

**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): August 3, 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
<b>Common Stock</b>	<b>BCRX</b>	<b>Nasdaq Global Select Market</b>

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 August 3, 2020, BioCryst Pharmaceuticals, Inc. (the "Company") issued a news release announcing that the U.S. Food and Drug Administration has granted Fast Track designation for its oral Factor D inhibitor, BCX9930, for the treatment of paroxysmal nocturnal hemoglobinuria. A copy of the news release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, 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 Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits.****Exhibit No.   Description**

[99.1](#)            [Press release dated August 3, 2020 entitled "FDA Grants Fast Track Designation for BCX9930 in PNH"](#)

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**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: August 3, 2020

By: /s/ Alane Barnes

Alane Barnes

Senior Vice President and Chief Legal Officer

## FDA Grants Fast Track Designation for BCX9930 in PNH

RESEARCH TRIANGLE PARK, N.C., Aug. 03, 2020 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for its oral Factor D inhibitor, BCX9930, for the treatment of paroxysmal nocturnal hemoglobinuria (PNH).

According to the FDA, the purpose of the Fast Track designation is to get important new drugs to the patient earlier by facilitating the development, and expediting the review, of drugs to treat serious conditions and fill an unmet medical need.

A drug that receives Fast Track designation is eligible for some or all of the following:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval.
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers.
- Eligibility for accelerated approval and priority review, if relevant criteria are met.
- Rolling review, which means that a drug company can submit completed sections of its new drug application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed.

"PNH patients have a tremendous need for therapy improvements and it is exciting for patients that the FDA has reviewed our proof of concept PNH data and granted Fast Track status. This designation can significantly accelerate the development timeline for BCX9930," said Dr. William Sheridan, chief medical officer of BioCryst.

"We look forward to working closely with the FDA to fully utilize the opportunities presented by our Fast Track designation to advance this important medicine to patients as quickly as possible in PNH. In addition, we look forward to regulatory discussions later this year on clinical trials for BCX9930 in nephrology indications," Sheridan added.

### 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 ORLADEYO™ (berotralstat), an oral treatment for hereditary angioedema, BCX9930, an oral Factor D inhibitor for the treatment of complement-mediated diseases, galidesivir, a potential treatment for COVID-19, 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](http://www.BioCryst.com).

### Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding potential benefits associated with an FDA Fast Track designation. These statements involve known and unknown risks, uncertainties and other factors which may cause the opportunities associated with the Fast Track designation for BCX9930 to be materially different from those expressed or implied by the forward-looking statements. These statements reflect our current views 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: Fast Track designation by the FDA may not lead to a faster development, regulatory review, or approval process with the FDA and does not increase the likelihood that BCX9930 will receive marketing approval; the ongoing COVID-19 pandemic could create challenges in all aspects of BioCryst's business, including without limitation delays, stoppages, difficulties and increased expenses with respect to BioCryst's and its partners' development, regulatory processes and supply chains, negatively impact BioCryst's ability to access the capital or credit markets to finance its operations, or have the effect of heightening many of the risks described below or in the documents BioCryst files periodically with the Securities and Exchange Commission; ongoing and future preclinical and clinical development of BCX9930 may not have positive results; BioCryst may not be able to enroll the required number of subjects in planned clinical trials of product candidates; BioCryst may not advance human clinical trials with product candidates as expected; and the FDA may require additional studies beyond the studies planned for product candidates, may not provide regulatory clearances which may result in delay of planned clinical trials, may impose a clinical hold with respect to such product candidates, or may withhold 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.

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