BIOCRYST PHARMACEUTICALS INC
Form 8-K
July 22, 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 (Date of earliest event reported): July 22, 2013

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 #)**

4505 Emperor Blvd., Suite 200

Durham, North Carolina 27703

(Address of Principal Executive Office)

(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 7.01. Regulation FD Disclosure.

On July 22, 2013, BioCryst Pharmaceuticals, Inc. (BioCryst) issued a news release announcing the results of its BCX4161 Phase 1 clinical trial for the treatment of hereditary angioedema (HAE), as further described in Item 8.01 below. A copy of the news release is attached hereto as Exhibit 99.1 and is incorporated into this Item 7.01 by reference.

BioCryst s management will host a conference call and webcast on July 22, 2013 at 8:30 a.m. Eastern Time to discuss the results of the BCX4161 Phase 1 clinical trial and other aspects of BioCryst s HAE development program. The webcast can be accessed by logging onto www.biocryst.com, and slides that will be used in connection with the conference call and webcast are available for viewing, downloading and printing on the website.

The information in this Item 7.01 is furnished and is not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, is not subject to the liabilities of that section and is not deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Item 8.01. Other Events.

On July 22, 2013, BioCryst announced that the randomized, placebo-controlled, Phase 1 clinical trial of orally-administered BCX4161 in healthy volunteers successfully met all of its objectives. The safety, tolerability, drug exposure and on-target kallikrein inhibition results of this Phase 1 trial strongly support advancing the development program into a Phase 2a study in HAE patients.

Overall, 87 healthy volunteers completed the study; 30 received a single dose of BCX4161 from 50 mg up to 1000 mg, 40 subjects received 100 mg, 200 mg, 400 mg, or 800 mg BCX4161 every eight hours for seven days and 17 received placebo.

Oral administration of BCX4161 was generally safe and well tolerated. There were no serious adverse events and no dose limiting adverse events. Laboratory tests of coagulation remained normal. Drug exposure was dose proportional through 400 mg three times a day. Steady state (day seven) blood levels were 30% higher compared to the first day of dosing. At 400 mg three times a day, pre-dose geometric mean (coefficient of variance, CV) drug levels on day 7 were 28.6 ng/mL (CV 77%) and post-dose maximum drug levels were 152 ng/mL (CV 57%). Kallikrein inhibition was observed throughout the dosing interval, $p<0.0001$ compared to placebo.

The Phase 2a clinical trial in patients with HAE is expected to begin in the fourth quarter of 2013. This trial will test 400 mg of BCX4161 administered three times daily for 28 days in a randomized, placebo-controlled, two-period cross-over design. Approximately 25 HAE patients who have a high frequency of attacks (1 per week) will be enrolled. The main goals for this clinical trial are to evaluate the safety and tolerability of BCX4161 and to estimate the degree of efficacy in reducing the frequency of attacks. This study is designed to provide proof of concept for oral kallikrein inhibition as a treatment strategy for hereditary angioedema.

As a part of BioCryst s strategy to become a leader in the treatment of HAE, BioCryst is finalizing its evaluation of multiple potent and specific second generation oral kallikrein inhibitors. Oral bioavailability of these compounds ranges between 20% and 60% in animals. One or more candidates are expected to enter preclinical development by the end of 2013.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated July 22, 2013 entitled Biocryst Successfully Completes its Phase 1 Clinical Trial of BCX4161 for the Treatment Of Hereditary Angioedema

Forward-Looking Statements

This Current Report on Form 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 BioCryst 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 BioCryst may not be able to enroll the required number of subjects in the Phase 2a clinical trial of BCX4161; that the Phase 2a trial of BCX4161 may not have a favorable outcome or may not be successfully completed; that the FDA or similar regulatory agency may refuse to approve subsequent studies, or delay approval of clinical studies which may result in a delay of planned clinical studies and increase development costs of a product candidate; that the FDA may withhold market approval for product candidates; that ongoing and future preclinical and clinical development of HAE second generation candidates may not have positive results; that BioCryst 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 BioCryst 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. 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.

BioCryst Pharmaceuticals, Inc.

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

Dated: July 22, 2013

EXHIBIT INDEX

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