

BIOCRYST PHARMACEUTICALS INC  
Form 8-K  
May 27, 2014

**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): May 27, 2014**

**BioCryst Pharmaceuticals, Inc.**

**(Exact Name of Registrant as Specified in Charter)**

**Delaware  
(State or Other Jurisdiction  
of incorporation)**

**000-23186  
(Commission  
File Number)  
4505 Emperor Blvd., Suite 200**

**62-1413174  
(IRS Employer  
Identification #)**

**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 May 27, 2014, BioCryst Pharmaceuticals, Inc. ( BioCryst ) issued a news release announcing the results of the BCX4161 OPuS-1 trial, 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 team will host a conference call and webcast on May 27, 2014 at 8:30 a.m. Eastern Time to discuss the results of the BCX4161 OPuS-1 trial and other aspects of BioCryst's HAE development program. The conference call can be accessed by dialing 1-877-303-8027 (United States) or 1-760-536-5165 (International). The webcast can be accessed by logging onto [www.biocryst.com](http://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 May 27, 2014, BioCryst announced preliminary results from its OPuS-1 (Oral Prophylaxis-1) proof of concept Phase 2a clinical trial of orally-administered BCX4161 in patients with hereditary angioedema ( HAE ). The trial met the primary efficacy endpoint, several secondary endpoints and all other objectives established for the trial.

OPuS-1 evaluated 400 mg of BCX4161 administered three times a day for 28 days in HAE patients with a high attack frequency (≥ 1 per week), in a randomized, placebo-controlled, two-period cross-over design. The primary goals for the trial were to estimate the degree of efficacy of BCX4161 in reducing the frequency of angioedema attacks, and to evaluate the safety and tolerability of 28 days of BCX4161 treatment.

Twenty four patients received study drug, and all completed the study. The primary efficacy endpoint for the trial was the by-subject difference in mean angioedema attack rate on BCX4161 compared to placebo. Treatment with BCX4161 demonstrated a statistically significant mean attack rate reduction of 0.45 attacks per week versus placebo,  $p < 0.001$ . The mean attack rate per week was 0.82 on BCX4161 treatment, compared to 1.27 on placebo.

Oral administration of BCX4161 was generally safe and well tolerated, with an adverse event profile similar to that observed for placebo. There was one serious adverse event reported, an abdominal HAE attack during the placebo period. Patient dosing compliance was 98 percent.

The mean number of attack-free days during each treatment period improved from 19 for placebo to 22 for BCX4161,  $p = 0.008$ . Three subjects were attack-free during the BCX4161 period, compared to none during the placebo period. Quality of life was measured by the Angioedema Quality of Life questionnaire, AeQoL, and disease activity by the Angioedema Activity Score, AAS28. For BCX4161, the mean total AeQoL score improved by 8.4 units from baseline compared to 0.5 for placebo,  $p = 0.004$ , and the AAS28 was 21.4 for BCX4161 compared to 28.2 for placebo,  $p = 0.022$ .

Plasma drug concentrations and the degree of plasma kallikrein inhibition achieved after oral dosing with BCX4161 in OPuS-1 HAE patients were similar to those seen in healthy subjects in the Phase 1 trial. In OPuS-1, higher drug exposure was associated with a better clinical outcome.

**About BCX4161**

Discovered by BioCryst, BCX4161 is a novel, selective inhibitor of plasma kallikrein in development for prevention of attacks in patients with hereditary angioedema (HAE). By inhibiting plasma kallikrein, BCX4161 suppresses

bradykinin production. Bradykinin is the mediator of acute swelling attacks in HAE patients.

**About Hereditary Angioedema**

HAE is a rare, severely debilitating and potentially fatal genetic condition that occurs in about 1 in 10,000 to 1 in 50,000 people. HAE symptoms include recurrent episodes of edema in various locations, including the hands, feet, face, genitalia and airway. In addition, patients often have bouts of excruciating abdominal pain, nausea and vomiting that are caused by swelling in the intestinal wall. Airway swelling is particularly dangerous and can lead to death by asphyxiation. Further information regarding HAE can be found at [www.haea.org](http://www.haea.org).

**About BioCryst Pharmaceuticals**

BioCryst Pharmaceuticals designs, optimizes and develops novel small molecule drugs that block key enzymes involved in infectious and rare diseases, with the goal of addressing unmet medical needs of patients and physicians. BioCryst's core development programs include BCX4161 and two next generation oral inhibitors of plasma kallikrein for hereditary angioedema; peramivir, a viral neuraminidase inhibitor for the treatment of influenza; and BCX4430, a broad spectrum antiviral for hemorrhagic fevers. The company has been issued approximately 100 patents on its programs, with approximately 25 of those patents issued in the United States. For more information, please visit the Company's website at [www.BioCryst.com](http://www.BioCryst.com).

**Item 9.01 Financial Statements and Exhibits.**

*(d) Exhibits*

**Exhibit**

No.	Description
99.1	Press release dated May 27, 2014 entitled "BioCryst Announces Positive Results from OPuS-1, a Phase 2 Trial of BCX4161 for the Prophylactic 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 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 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 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; that the Company 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

Vice President, General Counsel and  
Corporate Secretary

Dated: May 27, 2014

**EXHIBIT INDEX**

**Exhibit  
No.**

**Description**

99.1	Press release dated May 27, 2014 entitled BioCryst Announces Positive Results from OPuS-1, a Phase 2 Trial of BCX4161 for the Prophylactic Treatment of Hereditary Angioedema
------	---