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 9, 2023

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 January 9, 2023, BioCryst Pharmaceuticals, Inc. (the "Company") issued a press release announcing preliminary, unaudited ORLADEYO® (berotralstat) net revenue for the fourth quarter and full year ended December 31, 2022 and providing new guidance for full year 2023 ORLADEYO net revenue and expected peak ORLADEYO sales. The press release also referenced a previously announced, upcoming webcast presentation by the Company at the 41st Annual J.P. Morgan Healthcare Conference in San Francisco on January 10, 2023 at 6:00 p.m. ET. 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.

On January 9, 2023, the Company also issued a press release announcing initial data from ongoing phase 1 single ascending dose and multiple ascending dose trials in healthy volunteers. These data support the development of BCX10013 as a potential best-in-class, once-daily, oral Factor D inhibitor for multiple complement-mediated diseases. A copy of the press release is furnished as Exhibit 99.2 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 9, 2023 entitled "BioCryst Announces Preliminary Full Year 2022 ORLADEYO® (berotralstat) Net Revenue and Provides Full Year 2023 ORLADEYO Net Revenue Guidance"
99.2	Press release dated January 9, 2023 entitled "BioCryst Reports Initial Clinical Data with Oral Factor D Inhibitor BCX10013 Supporting Development as a Once-daily Treatment for Complement-mediated Diseases"
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 9, 2023

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

BioCryst Announces Preliminary Full Year 2022 ORLADEYO® (berotralstat) Net Revenue and Provides Full Year 2023 ORLADEYO Net Revenue Guidance

—ORLADEYO preliminary 2022 full year net revenue of $251.6 million (+105 percent y-o-y)—

—ORLADEYO net revenue expected to be no less than $320 million in 2023—

—Company expects ORLADEYO peak sales of $1 billion—

RESEARCH TRIANGLE PARK, N.C., Jan. 09, 2023 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced preliminary, unaudited ORLADEYO® (berotralstat) net revenue for the fourth quarter and full year 2022 and provided guidance for full year 2023 ORLADEYO net revenue and expected peak ORLADEYO sales.

"In our second year on the market we more than doubled our first year ORLADEYO sales and are more than a quarter of the way towards $1 billion in peak sales. This continues to be an exceptional launch of an oral rare disease drug and we expect this success to continue creating real value for patients and for shareholders this year and for many years to come," said Jon Stonehouse, president and chief executive officer of BioCryst.

Preliminary, unaudited ORLADEYO net revenue in the fourth quarter of 2022 was $70.7 million (+53 percent y-o-y). Preliminary, unaudited ORLADEYO net revenue for full year 2022 was $251.6 million (+105 percent y-o-y).

Fourth Quarter and Full Year 2022 ORLADEYO Revenue Dynamics

"The number of patients on therapy at the end of 2022 was in-line with our expectations as patients continued to switch to ORLADEYO in the fourth quarter. Revenue in the quarter lagged our expectations slightly as we saw fewer paid product shipments based on seasonal factors and lower conversion from free to paid product than expected. We see continued growth in 2023 in the U.S. and around the world as we advance toward $1 billion in peak ORLADEYO sales," said Charlie Gayer, chief commercial officer of BioCryst.

2023 Financial Outlook

The company expects full year 2023 global net ORLADEYO revenue to be no less than $320 million. As in 2022, due to the seasonal impact of managed care reauthorizations in the first quarter of the year, the company expects revenue in the first quarter of 2023 to be similar to revenue in the fourth quarter of 2022.

Presentation Tomorrow at 41st Annual J.P. Morgan Healthcare Conference

On Tuesday, January 10, 2023 at 6:00 p.m. ET, the company will present at the 41st Annual J.P. Morgan Healthcare Conference in San Francisco. Links to a live audio webcast and replay of the presentation may be accessed in the Investors section of BioCryst's website at https://www.biocryst.com/.

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 many global markets. BioCryst has active programs to develop oral medicines for multiple targets across the complement system, including BCX10013, an oral Factor D inhibitor in clinical development. RAPIVAB® (peramivir injection) is approved in the U.S. and multiple global markets, with post-marketing commitments 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 preliminary, unaudited net revenue results and 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 preliminary, unaudited net revenue results and 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: BioCryst's completion of its customary closing, review and audit procedures for the fourth quarter and full year 2022, which may cause actual net revenue results for these periods to differ materially from the preliminary, unaudited revenue results; 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 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; the FDA 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 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, which identify important factors that could cause actual results to differ materially from those contained in BioCryst's projections and forward-looking statements.

