BIOCRYST PHARMACEUTICALS INC
Form 8-K
February 08, 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): February 8, 2016

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)	(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)

]
[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))

]

Item 8.01. Other Events.

On February 8, 2016, BioCryst Pharmaceuticals, Inc. (the "Company") announced results from Oral ProphylaxiS-2 ("OPuS-2"), a clinical trial of avoralstat administered three times daily as a liquid-filled soft gel formulation for the prophylactic treatment of hereditary angioedema ("HAE") attacks.

In the OPuS-2 study, HAE patients with a historical attack frequency of greater than 0.45 attacks per week were randomized to treatment with either 500 mg or 300 mg of avoralstat, or placebo, administered three times daily for 12 weeks. The primary goals of the trial were to characterize the efficacy of avoralstat in reducing the frequency of angioedema attacks, and to evaluate the safety and tolerability of 12 weeks of avoralstat treatment. The primary efficacy endpoint was angioedema attack frequency. Thirty-eight subjects received avoralstat 500 mg, 36 subjects received avoralstat 300 mg, and 36 subjects received placebo. Treatment with 500 mg and 300 mg of avoralstat three times daily failed to demonstrate a statistically significantly lower mean attack rate versus placebo.

On February 8, 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 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 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 and BCX7353 and may also increase development costs; that the FDA may withhold market approval for avoralstat and BCX7353. That development of the novel solid dosage form of avoralstat may not achieve twice daily dosing at desired drug exposure levels. That APeX-1 may not be successfully completed or APeX-1 may not result in a positive clinical outcome. 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 Vurrent 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 February 8, 2016 entitled "BioCryst Announces Results from OPuS-2"

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: February 8, 2016

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

EXHIBIT INDEX

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