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): January 22, 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 January 22, 2021, BioCryst Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the Ministry of Health, Labor and Welfare (MHLW) in Japan has granted marketing and manufacturing approval for oral, once-daily ORLADEYO™ (berotralstat) 150 mg for prophylactic treatment of hereditary angioedema in adults and pediatric 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 January 22, 2021 entitled “BioCryst Announces Approval of ORLADEYO™ (berotralstat) in Japan for the Prophylactic Treatment of Hereditary Angioedema”
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: January 22, 2021

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

EXHIBIT 99.1

BioCryst Announces Approval of ORLADEYO™ (berotralstat) in Japan for the Prophylactic Treatment of Hereditary Angioedema

RESEARCH TRIANGLE PARK, N.C., Jan. 22, 2021 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that the Ministry of Health, Labor and Welfare (MHLW) in Japan has granted marketing and manufacturing approval for oral, once-daily ORLADEYO™ (berotralstat) 150 mg for prophylactic treatment of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older.

ORLADEYO is the first and only prophylactic HAE medication approved in Japan. One capsule of ORLADEYO per day works to prevent HAE attacks by decreasing the activity of plasma kallikrein.

ORLADEYO will be commercialized in Japan by BioCryst's partner, Torii Pharmaceutical Co., Ltd. OrphanPacific, Inc. is BioCryst's representative partner in Japan and holds the marketing authorization.

Torii will launch ORLADEYO in Japan following the successful completion of BioCryst's pricing negotiations with the Japanese National Health Insurance System (NHI).

"Until now, HAE patients in Japan had no therapies approved to prevent attacks, so the approval of ORLADEYO marks a significant advance in HAE treatment," said Goichi Matsuda, president of Torii. "We are pleased to have the opportunity to bring the first oral treatment option to Japanese HAE patients and are actively preparing for the commercialization."

"Today's approval of ORLADEYO in Japan represents important progress towards our goal to bring an oral, once-daily treatment to HAE patients around the world," said Jon Stonehouse, president and chief executive officer of BioCryst. "Thank you to the HAE patients who participated in our APeX-J trial, to the investigators who conducted it, and to Torii and OrphanPacific for their partnership to achieve this milestone to offer a much-needed new treatment option to HAE patients and physicians in Japan."

BioCryst received Orphan Drug and Sakigake designation for ORLADEYO in Japan and the approval is based on data from the APeX-J and APeX-2 clinical trials. The APeX-J trial in Japan met its primary endpoint ($p=0.003$) of a reduction in HAE attacks from baseline for ORLADEYO 150 mg compared to placebo, and ORLADEYO was safe and generally well-tolerated in the trial. In APeX-2, ORLADEYO also met its primary endpoint ($p<0.001$) for ORLADEYO 150 mg compared to placebo and was safe and generally well-tolerated.

In December 2020, the U.S. Food & Drug Administration (FDA) approved ORLADEYO in the U.S. In Europe, the European Medicines Agency (EMA) validated its marketing authorization application (MAA) submission for ORLADEYO and formal review of the MAA under the centralized procedure is underway. The company expects an approval decision in Europe in the second quarter of 2021.

With the approval in Japan, BioCryst is eligible to receive an additional milestone payment of $15 million from Torii upon receipt of a reimbursement price approval from Japan's National Health Insurance system in excess of the threshold specified in the agreement with Torii. In addition, BioCryst will receive tiered royalties ranging from 20 percent to potentially 40 percent of Japanese net sales.

About ORLADEYO™ (berotralstat)

ORLADEYO™ (berotralstat) is the first and only oral therapy designed specifically to prevent attacks of hereditary angioedema (HAE) in adults 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.

U.S. Indication and Important Safety Information

INDICATION
ORLADEYO™ (berotralstat) is a plasma kallikrein inhibitor indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older.

Limitations of use
The safety and effectiveness of ORLADEYO for the treatment of acute HAE attacks have not been established. ORLADEYO should not be used for the treatment of acute HAE attacks. Additional doses or dosages of ORLADEYO higher than 150 mg once daily are not recommended due to the potential for QT prolongation.

