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): November 3, 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 2.02. Results of Operations and Financial Condition.

On November 3, 2021, BioCryst Pharmaceuticals, Inc. (the "Company") issued a press release announcing recent corporate developments and its financial results for the third quarter ended September 30, 2021, which also referenced a conference call and webcast to discuss these recent corporate developments and financial results. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

The information furnished on Exhibit 99.1 is incorporated by reference under this Item 7.01 as if fully set forth herein.

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 November 3, 2021 entitled "BioCryst Reports Third Quarter 2021 Financial Results and Upcoming Key Milestones"
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: November 3, 2021

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

EXHIBIT 99.1

BioCryst Reports Third Quarter 2021 Financial Results and Upcoming Key Milestones

—3Q 2021 revenue of $41.0 million—

—ORLADEYO® (berotralstat) net revenue of $37.0 million—

—Full year 2021 ORLADEYO net revenue expected to be $115-$120 million—

RESEARCH TRIANGLE PARK, N.C., Nov. 03, 2021 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today announced financial results for the third quarter ended September 30, 2021, and provided a corporate update.

“With the significant revenue of $115 million to $120 million we expect to generate with ORLADEYO in its first year of launch, and an even larger fast-following pipeline that includes four separate indications currently in pivotal or proof of concept trials in the complement space with BCX9930, BioCryst plans to repeat our clinical and commercial success with ORLADEYO again and again as we bring these much-needed oral medicines to the patients who are waiting for them,” said Jon Stonehouse, president and chief executive officer of BioCryst.

Program Updates and Key Milestones

ORLADEYO® (berotralstat): Oral, Once-daily Treatment for Prevention of Hereditary Angioedema (HAE) Attacks

U.S. Launch

“Almost a year into the launch of ORLADEYO, we continue to see strong, consistent demand from new patients switching to ORLADEYO from their existing injectable prophylactic and acute therapies, and it is exciting to see the positive impact ORLADEYO is having on their lives. With the excellent start to the launch, and the excitement we hear from physicians and patients, ORLADEYO is now on a trajectory to become the market leader in HAE prophylaxis,” said Charlie Gayer, chief commercial officer of BioCryst.

- ORLADEYO net revenue in the third quarter of 2021 was $37.0 million.
- New patient demand for ORLADEYO remains strong and consistent with as many new patients added in Q3 as in Q2.
- Patient switches continue to drive the launch with more than half of patients who were new to ORLADEYO in the third quarter switching from other prophylactic medicine to ORLADEYO and the remainder from acute-only treatment.
- The number of new physicians prescribing ORLADEYO grew by another 25 percent in the third quarter and the ORLADEYO prescriber base has now increased to include nearly half of the top 500 hereditary angioedema (HAE)-treating physicians in the United States.
- ORLADEYO has been very well received by payors and is now covered by nearly all national and regional pharmacy benefit managers.
- Most patients continue to have an excellent experience on ORLADEYO and remain on therapy. Through the launch thus far, patient retention on therapy remains consistent with the one-year patient retention rate observed in the APeX-2 clinical trial.

ORLADEYO: Global Updates

- ORLADEYO has received reimbursement approval in Norway and is expected to launch in Norway in early December.
- On September 15, 2021, the company announced that the United Kingdom’s National Institute for Health and Care Excellence had recommended ORLADEYO for preventing recurrent attacks of HAE in eligible patients 12 years and older if they have at least two attacks per month.
- On September 9, 2021, the company announced that the Ministry of Health and Prevention in the United Arab Emirates (UAE) had granted marketing authorization for ORLADEYO for the prevention of recurrent attacks in patients with HAE 12 years and older. To support commercialization efforts in the UAE, BioCryst has entered into a supply and distribution agreement with NewBridge Pharmaceuticals, which also covers the Gulf Cooperation Council and Iraq.
- On August 25, 2021, the company announced that the new drug submission for ORLADEYO had been accepted for review by Health Canada for the prevention of recurrent attacks in patients with HAE 12 years and older. The company also announced that Swissmedic has accepted BioCryst’s marketing authorization application for ORLADEYO for review.

Complement Oral Factor D Inhibitor Program – BCX9930

- Trial site start-up activities are underway at sites around the world for REDEEM-1 and REDEEM-2, two pivotal trials with the company's oral Factor D inhibitor, BCX9930, in patients with paroxysmal nocturnal hemoglobinuria (PNH). REDEEM-1 is a randomized, open-label, active, comparator-controlled comparison of the efficacy and safety of BCX9930 (500 mg bid) monotherapy in approximately 81 PNH patients with an inadequate response to a C5 inhibitor. REDEEM-2 is a randomized, placebo-controlled trial to evaluate the efficacy and safety of BCX9930 (500 mg bid) as monotherapy versus placebo in approximately 57 PNH patients not currently receiving complement inhibitor therapy. The primary endpoint for both trials is the change from baseline in hemoglobin, assessed at weeks 12 to 24 in REDEEM-1 and at week 12 in REDEEM-2. Patient enrollment is expected to begin in the fourth quarter of 2021.

- In the fourth quarter of 2021, the company also is preparing to initiate a proof of concept trial of oral BCX9930 (500 mg bid) in renal complement-mediated diseases. The trial will be a basket study to evaluate BCX9930 for the potential to treat patients with C3 glomerulopathy, IgA nephropathy and primary membranous nephropathy.

- The company has completed a proof of concept trial in patients with PNH, including both treatment-naïve and those patients with an inadequate response to C5 inhibitors. Patients on BCX9930 have been allowed to roll over with continued follow-up into a long-term safety trial. The safety and efficacy data collected from these patients in the long-term safety trial provides the company with a high degree of confidence for the success of the pivotal trials.

Additional Updates

- On September 20, 2021, the company announced the appointment of Amy McKee, M.D. to the BioCryst board of directors.

