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): April 30, 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 April 30, 2021, BioCryst Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the European Commission has approved oral, once-daily ORLADEYO™ (berotralstat) for the 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.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press release dated April 30, 2021 entitled "BioCryst Receives European Commission 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: April 30, 2021

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

EXHIBIT 99.1

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

RESEARCH TRIANGLE PARK, N.C., April 30, 2021 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that the European Commission (EC) has approved oral, once-daily ORLADEYO™ (berotralstat) for the prevention of recurrent hereditary angioedema (HAE) attacks in HAE patients 12 years and older.

“As the first targeted oral prophylactic therapy approved in Europe, ORLADEYO represents a major advance in treatment for HAE patients who have been waiting for a preventive therapy. Physicians will be delighted to discuss this new option with their patients,” said Emel Aygören-Pürsün, M.D., head of the HAE Center at the University Hospital in Frankfurt.

“ORLADEYO offers people with HAE in Europe and their physicians the first orally administered non-steroidal option for preventing HAE attacks and represents a vitally important and most welcome step in making more treatment options available,” said Henrik Balle Boysen, executive vice president and chief operating officer of HAE International, a global non-profit network of patient associations dedicated to improving the lives of people with HAE.

The EC approval of ORLADEYO is applicable to all European Union member states plus Iceland, Norway and Liechtenstein.

BioCryst has its European commercial team in place and expects to launch ORLADEYO this quarter in Germany, with launches in other European markets to follow. HAE patients in France currently have access to ORLADEYO through an Autorisation Temporaire d'Utilisation de cohorte (cohort ATU).

In the United Kingdom, HAE patients also currently have access to ORLADEYO through an approved early access to medicines scheme (EAMS). A marketing authorization application (MAA) has been submitted to the Medicines and Healthcare products Regulatory Agency (MHRA). Under the new European Commission Decision Reliance Procedure, the MHRA will aim to complete the review of the UK MAA as soon as possible following the EC approval decision.

“Most European HAE patients today treat their disease with on-demand therapy or androgens and we believe the approval of oral, once-daily ORLADEYO provides an exciting new opportunity for these patients to reduce their burden of therapy by moving to prophylaxis with ORLADEYO,” said Jon Stonehouse, president and chief executive officer of BioCryst.

“We saw tremendous enthusiasm and participation from European HAE patients in our clinical trials and we have invested in an experienced European commercial team that is excited to bring ORLADEYO to HAE patients across Europe,” he added.

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). [1,2]

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 full European Summary of Product Characteristics (SMPC) for ORLADEYO will be available from the European Medicines Association website at www.ema.europa.eu.

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 and Japan for the prevention of HAE attacks in adults and pediatric patients 12 years and older, and under regulatory review for approval in the United Kingdom. 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, 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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[1] Johnston, D.T., *et al. Berotralstat Improves Patient-Reported Quality of Life Through 48 Weeks in the Phase 3 APeX-2 Trial; Annual Scientific Meeting of the American College of Allergy, Asthma & Immunology;* ***Poster 154, Nov (2020)***

[2] Jacobs, J, *et al. Berotralstat Positively Impacts Patient-Reported Satisfaction: Results from the Phase 3 APeX-2 trial; Annual Scientific Meeting of the American College of Allergy, Asthma & Immunology;* ***Poster 158, Nov (2020)***