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 4, 2024

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 4, 2024, BioCryst Pharmaceuticals, Inc. (the "Company") issued a press release announcing recent corporate developments and its financial results for the third quarter ended September 30, 2024, 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, including Exhibit 99.1 furnished hereto, 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 4, 2024 entitled "BioCryst Reports Third Quarter 2024 Financial Results and Provides Business Update"
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 4, 2024

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

BioCryst Reports Third Quarter 2024 Financial Results and Provides Business Update

— Q3 2024 ORLADEYO net revenue of $116.3 million (+35.7 percent y-o-y) —

— Full-year 2024 ORLADEYO revenue guidance adjusted to $430-$435 million (top end of prior guidance range) —

— Company introduces full-year 2024 total product revenue guidance of $443-$448 million based on additional 2024 revenue from RAPIVAB —

— BCX17725 for Netherton syndrome advances into the clinic —

— Company generates GAAP operating profit of $7.7 million in third quarter ($24.9 million non-GAAP operating profit) —

RESEARCH TRIANGLE PARK, N.C., Nov. 04, 2024 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today reported financial results for the third quarter ended September 30, 2024, and provided a corporate update.

“Our third quarter performance continues to build on the outstanding year we are having, with significant revenue growth, strong patient demand, pipeline advancement and operating profitability in the quarter. As we look ahead, we see robust and durable revenue growth, new opportunities for younger children to benefit from ORLADEYO, and data readouts from BCX17725 in Netherton syndrome and avoralstat in DME, all while moving closer to sustainable profitability,” said Jon Stonehouse, president and chief executive officer of BioCryst.

Program Updates

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

“The real-world efficacy and convenience patients and physicians are experiencing with ORLADEYO are driving accelerated commercial momentum that translates to nearly 36 percent revenue growth in our fourth year on the market. Based on this established sales trajectory, and the continued, durable strength of patient demand we see for ORLADEYO, we are more confident than ever of achieving peak sales of $1 billion for ORLADEYO,” said Charlie Gayer, chief commercial officer of BioCryst.

- ORLADEYO net revenue in the third quarter of 2024 was $116.3 million (+35.7 percent year-over-year (y-o-y)).
- Start forms in the U.S. are up 14.2 percent over the past 12 months compared to the prior 12 months; and 67 new U.S. prescribers were added during the third quarter, one of the highest totals over the most recent eight quarters.
- The reimbursed product rate in the U.S. increased 0.4 percent in the third quarter to 74.8 percent.
- Sales from outside the U.S. contributed 11.4 percent of global ORLADEYO net revenues in the third quarter.
- Since launch, approximately half of patients who have started ORLADEYO have switched from another prophylactic therapy. The company has begun the observational Phase 4 APeX-T study, designed to generate real-world data to inform physicians on the best individual approaches to support transition to ORLADEYO.

Rare Disease Pipeline

“The goal with our pipeline is to build on our success with ORLADEYO by bringing the next highly differentiated product to patients living with rare disease. We are making excellent progress, with BCX17725 now in the clinic, avoralstat nearing the clinic and initial patient data from both programs expected next year. These programs would address significant unmet needs for patients with Netherton syndrome and DME, respectively,” said Dr. Helen Thackray, chief research and development officer at BioCryst.

- The company has advanced BCX17725, its KLK5 inhibitor for the treatment of Netherton syndrome, into clinical trials and expects initial data from the program in 2025.
    - Netherton syndrome is a serious, rare, lifelong genetic disorder affecting the skin, hair, and immune system, caused by lack of normal function of a natural inhibitor of KLK5. People with Netherton syndrome often have red, scaly, inflamed skin, fragile hair, and are more likely to develop skin infections, allergies, asthma and eczema. Netherton syndrome can be life threatening, especially during infancy when patients are vulnerable to dehydration and recurrent infections. Currently, there are no approved treatments for Netherton syndrome.
- In 2025, the company plans to advance avoralstat, a plasma kallikrein inhibitor, into a clinical trial of patients with diabetic macular edema (DME).
    - DME is an important cause of vision loss in diabetes and is due to leakage from the blood vessels in the retina. While current treatments focus on VEGF inhibition, DME can develop from other mechanisms, such as the kallikrein-