- On September 1, 2021, the company announced that the U.S. Department of Health and Human Services had exercised its option to purchase an additional 10,000 doses of BioCryst's antiviral influenza therapy, RAPIVAB® (peramivir injection), for approximately $7 million.

- On August 26, 2021, the company announced the appointment of Steven Galson, M.D., MPH to the BioCryst board of directors.

- On July 28, 2021, the company announced the appointment of Vincent Milano to the BioCryst board of directors.

Third Quarter 2021 Financial Results

For the three months ended September 30, 2021, total revenues were $41.0 million, compared to $6.1 million in the third quarter of 2020. The increase was primarily due to $37.0 million in ORLADEYO net revenue in the third quarter of 2021.

Research and development expenses for the third quarter of 2021 increased to $50.0 million from $30.2 million in the third quarter of 2020, primarily due to increased investment in the development of BCX9930 and other research, preclinical and development costs, offset by a reduction in spend on the ORLADEYO program following our commercial launch in December 2020.

Selling, general and administrative expenses for the third quarter of 2021 increased to $35.0 million, compared to $17.2 million in the third quarter of 2020. The increase was primarily due to increased investment to support the U.S. commercial launch of ORLADEYO and expanded international operations.

Interest expense was $14.1 million in the third quarter of 2021, compared to $2.9 million in the third quarter of 2020. The increase was due to service on the royalty and debt financings, which were completed in December 2020. The interest payment-in-kind (PIK) option on the Athyrium term loan has been exercised and $5.4 million has been added in the third quarter of 2021 and $12.9 million since issuance, to the $125 million principal.

Net loss for the third quarter of 2021 was $58.8 million, or $0.33 per share, compared to a net loss of $46.1 million, or $0.26 per share, for the third quarter of 2020.

Cash, cash equivalents, restricted cash and investments totaled $203.9 million at September 30, 2021, compared to $148.5 million at September 30, 2020. Operating cash use for the third quarter of 2021 was $18.8 million.

Financial Outlook for 2021

Based on the strength of the ORLADEYO launch, and continued growth from new patient demand expected in the fourth quarter, the company now expects full year 2021 net ORLADEYO revenue to be between $115 million and $120 million. Based on our expectations for revenue, operating expenses, and our option to access an additional $75 million from our existing credit facility, we believe our current cash runway takes us into 2023.

Conference Call and Webcast

BioCryst management will host a conference call and webcast at 8:30 a.m. ET today to discuss the financial results and provide a corporate update. The live call may be accessed by dialing 877-303-8027 for domestic callers and 760-536-5165 for international callers and using conference ID # 2592545. A live webcast of the call and any slides will be available online at the investors

section of the company website at www.biocryst.com. A telephone replay of the call will be available by dialing 855-859-2056 for domestic callers or 404-537-3406 for international callers and entering the conference ID # 2592545.

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, the European Union, Japan, the United Kingdom and the United Arab Emirates. 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) 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 future results, performance or achievements. 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, 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 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 third parties, including NewBridge Pharmaceuticals and Torii Pharmaceutical Co., Ltd. ("Torii"), may not meet BioCryst's current expectations; risks related to government actions, including that decisions and other actions, including as they relate to pricing, 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 also impact the amount of any related royalties BioCryst would be entitled to receive from Torii; ongoing and future preclinical and clinical development of BCX9930, BCX9250 and galidesivir may not have positive results; BioCryst may not be able to enroll the required number of subjects in planned clinical trials of product candidates; BioCryst may not advance human clinical trials with product candidates as expected; the FDA, Health Canada, Swissmedic 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; product candidates, if approved, may not achieve market acceptance; BioCryst's ability to successfully commercialize its products and product candidates, 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 revenue, 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 projections and forward-looking statements.

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BIOCRYST PHARMACEUTICALS, INC.
CONSOLIDATED FINANCIAL SUMMARY
(in thousands, except per share)

Statements of Operations (Unaudited)

	Three Months Ended	Nine Months Ended

	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
Revenues:				
Product sales	$ 39,141	$ 2,478	$ 90,442	$ 2,696
Royalty revenue	322	254	(447)	2,243
Collaborative and other research and development	1,531	3,370	20,017	8,857
Total revenues	40,994	6,102	110,012	13,796
Expenses:				
Cost of product sales	591	1,517	6,811	1,517
Research and development	49,971	30,245	145,279	87,610
Selling, general and administrative	34,992	17,195	83,431	46,943
Royalty	24	9	34	78
Total operating expenses	85,578	48,966	235,555	136,148
Loss from operations	(44,584)	(42,864)	(125,543)	(122,352)
Interest and other income	9	(312)	48	8,892
Interest expense	(14,115)	(2,927)	(40,514)	(8,892)
Gain (loss) on foreign currency derivative	(111)	(12)	(274)	31
Net loss	$ (58,801)	$ (46,115)	$ (166,283)	$ (122,321)
Basic and diluted net loss per common share	$ (0.33)	$ (0.26)	$ (0.93)	$ (0.75)
Weighted average shares outstanding	179,106	176,521	178,199	164,127

Balance Sheet Data (in thousands)

	September 30, 2021 (Unaudited)	December 31, 2020 (Note 1)
Cash, cash equivalents and investments	$ 199,597	$ 300,366
Restricted cash	4,296	2,221
Trade receivables	26,212	8,646
Total assets	265,763	334,715
Non-recourse notes payable	30,000	30,000
Secured term loan	132,050	119,735
Royalty financing obligation	142,114	124,717
Accumulated deficit	(1,189,725)	(1,023,442)
Stockholders’ deficit	(147,044)	(19,262)
Shares of common stock outstanding	179,791	176,883

Note 1: Derived from audited financial statements.