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): December 3, 2020

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 December 3, 2020, BioCryst Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has approved oral, once-daily ORLADEYO™ (berotralstat) for prophylaxis to prevent attacks of hereditary angioedema in adult 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 Company has established a wholesale acquisition cost (WAC) for ORLADEYO in the United States of $485,004 on an annual basis ($37,308 per 28-day pack of either 150mg or 110mg capsules).

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 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, performances, or achievements expressed or implied by the forward-looking statements. These statements reflect our current views and are based on assumptions and 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 the Company's and its partners' development, regulatory processes, and supply chains, negatively impact the Company'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 the Company files periodically with the Securities and Exchange Commission (SEC); the Company's ability to successfully implement its commercialization plans for, and to commercialize, ORLADEYO, which could take longer or be more expensive than planned; the outcome of pricing, coverage, and reimbursement negotiations with third-party payors for ORLADEYO; 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 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 ORLADYEO, may impose a clinical hold with respect to such product candidates, or may withhold or withdraw market approval for such product candidates; the Company's ability to successfully manage its growth and compete effectively; risks related to the international expansion of the Company's business; and actual financial results may not be consistent with expectations, including that 2020 operating expenses and cash usage may not be within management's expected ranges. Please refer to the documents the Company files periodically with the SEC, 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, which identify important factors that could cause actual results and developments to differ materially from those contained in the Company's forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press release dated December 3, 2020 entitled "BioCryst Announces FDA 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: December 3, 2020

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

EXHIBIT 99.1

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

—Significant and sustained reduction in HAE attacks—

—Oral, once-daily prophylactic option enables HAE patients to reduce burden of therapy[1] —

—ORLADEYO approved for adult and pediatric patients 12 years and older—

RESEARCH TRIANGLE PARK, N.C., Dec. 03, 2020 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that the U.S. Food and Drug Administration (FDA) has approved oral, once-daily ORLADEYO™ (berotralstat) for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older.

“ORLADEYO offers people with HAE and their physicians the first orally administered non-steroidal option for preventing HAE attacks and represents an important and welcome step in making more treatment options available to physicians and patients,” said Anthony J. Castaldo, president and chief executive officer of the US Hereditary Angioedema Association (HAEA).

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.

“Patients and physicians acknowledge that HAE treatments can add a burden to patients’ lives. As an oral, once-daily option, ORLADEYO can provide significant attack reduction and lessen the burden associated with injections and infusions,” said Marc Riedl, M.D., professor of medicine and clinical director, U.S. Hereditary Angioedema Association Center at the University of California, San Diego, and an investigator in the APeX-2 trial.

“With this new treatment option, physicians and patients can continue to have collaborative discussions to choose the treatment that meets each patient’s needs, life circumstances and preferences,” Riedl added.

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 and 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).[2,3]

“The FDA approval of ORLADEYO fulfills a promise BioCryst made to HAE patients that we were committed to helping them achieve the dream of an oral, once-daily medicine to prevent and reduce the burden of their attacks,” said Jon Stonehouse, president and chief executive officer of BioCryst.

“Thank you to the HAE patients who participated in our clinical trials, to the investigators around the world who conducted these trials, to the HAEA for their patient advocacy and to our employees who never forgot that patients were waiting. We will stay focused on enabling access and providing personalized support to HAE patients and physicians,” Stonehouse added.

Commitment to Patient Access

BioCryst is committed to supporting HAE patients taking ORLADEYO through a new program designed to streamline access to therapy. Through EMPOWER Patient Services, each HAE patient and their healthcare provider will have a single point of contact for access to ORLADEYO. A dedicated care coordinator will support access for each patient with comprehensive financial support tools and reimbursement support.

EMPOWER Patients Services is administered by Optime Care Inc., the exclusive specialty pharmacy provider for ORLADEYO. Physicians can begin writing prescriptions for ORLADEYO immediately, with direct to patient shipments from Optime Care expected to begin by the end of December 2020.

Additional information is available at www.ORLADEYO.com and 1-866-5-EMPOWER (1-866-536-7693).

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 for the prevention of HAE attacks in adults and pediatric patients 12 years and older, and under regulatory review for approval in Japan and the European Union. BioCryst has several ongoing development programs including, 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.

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 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 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 2020 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] Radojicic, C, *et al. Patient Perspectives on the Treatment Burden of Injectable Medication Administration for Hereditary Angioedema. Annual Scientific Meeting of the American College of Allergy, Asthma & Immunology;* ***Poster 160, Nov (2020)***

[2] 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)***

[3] 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)***

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/bf57a925-5da4-4c72-8a93-02e9c4308123