

BIOCRYST PHARMACEUTICALS INC

Form 8-K

August 11, 2016

**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): August 11, 2016

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
(I.R.S. Employer Identification
Number)

**4505 Emperor Blvd., Suite 200, Durham, North
Carolina 27703**
(Address of Principal Executive Offices) (Zip Code)

(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:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

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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 August 11, 2016, BioCryst Pharmaceuticals, Inc. (the “Company”) announced that it has dosed the first subject in the APeX-1 clinical trial (“APeX-1”) of BCX7353 for the oral treatment of hereditary angioedema (“HAE”). APeX-1 is a two part, Phase 2, randomized, double-blind, placebo-controlled dose ranging trial to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of BCX7353 as a preventative treatment to eliminate or reduce the frequency of angioedema attacks in HAE patients. Up to approximately 50 eligible subjects with HAE will be enrolled in the study.

On August 11, 2016, 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 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 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 BioCryst 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 second generation kallikrein inhibitor 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 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit

No.	Description
99.1	Press release dated August 11, 2016 entitled “BioCryst Announces Initiation of the APeX-1 Clinical Trial of BCX7353 for Hereditary Angioedema”

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.

Date: August 11, 2016

By: /s/ Alane Barnes
Alane Barnes
Vice President, General Counsel,
and Corporate Secretary

EXHIBIT INDEX

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