

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 it has completed enrollment in Oral Prophylaxis-2 ("OPuS-2"), a blinded, randomized, placebo-controlled clinical trial of orally-administered avoralstat in patients with hereditary angioedema ("HAE").

OPuS-2 is a 12-week, three-arm, parallel cohort trial designed to evaluate the efficacy and safety of two doses of avoralstat, 300 mg and 500 mg, administered three-times daily compared with placebo. This trial is being conducted in the U.S., Canada and Europe. The primary efficacy endpoint for the trial will be the mean angioedema attack rate, which will be reported for each avoralstat dose group compared to placebo.

The Company anticipates the final OPuS-2 patient visits will occur in January 2016. Therefore, the Company expects to report OPuS-2 results in early 2016. The results of this trial will then be provided for regulatory discussions intended to determine the scope of any additional information that may be required for completion of avoralstat registration.

The Company has been corresponding with regulatory agencies regarding deferral of a two-year rat carcinogenicity study for avoralstat. The results from this type of study are normally required to be available at the time of submission for approval. Currently, the Company has agreement with the European Medicines Agency ("EMA") regarding its request to defer submission of results as a post-filing commitment. Agreement has not been reached with the U.S. Food and Drug Administration ("FDA") regarding a deferral at this time. At the end-of-Phase 2 meeting following the completion of OPuS-2, the Company will engage in further dialogue with the FDA to discuss deferral, in the context of all available toxicology and clinical data. We plan to initiate a rat carcinogenicity study in early 2016. Without a deferral, our NDA filing would occur in 2018.

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 OPuS-2 trial may not have a favorable outcome or may not be successfully completed; that the OPuS-2 trial may cost more or take longer to complete than expected; that the FDA or similar regulatory agency may refuse to approve subsequent HAE studies, or delay approval of clinical studies which may result in a delay of other planned clinical studies and increased development costs of avoralstat; that regulatory determinations regarding the requirements for pre-clinical and clinical studies (including, toxicology, carcinogenicity or long-term safety studies) may negatively impact planned filing for market approval of avoralstat; that the FDA may withhold market approval for avoralstat. 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 Completion of Patient Enrollment in OPuS-2: A Clinical Trial of Avoralstat in Patients with HAE"

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)

/s/ **ALANE BARNES**

October 8, 2015

(Date)

Alane Barnes

*Vice President, General Counsel,
and Corporate Secretary*

EXHIBIT INDEX

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