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): May 21, 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. [ ]

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	**BCRX**	**Nasdaq global select market**

Item 8.01. Other Events.

On May 21, 2019, BioCryst Pharmaceuticals, Inc. (the "Company") announced that the randomized (n=121), double-blind, placebo-controlled, Phase 3 APeX-2 trial of once-daily, oral BCX7353 for the prevention of hereditary angioedema ("HAE") attacks achieved its primary endpoint for both dose levels (110 mg and 150 mg), with the 150 mg dose reducing the attack rate in HAE patients by 44 percent ($p<0.001$) compared to placebo. Fifty percent of patients receiving 150 mg BCX7353 in APeX-2 had a ≥ 70 percent reduction in their HAE attack rate compared to baseline, compared to 15 percent of placebo patients ($p=0.002$). In APeX-2, both the 110 mg and 150 mg dose levels of once-daily oral BCX7353 were generally safe and well-tolerated. No drug-related serious adverse events were reported. The results from APeX-2 support the submission of a new drug application ("NDA") to the U.S. Food and Drug Administration ("FDA"). The Company plans to submit an NDA to the FDA in the fourth quarter of 2019 and a Marketing Authorization Application to the European Medicines Agency ("EMA") in the first quarter of 2020.

On May 21, 2019, the Company issued a news release announcing the events described in this Item 8.01, which also referenced a conference call and webcast to discuss these recent corporate developments. 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 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 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 developing BCX7353 may take longer or may be more expensive than planned; that ongoing and future preclinical and clinical development of BCX7353 may not advance as expected; that future studies may not enroll the required number of subjects or have positive results; and that the FDA, EMA or other applicable regulatory agencies may require additional studies beyond the studies planned, may not provide regulatory clearances, may impose a clinical hold or may withhold market approval with respect to BCX7353. 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

Exhibit No.	Description
99.1	Press release dated May 21, 2019 entitled "BioCryst's Oral BCX7353 Meets Primary Endpoint in Phase 3 APeX-2 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: May 21, 2019

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

EXHIBIT 99.1

BioCryst's Oral BCX7353 Meets Primary Endpoint in Phase 3 APeX-2 Trial

NDA filing on-track for Q4 2019

RESEARCH TRIANGLE PARK, N.C., May 21, 2019 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that the randomized (n=121), double-blind, placebo-controlled, Phase 3 APeX-2 trial of once-daily, oral BCX7353 for the prevention of hereditary angioedema (HAE) attacks achieved its primary endpoint for both dose levels (110 mg and 150 mg), with the 150 mg dose reducing the attack rate in HAE patients by 44 percent ($p<0.001$) compared to placebo.

Fifty percent of patients receiving 150 mg BCX7353 in APeX-2 had a ≥ 70 percent reduction in their HAE attack rate compared to baseline, compared to 15 percent of placebo patients ($p=0.002$).

In patients on the 150 mg dose with a baseline attack rate of < 2 attacks per month, BCX7353 reduced the HAE attack rate by 66 percent compared to placebo ($p=0.009$). In patients with a baseline attack rate of ≥ 2 attacks per month, the attack rate was reduced by 40 percent ($p=0.005$).

Of 108 patients who completed 24 weeks of study drug treatment, 100 percent continued into the ongoing 48 week extension phase of the trial.

In APeX-2, both the 110 mg and 150 mg dose levels of once-daily oral BCX7353 were generally safe and well-tolerated. No drug-related serious adverse events were reported.

The most common drug-related adverse events reported in at least five percent of patients in APeX-2 were: nausea (9.8% 110 mg, 7.5% 150 mg, 15.4% placebo), dyspepsia (9.8% 110 mg, 7.5% 150 mg, 5.1% placebo) and diarrhea (7.3% 110 mg, 10% 150 mg, 0% placebo).

"HAE patients around the world desperately want access to a cost-effective, convenient, oral therapy to manage their disease. Given the profile of the 150 mg dose of BCX7353 in APeX-2, with half of patients experiencing at least a 70 percent reduction in attack rate, we have a new oral therapy that patients will want to try," said Jon Stonehouse, chief executive officer of BioCryst.

"With successful results from APeX-2, BioCryst is committed to making it easy for HAE patients around the world to access this potentially life-changing oral therapy, and we believe BCX7353 is positioned to become a front-line therapy option," Stonehouse added.

The results from APeX-2 support the submission of a new drug application (NDA) to the U.S. Food and Drug Administration (FDA). BioCryst plans to submit an NDA to the FDA in the fourth quarter of 2019 and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in the first quarter of 2020.

