BIOCRYST PHARMACEUTICALS INC
Form 8-K/A
September 04, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 8-K/A

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): September 4, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Explanatory Note

In a news release issued under the same headline earlier today by BioCryst Pharmaceuticals, Inc. (the "Company"), the values for the change from baseline in VAS score through 4 hours under BCX7353 Treated Attacks and Placebo Treated Attacks were incorrectly expressed as percentages rather than numbers. The Company has issued a corrected version of the release. In addition, a footnote has been added to the end of the table within the corrected release, which notes baseline composite VAS scores for both BCX7353 treated attacks and placebo treated attacks. The Company hereby amends its Form 8-K dated September 4, 2018 to file the corrected release.

Item 8.01. Other Events.

On September 4, 2018, BioCryst Pharmaceuticals, Inc. (the "Company") announced initial results from the ZENITH-1 trial showing that a single 750 mg oral dose of BCX7353 was well tolerated and superior to placebo ($p<0.05$) against the majority of efficacy endpoints evaluated in HAE patients suffering an acute attack. BCX7353 is a novel oral plasma kallikrein inhibitor being developed for both prophylactic and acute treatment of HAE attacks.

On September 4, 2018, 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/A contains forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors that may cause BioCryst's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These statements reflect BioCryst's current views with respect to future events and are based on assumptions and are 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 remaining cohorts of the ongoing ZENITH-1 trial may not be completed as expected; that the current results of the ZENITH-1 trial may not be predictive of future results, including the results of the remaining cohorts of ZENITH-1 and the APeX-2, APeX-S, and APeX-J trials; that developing BCX7353 for acute or prophylactic treatment may take longer or be more expensive than planned or may ultimately be unsuccessful; that producing a commercial formulation of BCX7353 may take longer than expected or may not occur as planned; that the Food and Drug Administration or other regulatory agencies may require additional studies beyond the studies currently planned, may not support trial designs, or may not provide regulatory clearances, which could result in delay of planned clinical trials; that we may never obtain market approval for BCX7353 or that commercialization of BCX7353 may ultimately be unsuccessful. 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 September 4, 2018 entitled "BioCryst Reports Positive Results across Multiple Endpoints in ZENITH-1 Trial of Oral BCX7353 as Acute Therapy for Hereditary Angioedema (HAE)

Attacks"

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: September 4, 2018

By: /s/ Alane Barnes
Alane Barnes
Senior Vice President and Chief Legal Officer