testing of BCX4161 will be delayed approximately three months.

Forward-Looking Statements

This 8-K 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 the Company s 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 the FDA or similar regulatory agencies may not provide regulatory clearances with respect to BCX4161, which may result in further delay or ultimately a termination of the program; that the Company may misinterpret information conveyed by the FDA resulting in the Company reaching erroneous conclusions, which may result in further delay of development or termination of BCX4161; that the Company may be unable to move forward with development of BCX4161 as planned; that future preclinical and clinical development of BCX4161 may not prove safe and effective; that the Company may not have sufficient cash to continue funding the development, manufacturing, marketing or distribution of BCX4161 and that additional funding, if necessary, may not be available at all or on terms acceptable to the Company. 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: November 26, 2012

BioCryst Pharmaceuticals, Inc.

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