"The additional clinical information we now have from APeX-2 confirms that this is an oral kallikrein inhibitor that is effective at preventing HAE attacks in a large segment of the HAE patient population while having a very attractive tolerability profile. Based on this profile, and the consistent observation that real world efficacy has been higher than clinical trial efficacy with HAE therapies, I expect many patients will want to try this oral option to see how well it works for them," said Bruce Zuraw, M.D., professor of medicine and chief of the Division of Rheumatology, Allergy and Immunology at the University of California School of Medicine, and principal investigator of the APeX-2 trial.

The company plans to submit detailed results from the APeX-2 trial for peer-reviewed publication and presentation.

About APeX-2

APeX-2 is a randomized, double-blind, placebo-controlled, three-arm trial testing two dose levels of orally administered once-daily BCX7353 (110 mg and 150 mg) for prevention of angioedema attacks. The trial enrolled 121 patients with Type I and II HAE in the United States, Canada and Europe.

The primary efficacy endpoint of APeX-2 is the rate of investigator confirmed angioedema attacks over 24 weeks of study drug administration. Following study qualification during a run-in period of 14 to 56 days, patients were randomized 1:1:1 to receive placebo or one of the two doses of BCX7353. Randomization was stratified on a baseline attack rate of <2/month or ≥2/month. Forty-one patients were randomized to 110 mg BCX7353, 40 to 150 mg BCX7353, and 40 to placebo. There was a clear dose response, with the 110 mg dose of BCX7353 reducing HAE attack rate by 30 percent ($p=0.024$) compared to placebo. As noted above, the 150 mg dose reduced attack rate by 44 percent ($p<0.001$) compared to placebo.

To qualify for the trial, patients were required to have a specified number of investigator-confirmed HAE attacks during the run-in period of a maximum of 56 days from the screening visit. The average baseline attack rate prior to randomization was 3.0 per 28 days.

Following completion of the 24 week analysis period, patients continued on study drug in an ongoing extension phase of APeX-2 through 48 weeks. Patients randomized to placebo for 24 weeks were re-randomized to receive one of the two doses of study drug in the extension phase of the trial. Patients who complete 48 weeks may continue in the trial on open-label BCX7353 for up to 96 weeks.

About BCX7353
Discovered by BioCryst, BCX7353 is a novel, oral, once-daily, selective inhibitor of plasma kallikrein currently in advanced clinical development for the prevention and treatment of angioedema attacks in patients with HAE. BCX7353 was generally safe and well tolerated in the Phase 3 APeX-2 and Phase 2 APeX-1 clinical trials. In APeX-2, BCX7353 (150 mg) reduced the HAE attack rate by 44 percent ($p<0.001$) compared to placebo, and reduced the HAE attack rate by ≥ 70 percent in 50 percent of patients. BioCryst is currently conducting APeX-S, a long-term safety clinical trial, and plans to submit an NDA to the FDA in the fourth quarter of 2019 and an MAA to the EMA in the first quarter of 2020. BioCryst has also completed the ZENITH-1 clinical trial. ZENITH-1 was a proof-of-concept Phase 2 clinical trial testing oral BCX7353 for the treatment of acute angioedema attacks.

Conference Call and Webcast
BioCryst management will host a conference call and webcast today, Tuesday, May 21, at 8:30 a.m. ET today to discuss the APeX-2 results. The live call may be accessed by dialing 877-303-8027 for domestic callers and 760-536-5165 for international callers and using conference ID # 8068168. A live webcast of the call and any slides will be available online at the investors section of the company website at www.biocryst.com. A telephone replay of the call will be available by dialing 855-859-2056 for domestic callers or 404-537-3406 for international callers and entering the conference ID# 8068168.

About BioCryst Pharmaceuticals
BioCryst discovers novel, oral small-molecule medicines that treat rare diseases in which significant unmet medical needs exist and an enzyme plays a key role in the biological pathway of the disease. BioCryst has several ongoing development programs including BCX7353, an oral treatment for hereditary angioedema; BCX9930, an oral Factor D inhibitor for the treatment of complement-mediated diseases; galidesivir, a potential treatment for Marburg virus disease and Yellow Fever, and a preclinical program to develop oral ALK-2 inhibitors for the treatment of fibrodysplasia ossificans progressiva. RAPIVAB® (peramivir injection), a viral neuraminidase inhibitor for the treatment of influenza, is BioCryst's first approved product and has received regulatory approval in the U.S., Canada, Australia, Japan, Taiwan, Korea and the European Union. Post-marketing commitments for RAPIVAB are ongoing. For more information, please visit the Company's website at www.BioCryst.com.

Forward-Looking Statements
This press release 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 developing BCX7353 may take longer or may be more expensive than planned; that ongoing and future preclinical and clinical development of BCX7353 may not advance as expected; that future studies may not enroll the required number of subjects or have positive results; and that the FDA, EMA or other applicable regulatory agencies may require additional studies beyond the studies planned, may not provide regulatory clearances, may impose a clinical hold or may withhold market approval with respect to BCX7353. 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.

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