bradykinin pathway. This is supported by observations that many DME patients have an incomplete response to intravitreal anti-VEGF therapies that are administered every four to eight weeks. Avoralstat targets the kallikrein-bradykinin system on the retinal vascular endothelial cells and may result in less vascular leakage and less edema. Avoralstat, delivered to the suprachoroidal space as a depot formulation, is designed to provide high dose levels to the retinal vessels with long-lasting exposure, which could result in less frequent injections and a reduced burden on patients and the healthcare system.

Third Quarter 2024 Financial Results

“It is exciting to see continued ORLADEYO growth alongside the significant progress advancing our pipeline, and another quarter of operating profit. BioCryst is in the strongest financial position in its history,” said Anthony Doyle, chief financial officer at BioCryst.

For the three months ended September 30, 2024, total revenues were $117.1 million, compared to $86.7 million in the third quarter of 2023 (+35.1 percent y-o-y). The increase was primarily due to $116.3 million in ORLADEYO net revenue in the third quarter of 2024, compared to $85.7 million in ORLADEYO net revenue in the third quarter of 2023 (+35.7 percent y-o-y).

Research and development expenses for the third quarter of 2024 decreased to $41.1 million from $46.9 million in the third quarter of 2023 (-12.4 percent y-o-y), primarily due to decreased investment following the discontinuation of the BCX10013 program, partially offset by investments to advance our early clinical and discovery programs and an increased investment in the APeX-P program in preparation for regulatory filings next year.

Selling, general and administrative expenses for the third quarter of 2024 increased to $65.1 million, compared to $50.6 million in the third quarter of 2023 (+28.7 percent y-o-y). The increase was primarily due to increased commercial investment to support our growing revenue, newly launched regions and expanded international operations. There was also an increase in general and administrative expenses to support commercial growth.

Interest expense was $24.8 million in the third quarter of 2024, compared to $27.3 million in the third quarter of 2023 (-9.2 percent y-o-y). The decrease was primarily due to a decrease in the amortization of interest associated with our royalty financing obligations. Due to the strong cash position of the company, we declined to elect the payment-in-kind (PIK) option related to the Pharmakon term loan for the third quarter of 2024, resulting in a cash interest payment of $10.2 million in the third quarter of 2024 compared to $4.9 million in the third quarter of 2023. The PIK option has now expired. Additionally, the company chose not to execute its option, which expired September 30, 2024, to draw the additional $150 million of debt available to it from Pharmakon.

GAAP operating profit for the third quarter of 2024 was $7.7 million, compared to a GAAP operating loss of $11.9 million for the third quarter of 2023. Non-GAAP operating profit, excluding stock-based compensation expense, was $24.9 million for the third quarter of 2024 compared to $0.4 million for the third quarter of 2023.

Net loss for the third quarter of 2024 was $14.0 million, or $0.07 per share, compared to a net loss of $36.1 million, or $0.19 per share, for the third quarter of 2023.

Cash, cash equivalents, restricted cash and investments totaled $351.7 million at September 30, 2024, compared to $399.2 million at September 30, 2023. Operating cash increased by $13.1 million in the third quarter of 2024.

Financial Outlook for 2024

Based on the strength of patient demand for ORLADEYO seen in the third quarter, and expected continued strength in the fourth quarter, the company is adjusting its outlook for full year 2024 global net ORLADEYO revenue to be between $430 million and $435 million (top end of prior range) and introducing full-year 2024 total revenue guidance of between $443 and $448 million based on additional 2024 RAPIVAB revenue.