IMPORTANT SAFETY INFORMATION
An increase in QT prolongation was observed at dosages higher than the recommended 150 mg once-daily dosage and was concentration dependent.

The most common adverse reactions (≥10% and higher than placebo) in patients receiving ORLADEYO were abdominal pain, vomiting, diarrhea, back pain, and gastroesophageal reflux disease.

A reduced dosage of 110 mg taken orally once daily with food is recommended in patients with moderate or severe hepatic impairment (Child-Pugh B or C) and in patients taking chronically administered P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP) inhibitors (eg, cyclosporine).

Berotralstat is a substrate of P-gp and BCRP. P-gp inducers (eg, rifampin, St. John's wort) may decrease berotralstat plasma concentration, leading to reduced efficacy of ORLADEYO. The use of P-gp inducers is not recommended with ORLADEYO.

ORLADEYO at a dose of 150 mg is a moderate inhibitor of CYP2D6 and CYP3A4. For concomitant medications with a narrow therapeutic index that are predominantly metabolized by CYP2D6 or CYP3A4, appropriate monitoring and dose titration is recommended. ORLADEYO at a dose of 300 mg is a P-gp inhibitor. Appropriate monitoring and dose titration is recommended for P-gp substrates (eg, digoxin) when coadministering with ORLADEYO.

The safety and effectiveness of ORLADEYO in pediatric patients <12 years of age have not been established.

There are insufficient data available to inform drug-related risks with ORLADEYO use in pregnancy. There are no data on the presence of berotralstat in human milk, its effects on the breastfed infant, or its effects on milk production.

To report SUSPECTED ADVERSE REACTIONS, contact BioCryst Pharmaceuticals, Inc. at 1-833-633-2279 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information.

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 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 European Union. 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.

About Torii Pharmaceutical Co., Ltd.
The corporate mission of Torii Pharmaceutical Co., Ltd. is to contribute to the improvement of human health and to fulfill its responsibilities to customers, shareholders, society and employees, by supplying world-class pharmaceutical products. Torii Pharma focuses on Renal diseases, Hemodialysis, Allergy and Skin diseases as its therapeutic areas of importance. Torii is a member of Japan Tobacco Inc. (JT) group. Collaboration with JT takes the form of functional focus, with JT undertaking R&D on new compounds and Torii integrating manufacture and marketing. In addition to Torii's independent activities, Torii's partnership with JT includes in-licensing of high-quality pharmaceuticals. More details can be found on the corporate website https://www.torii.co.jp/en/.

About OrphanPacific, Inc.
OrphanPacific is dedicated to providing orphan drugs and also developing sales business of essential drugs in Japan. OrphanPacific, a member of the CMIC Group, is pivotal to the Group's Innovative Pharma Model (IPM) strategy, designed to provide support and expertise to global specialty pharmaceutical companies that focus on acquiring the manufacturing and marketing rights of prescription medicines across a broad range of therapeutic areas worldwide but don't have a license to manufacture and distribute the pharmaceutical products in Japan. For more information, please visit www.orphanpacific.com/en/.

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 BioCryst'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: 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 files periodically 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; the results of BioCryst's partnerships with Torii and OrphanPacific may not meet BioCryst's current expectations; risks related to government actions, including that decisions and other actions relating to pricing and exclusivity of ORLADEYO in Japan 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, which could impact the amount of any related royalties BioCryst would be entitled to receive from Torii; the FDA, EMA, PMDA or other applicable regulatory agency may require additional studies beyond the studies planned for product

candidates, including to support the continued commercialization of ORLADEYO, may not provide regulatory clearances which may result in delay of planned clinical trials, may impose certain restrictions, warnings, or other requirements on product candidates, including ORLADEYO, may impose a clinical hold with respect to such product candidates, or may withhold or withdraw market approval for such 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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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/3c7764e3-37b3-428c-8dbf-b81655b08a6c