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): March 18, 2021

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)	(IRS Employer Identification No.)

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 7.01. Regulation FD Disclosure.

On March 18, 2021, following a meeting with the Committee for Orphan Medicinal Products, which is the European Medicines Agency's ("EMA") committee responsible for recommending orphan designation of medicines for rare diseases, BioCryst Pharmaceuticals, Inc. (the "Company") withdrew its application for orphan medicinal product designation for ORLADEYO™ (berotralstat) in the European Union ("EU"). Orphan medicinal product designation conveys 10 years of market exclusivity on a product and allows a pharmaceutical company to benefit from incentives from the EU, such as protection from competition once approved. The current patent and patent applications covering ORLADEYO in the EU extend beyond that 10-year period into 2039.

Previously, on February 25, 2021, the Company announced that the Committee for Medicinal Products for Human Use of the EMA had adopted a positive opinion recommending the approval of ORLADEYO for routine prevention of recurrent attacks of hereditary angioedema in adult and adolescent patients aged 12 years and older. Based on this positive opinion, the Company expects an approval decision on ORLADEYO in the EU in the second quarter of 2021.

The information in this Current Report on Form 8-K shall not be deemed "filed" for 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 Securities Act of 1933, as amended, or the Exchange Act, 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 the Company's expectations for ORLADEYO. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements to be materially different from those 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: the ongoing COVID-19 pandemic, which could create challenges in all aspects of the Company's business, including without limitation delays, stoppages, difficulties and increased expenses with respect to regulatory processes or have the effect of heightening the risks described below or in the documents the Company periodically files with the Securities and Exchange Commission; and the EMA or other applicable regulatory agency may require additional studies beyond the studies planned for products and product candidates, may not provide regulatory clearances which may result in delay of planned clinical trials, may impose certain restrictions, warnings, or other requirements on products and product candidates, may impose a clinical hold with respect to product candidates, or may withhold, delay, or withdraw market approval for products and product candidates. 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 actual results to differ materially from those contained in the Company's forward-looking statements.

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.

Date: March 18, 2021

BioCryst Pharmaceuticals, Inc.

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