

**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 18, 2020

BioCryst Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

000-23186
(Commission File Number)

62-1413174
(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))

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

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 8.01. Other Events.

On February 18, 2020, BioCryst Pharmaceuticals, Inc. (the “Company”) that the U.S. Food and Drug Administration (“FDA”) has accepted and filed its new drug application (“NDA”) for the approval of oral, once daily berotralstat (BCX7353) for the prevention of hereditary angioedema (“HAE”) attacks.

The Prescription Drug User Fee Act (PDUFA) date for the NDA is December 3, 2020.

In the NDA filing acceptance letter, the FDA stated that they are not currently planning to hold an advisory committee meeting to discuss the NDA.

On February 3, 2020, 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 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 the FDA, PMDA, EMA or other applicable regulatory agency may not approve berotralstat, within the timeframe expected, or at all, may ultimately determine that there are deficiencies in the development program or execution thereof, may require additional information or studies, may disagree with our analyses regarding the safety and efficacy conclusions; in the future they could determine that an advisory committee is necessary; we may learn of previously unknown issues; ongoing studies may take longer or may be more expensive than planned; in the event that berotralstat is approved in any territory, we or our partners may be unable to successfully commercialize as expected; that actual financial results may not be consistent with expectations, including that operating expenses and cash usage may not be within management’s expected ranges. 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

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press release dated February 18, 2020 entitled “FDA Accepts BioCryst’s NDA for Oral, Once Daily Berotralstat (BCX7353) to Prevent HAE Attacks”</u>

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 18, 2020

By: /s/ Alane Barnes

Alane Barnes

Senior Vice President and Chief Legal Officer

FDA Accepts BioCryst's NDA for Oral, Once Daily Berotralstat (BCX7353) to Prevent HAE Attacks

PDUFA date is December 3, 2020

RESEARCH TRIANGLE PARK, N.C., Feb. 18, 2020 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) announced that the U.S. Food and Drug Administration (FDA) has accepted and filed its new drug application (NDA) for the approval of oral, once daily berotralstat (BCX7353) for the prevention of hereditary angioedema (HAE) attacks.

The Prescription Drug User Fee Act (PDUFA) date for the NDA is December 3, 2020.

In the NDA filing acceptance letter, the FDA stated that they are not currently planning to hold an advisory committee meeting to discuss the NDA.

"HAE patients and their physicians tell us they have been waiting for a once daily oral therapy to prevent attacks, and the acceptance of our submission, with a PDUFA date this year, means their wait is nearly over," said Jon Stonehouse, chief executive officer of BioCryst. "We are sharply focused on building out a very experienced commercial team and executing our commercial plan, so we are ready to go fast when we get approval."

About BioCryst Pharmaceuticals

BioCryst Pharmaceuticals 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 berotralstat (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 BCX9250, an ALK-2 inhibitor 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, performance 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 the FDA, PMDA, EMA or other applicable regulatory agency may not approve berotralstat, within the timeframe expected, or at all, may ultimately determine that there are deficiencies in the development program or execution thereof, may require additional information or studies, may disagree with our analyses regarding the safety and efficacy conclusions; in the future they could determine that an advisory committee is necessary; we may learn of previously unknown issues; ongoing studies may take longer or may be more expensive than planned; in the event that berotralstat is approved in any territory, we or our partners may be unable to successfully commercialize as expected; that actual financial results may not be consistent with expectations, including that operating expenses and cash usage may not be within management's expected ranges. 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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