BIOCRYST PHARMACEUTICALS INC
Form 8-K
February 25, 2019

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 23, 2019

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. [ ]

Item 7.01. Regulation FD Disclosure.

On February 23, 2019, BioCryst Pharmaceuticals, Inc. (the "Company") reported additional topline data from the Phase 2 ZENITH-1 trial, including new data from the 250 mg and 500 mg dose cohorts. Data from the now complete trial confirm previously reported results showing a single dose of oral 750 mg 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 and demonstrate a clear dose response across the three dose levels.

Also, on February 23, 2019, the Company presented a poster with data from the ZENITH-1 trial of BCX7353 for the acute treatment of hereditary angioedema attacks at the American Academy of Allergy, Asthma & Immunology, or AAAAI, annual meeting, and published the poster on the investor relations section of the Company's website. The poster presented at AAAAI and published on the Company's website contained a typographical error, which incorrectly noted in the table titled *RESULTS—SAFETY* that a serious treatment-emergent adverse event, or TEAE occurred after treatment of 1 attack with 750 mg and 0 attacks treated with placebo. The table should have noted that a serious TEAE occurred after treatment of 0 attacks with 750 mg and 1 attack treated with placebo. On February 25, 2019, the Company published the corrected poster to the Company's website.

On February 23, 2019, the Company issued a news release describing the events in this Item 7.01. A copy of the news release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference. On February 25, 2019, the Company published the corrected poster describing the events in this Item 7.01. A copy of the corrected poster is furnished as Exhibit 99.2 hereto and is incorporated herein by reference.

The information furnished in this Item 7.01, including Exhibits 99.1 and Exhibits 99.2, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

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 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 ongoing and future preclinical and clinical development of HAE second generation drug candidates (including APeX-2, APeX-S and APeX-J) may not have positive results, may be more expensive or may not move as quickly as planned; that the FDA, EMA or other applicable regulatory agency may not provide regulatory clearances which may result in delay of planned clinical trials or failure to achieve market approval for 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated February 23, 2019 entitled "BioCryst Reports ZENITH-1 Results With Oral BCX7353 Which Confirm Rapid Onset of Action, Sustained Activity and Robust Dose Response for Treatment of Acute HAE Attacks"
99.2	Poster publication dated February 25, 2019 entitled "Oral Plasma Kallikrein Inhibitor BCX7353 is Safe and Effective as an On-Demand Treatment of Angioedema Attacks in Hereditary Angioedema (HAE) Patients: Results of the Zenith 1 Trial

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 23, 2019

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