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BioCryst Reports Initial Clinical Data with Oral Factor D Inhibitor BCX10013 Supporting Development as a Once-daily Treatment for Complement-mediated Diseases

—Company also expanding its discovery platform in complement-mediated diseases, including potent, selective, oral molecules targeting C2—

RESEARCH TRIANGLE PARK, N.C., Jan. 09, 2023 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that initial data from ongoing phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) trials in healthy volunteers show rapid, sustained and >97 percent suppression of the alternative pathway (AP) of the complement system 24 hours following a single 110 mg dose. BCX10013 has been safe and generally well-tolerated at all doses studied to date. These data support the development of BCX10013 as a potential best-in-class, once-daily, oral Factor D inhibitor for multiple complement-mediated diseases.

BioCryst has initiated plans to advance BCX10013 into patient studies in mid-2023, including in patients with paroxysmal nocturnal hemoglobinuria (PNH), to evaluate once-daily dosing.

The company expects to confirm the optimal dosing for pivotal trials by the end of the year, move directly into a pivotal trial in patients with immunoglobulin A nephropathy (IgAN), and rapidly expand into pivotal trials in additional indications.

“We remain committed to bringing better options to patients with complement-mediated diseases and we are excited to see the immediate and durable effect of BCX10013 in suppressing the alternative pathway. Our next step is to gather data from a small number of patients, utilizing the excellent biomarkers in PNH, to quickly confirm optimal clinical dosing this year. We then plan to rapidly advance the program into pivotal trials in multiple complement-mediated diseases, beginning next year with IgAN. We believe BCX10013 has the potential to be a best-in-class treatment option with an oral, once-daily profile,” said Dr. Helen Thackray, chief research and development officer at BioCryst.

In the SAD assessment to date, cohorts of healthy volunteers received a single dose of 1 mg, 3 mg, 10 mg, 40 mg, 80 mg or 110 mg of oral BCX10013 or placebo. In the MAD assessment to date, cohorts of healthy volunteers received 20 mg, 40 mg or 80 mg of oral BCX10013 or placebo administered once daily for seven days (20 mg cohort) or 14 days (40 mg and 80 mg cohorts).

Following single BCX10013 dose administration, the onset of AP inhibition occurred within one hour and increased in a dose-dependent manner. At 110 mg, the highest dose studied to date, AP activity was suppressed by a mean of 97.8 percent at 24 hours post-dose. Suppression of AP activity by BCX10013 was assessed using the AP Wieslab® assay, which measures functional activity of the complement system. In the MAD studies with once-daily dosing, exposure to BCX10013 was approximately dose proportional over the studied dose range and steady-state was achieved in 7 to 14 days with modest accumulation.

Additional data from the trial can be found in slides at the investors section of the company website at www.biocryst.com.

Expanding Programs in Complement-mediated Diseases

In addition to BCX10013, which targets Factor D in the alternative pathway of complement, BioCryst is pursuing oral medicines directed at other targets across the classical, lectin and terminal pathways of the complement system, including C2, a critical upstream serine protease enzyme for activation of the classical and lectin pathways. The company has developed potent, selective molecules targeting C2, which are currently in lead optimization.

“We believe that our ability to develop oral medicines as monotherapy against targets across multiple complement pathways, in addition to the alternative pathway, could allow us to help more patients with distinctly different complement-mediated rare diseases. With our oral approach, BioCryst also has the opportunity to develop combination therapies to improve therapeutic options for those diseases affecting multiple pathways of the complement system,” Thackray added.

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 many global markets. BioCryst has active programs to develop oral medicines for multiple targets across the complement system, including BCX10013, an oral Factor D inhibitor in clinical development. RAPIVAB® (peramivir injection) is approved in the U.S. and multiple global markets, with post-marketing commitments 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 our plans and expectations for our complement program and other 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; ongoing and future preclinical and clinical development of BCX10013 and other product candidates 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 or other applicable regulatory agency may require additional studies beyond the studies planned for 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 product candidates, may impose a clinical hold with respect to product candidates, or may withhold or delay market approval for product candidates; product candidates, if approved, may not achieve market acceptance; 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 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 actual results to differ materially from those contained in BioCryst's forward-looking statements.

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