

**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 5, 2024

BioCryst Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation)

000-23186

(Commission File Number)

62-1413174

(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 5, 2024, 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, 2023. The Company also provided guidance for full year 2024 ORLADEYO net revenue, full year 2024 operating expenses, expected peak ORLADEYO sales and an accelerated path to profitability. The press release also referenced a previously announced, upcoming webcast presentation by the Company at the 42nd Annual J.P. Morgan Healthcare Conference in San Francisco on January 9, 2024 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.

Effective January 8, 2024, the Company is implementing an increase in the wholesale acquisition cost (WAC) for ORLADEYO in the United States from \$40,348.60 per 28-day pack (of either 150mg or 110mg capsules) to \$42,366.03 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit**No.****Description**

<u>99.1</u>	<u>Press release dated January 5, 2024 entitled "BioCryst Announces Preliminary Full Year 2023 ORLADEYO® (berotralstat) Net Revenue of \$325 Million, Provides 2024 Guidance and Accelerated Path to Profitability"</u>
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 8, 2024

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

BioCryst Announces Preliminary Full Year 2023 ORLADEYO® (berotralstat) Net Revenue of \$325 Million, Provides 2024 Guidance and Accelerated Path to Profitability

—ORLADEYO preliminary 2023 full year net revenue of \$325 million (+29 percent y-o-y)—

—ORLADEYO net revenue expected to be between \$380-\$400 million in 2024, on trajectory for \$1 billion in peak sales—

—Operating expenses expected to remain flat (\$365-\$375 million) in 2024—

—Company expects operating profit in 2024, approaching positive EPS and positive cash flow in 2H 2025—

RESEARCH TRIANGLE PARK, N.C., Jan. 05, 2024 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced preliminary, unaudited ORLADEYO® (berotralstat) net revenue for the fourth quarter and full year 2023. The company also provided guidance for full year 2024 ORLADEYO net revenue, full year 2024 operating expenses, expected peak ORLADEYO sales and an accelerated path to profitability.

“After three years on the market, ORLADEYO continues on a steady growth trajectory to achieve \$1 billion at peak. This commercial success, alongside our proven discovery platform that is producing additional first-in-class or best-in-class molecules, uniquely positions BioCryst to achieve financial independence from the capital markets and accelerate our path to profitability,” said Jon Stonehouse, president and chief executive officer of BioCryst.

The company also announced that, if its ongoing proof-of-concept trial produces best-in-class data, it plans to out-license late-stage development and commercialization of BCX10013, its potential once-daily, oral Factor D inhibitor, to a partner that can drive the speed and breadth of investment required to accelerate BCX10013 for patients across multiple complement-mediated diseases and maximize the commercial potential of the program. As a result, the company has reduced the size of its R&D organization and accelerated its timeline to profitability.

Preliminary Fourth Quarter and Full Year 2023 ORLADEYO Revenue and 2024 ORLADEYO Outlook

Preliminary, unaudited ORLADEYO net revenue in the fourth quarter of 2023 was \$89.9 million (+27 percent y-o-y). Preliminary, unaudited ORLADEYO net revenue for full year 2023 was \$325 million (+29 percent y-o-y).

The company expects full year 2024 global net ORLADEYO revenue to be between \$380 million and \$400 million. The general pattern of revenue throughout 2024 is expected to be similar to past years, with the seasonal impact of prescription reauthorizations and the potential impact of the Inflation Reduction Act in the first quarter driving a quarter-over-quarter revenue decline in the first quarter, followed by a strong return to growth in the second quarter.

“ORLADEYO growth remained strong in the fourth quarter of 2023 as hereditary angioedema patients gain the excellent attack control they expect. Comparing U.S. patient trends year over year (y-o-y), we had more new patient prescriptions and a lower average rate of monthly discontinuations in 2023 compared to 2022. U.S. performance combined with continued global expansion keep ORLADEYO on track for \$1 billion in peak sales,” said Charlie Gayer, chief commercial officer of BioCryst.

Operating Expense and Profitability Outlook

The company expects full year 2024 operating expenses to be between \$365 million and \$375 million, flat to expected full year 2023 operating expenses. The company now expects that R&D expenses in 2024 will be reduced by \$20 million versus 2023. This represents a \$45 million to \$55 million reduction from the 2024 R&D expense guidance it provided at its R&D Day in November 2023, and reflects both the R&D restructuring and the postponement of previously planned capital expenditures at its Discovery Center in Alabama. SG&A expenses are expected to increase by \$20 million in 2024, primarily to support the continued U.S. and global growth of ORLADEYO to \$1 billion in peak sales.

This operating expense outlook does not reflect non-cash stock compensation expense, or one-time expenses related to the reduction of 59 jobs (10 percent of total organization) in the first quarter of 2024.

Based on the company’s disciplined approach to capital allocation, and the revenue expected from ORLADEYO, the company expects to achieve a full-year operating profit in 2024 (not including non-cash stock compensation), be approaching quarterly positive earnings per share (EPS) and positive cash flow in the second half of 2025 (not including non-cash stock compensation), and be profitable on an EPS basis, with positive cash flow, for full year 2026. The company expects it can achieve these financial milestones without raising additional funds and does not intend to draw the additional \$150 million of debt available to it from Pharmakon.

Presentation Tuesday at 42nd Annual J.P. Morgan Healthcare Conference

On Tuesday, January 9, 2024 at 6:00 p.m. ET, the company will present at the 42nd 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 is a global biotechnology company with a deep commitment to improving the lives of people living with complement-mediated and other rare diseases. BioCryst leverages its expertise in structure-guided drug design to develop first-in-class or best-in-class oral small-molecule and protein therapeutics to target difficult-to-treat diseases. BioCryst has commercialized ORLADEYO[®] (berotralstat), the first oral, once-daily plasma kallikrein inhibitor, and is advancing a pipeline of small-molecule and protein therapies. For more information, please visit www.biocryst.com or follow us on LinkedIn.

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 2023, 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; BioCryst's ability to successfully implement its plans for BCX10013, including any out-licensing of late-stage development and commercialization of BCX10013 as described herein; risks related to the reduction in size of BioCryst's R&D organization; 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; timing for achieving profitability and positive cash flow may not meet management's expectations; statements and projections regarding financial guidance and goals and the attainment of such goals may differ from actual results based on market factors and BioCryst's ability to execute its operational and budget plans; 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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