

BIOCRYST PHARMACEUTICALS INC

Form 8-K

October 08, 2015

**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): **October 8, 2015**

BioCryst Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-23186
(Commission File Number)

62-1413174
(IRS Employer Identification No.)

4505 Emperor Blvd., Suite 200
Durham, North Carolina
(Address of principal executive offices)

27703
(Zip Code)

Registrant's telephone number, including area code: **(919) 859-1302**

(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:

- ☐ 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 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01. Other Events.

On October 8, 2015, BioCryst Pharmaceuticals, Inc. (the "Company") announced that the randomized, placebo-controlled, Phase 1 clinical trial of orally-administered BCX7353 in healthy volunteers successfully met all of its objectives. The safety, tolerability, drug exposure and on-target plasma kallikrein inhibition results strongly support advancing the development program into a Phase 2 study in hereditary angioedema ("HAE") patients.

Oral BCX7353 was generally safe and well tolerated at all doses up to 500 mg once-daily for 7 days and 350 mg once-daily for 14 days in healthy volunteers, and no dose-limiting toxicity was identified. There were no serious adverse events ("AEs") and most AEs were mild. Two subjects discontinued the study due to moderate gastrointestinal AEs. One subject developed a delayed-type hypersensitivity rash after completing seven days of study drug; the rash resolved quickly with oral and topical steroids. No clinically significant laboratory abnormalities were seen at any dose or duration tested.

Plasma BCX7353 levels increased in approximate proportion to dose, and drug exposure was not affected by dosing with food. The half-life of BCX7353 was estimated at 50-60 hours. After daily dosing, blood levels met or exceeded a predicted target therapeutic range throughout the 24 hour dosing interval.

Inhibition of the target enzyme, plasma kallikrein, was measured in a sensitive and specific bioassay. Daily dosing with BCX7353 strongly inhibited plasma kallikrein at all four dose levels; the degree of inhibition was dose-related ($p < 0.0001$) and inhibition was sustained throughout the 24 hour dosing interval. This pharmacodynamic effect correlated strongly to achieved drug concentration ($r = 0.91$, $p < 0.0001$).

A Phase 2, four week dose ranging trial to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of BCX7353 as a preventative treatment to reduce the frequency of attacks in HAE patients is expected to begin by late 2015 or early 2016.

On October 8, 2015, the Company issued a news release announcing the events described in this Item 8.01. A copy of the news release is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

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 the Company'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 the Company may not be able to enroll the required number of subjects in the Phase 2 clinical trial of BCX7353; that the Phase 2 trial of BCX7353 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, delay approval of clinical studies or require other changes to our development plan, which may result in a delay of planned clinical studies and increase development costs of a product candidate, including BCX7353; that the FDA may withhold market approval for BCX7353; that ongoing and future preclinical and clinical development of HAE second generation candidates 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. Please refer to the documents the Company files periodically with the Securities and Exchange Commission, specifically the Company'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 the Company's projections and forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated October 8, 2015 entitled "BioCryst Announces Successful Phase 1 Clinical Trial of BCX7353"

SIGNATURE

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.

(Registrant)

October 8, 2015

(Date)

/s/ ALANE BARNES

Alane Barnes
*Vice President, General Counsel,
and Corporate Secretary*

EXHIBIT INDEX

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