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 12, 2021

BIOCRYST PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**000-23186**	**62-1413174**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. 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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 May 12, 2021, BioCryst Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the United Kingdom's (UK) Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorization for oral, once-daily ORLADEYO™ (berotralstat) for the routine prevention of recurrent hereditary angioedema (HAE) attacks in HAE patients 12 years and older. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

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.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release dated May 12, 2021 entitled "BioCryst Receives UK Approval of ORLADEYO™ (berotralstat), First Oral, Once-daily Therapy to Prevent Attacks in Hereditary Angioedema Patients"
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 12, 2021

By: /s/ Alane Barnes
Alane Barnes
Chief Legal Officer

EXHIBIT 99.1

BioCryst Receives UK Approval of ORLADEYO™ (berotralstat), First Oral, Once-daily Therapy to Prevent Attacks in Hereditary Angioedema Patients

RESEARCH TRIANGLE PARK, N.C., May 12, 2021 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorization for oral, once-daily ORLADEYO™ (berotralstat) for the routine prevention of recurrent hereditary angioedema (HAE) attacks in HAE patients 12 years and older.

"HAE UK welcomes the decision from the MHRA to grant marketing authorization for berotralstat in the UK. Hereditary angioedema is an unpredictable and life-threatening condition which causes significant emotional and economic burdens on people with HAE and their families and careers. These burdens negatively impact their mental health and well-being, on top of the physical demands of living with a chronic condition. An oral therapy that shows effective control of HAE attacks will provide a different treatment choice for clinicians and patients and will assist in improving the quality of life of those living with the condition," said Laura Szutowicz, chief executive officer of HAE UK.

"This is a significant milestone in furthering our ability to meet the needs of more patients living with HAE. As the first oral, once-daily therapy proven to reduce the number of HAE attacks, today's news has the potential to offer a convenient new treatment option to improve the lives and outcomes of patients with HAE," said Dr. Sorena Kiani, consultant immunologist at Barts Health NHS Trust.

A decision from the National Institute for Health and Care Excellence (NICE) and Scottish Medicines Consortium (SMC) for use of ORLADEYO under the UK's National Health Service (NHS) is anticipated in the fourth quarter of 2021.

"With the approval of the first oral, once-daily treatment in the UK, BioCryst continues to bring ORLADEYO to HAE patients and their families around the world," said Jon Stonehouse, president and chief executive officer of BioCryst.

In the pivotal Phase 3 APeX-2 trial, ORLADEYO significantly reduced attacks at 24 weeks, and this reduction was sustained through 48 weeks. HAE patients who completed 48 weeks of treatment (150 mg) saw reductions in their HAE attack rates, from a mean of 2.9 attacks per month at baseline to a mean of 1.0 attacks per month after 48 weeks of therapy. In the long-term open label APeX-S trial, patients completing 48 weeks of therapy (150 mg) had a mean attack rate of 0.8 attacks per month.

ORLADEYO was safe and well tolerated in both trials. The most frequently reported adverse reactions in patients receiving ORLADEYO compared with placebo were gastrointestinal reactions. These reactions generally occurred early after initiation of treatment with ORLADEYO, became less frequent with time and typically self-resolved.

HAE patients note a significant treatment burden associated with existing prophylactic therapy. In addition to reducing HAE attack rate, data from APeX-2 show that patients reported meaningful improvements in both quality of life, overall patient-reported satisfaction, and significant reductions in their monthly use of standard of care on-demand medicine, while taking oral, once-daily ORLADEYO (150 mg).

About ORLADEYO™ (berotralstat)
ORLADEYO™ (berotralstat) is the first and only oral therapy designed specifically to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 12 years and older. One capsule of ORLADEYO per day works to prevent HAE attacks by decreasing the activity of plasma kallikrein.

The UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) for ORLADEYO will be available from the MHRA website at https://products.mhra.gov.uk/.

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. Oral, once-daily ORLADEYO™ (berotralstat) is approved in the United States, European Union, Japan and the United Kingdom for the prevention of HAE attacks in adults and pediatric patients 12 years and older. BioCryst has several ongoing development programs including BCX9930, an oral Factor D inhibitor for the treatment of complement-mediated diseases, BCX9250, an ALK-2 inhibitor for the treatment of fibrodysplasia ossificans progressiva, and galidesivir, a potential treatment for Marburg virus disease and Yellow Fever. RAPIVAB® (peramivir injection), a viral neuraminidase inhibitor for the treatment of influenza, has received regulatory approval in the U.S., Canada, Australia, Japan, Taiwan and Korea. 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 BioCryst's plans and 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 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: the ongoing COVID-19 pandemic, which 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 periodically files with the Securities and Exchange Commission; BioCryst's ability to successfully implement its commercialization plans for, and to commercialize, ORLADEYO, which could take longer or be more expensive than planned; risks relating to government actions, including that decisions and other actions relating to pricing and reimbursements may not be taken when expected or at all, or that the outcomes of such decisions and other actions may not be in line with BioCryst's current expectations; the commercial viability of ORLADEYO, including its ability to achieve market acceptance; the FDA, EMA, MHRA, PMDA 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; BioCryst's ability to successfully manage its growth and compete effectively; risks related to the international expansion of BioCryst's business; and 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 forward-looking statements.

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