Directly related to the revenue strength for both ORLADEYO and RAPIVAB, the company is revising its guidance for operating expenses, and now expects full year 2024 operating expenses to be between $380 million and $390 million. The increase is driven primarily by increased COGS related to new RAPIVAB sales, increased variable costs, including incentive compensation and distribution costs related to the continued strong revenue performance for ORLADEYO and increased expenses that are seasonally booked in Q4 related to our support for the HAE community, including charitable donations. This operating expense outlook does not reflect non-cash stock compensation expense, or one-time expenses related to the previously announced workforce reduction implemented in the first quarter of 2024.

Based on the company’s disciplined approach to capital allocation, and the strong performance of ORLADEYO, the company is confident that it will 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.

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 1-844-481-2942 for domestic callers and 1-412-317-1866 for international callers. A live webcast and replay of the call will be available online in the investors section of the company website at 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 hereditary angioedema 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.

Non-GAAP Financial Measures

The information furnished in this release includes non-GAAP financial measures that differ from measures calculated in accordance with generally accepted accounting principles in the United States of America (GAAP), including financial measures labeled as "non-GAAP" or "adjusted."

We believe providing these non-GAAP measures, which show our results with these items adjusted, is valuable and useful since they allow management and investors to better understand the company's financial performance in the absence of certain one-time events and non-cash items such as stock-based compensation and allow investors to more accurately understand our third quarter 2023 and 2024 and first nine months 2023 and 2024 results and more easily compare them to future results. These non-GAAP measures also correspond with the way we expected Wall Street analysts to compare our results. Our non-GAAP measures should be considered only as supplements to, and not as substitutes for or in isolation from, our other measures of financial information prepared in accordance with GAAP, such as GAAP revenue, operating income, net income, and earnings per share.

Our references to our first nine months 2023 "non-GAAP" financial measures of adjusted net loss and adjusted earnings per share constitute non-GAAP financial measures. They refer to our GAAP results, adjusted to show the results without the one-time loss on the extinguishment of the Athyrium term loans. Our references to our first nine months 2024 "non-GAAP" financial measures of adjusted net loss and adjusted earnings per share constitute non-GAAP financial measures. They refer to our GAAP results, adjusted to show the results without the one-time R&D restructuring expense. Our reference to our third quarter 2023 and 2024 and first nine months 2023 and 2024 "non-GAAP" financial measure of non-GAAP operating profit constitutes a non-GAAP financial measure. It refers to our GAAP results, adjusted to show the results without including non-cash stock compensation expense.

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: BioCryst's ability to successfully implement or maintain its commercialization plans for ORLADEYO; risks related to the planned discontinuation of the development of BCX10013; BioCryst's ability to successfully progress its pipeline development plans 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 sustained market acceptance and demand; ongoing and future preclinical and clinical development of product candidates may take longer than expected and 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 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; BioCryst's ability to successfully manage its growth and compete effectively; risks related to the international expansion of BioCryst's business; timing for achieving and sustainability of 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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Contact:
John Bluth
+1 919 859 7910
jbluth@biocryst.com

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

Statements of Operations (unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues:				
ORLADEYO	$ 116,319	$ 85,684	$ 313,474	$ 235,107
Other	766	1,058	5,704	2,904
Total revenues	117,085	86,742	319,178	238,011
Expenses:				
Cost of product sales	3,211	1,099	6,175	2,924
Research and development	41,081	46,879	125,197	146,514
Selling, general and administrative	65,084	50,648	185,662	149,512
Royalty	17	37	179	100
Total operating expenses	109,393	98,663	317,213	299,050
Income (loss) from operations	7,692	(11,921)	1,965	(61,039)
Interest income	3,591	4,184	11,176	11,312
Interest expense	(24,828)	(27,345)	(74,067)	(83,656)
Foreign currency gains (losses), net	98	(737)	(37)	(665)
Loss on extinguishment of debt	—	—	—	(29,019)
Loss before income taxes	$ (13,447)	$ (35,819)	$ (60,963)	$ (163,067)
Income tax expense	586	330	1,123	1,741
Net loss	$ (14,033)	$ (36,149)	$ (62,086)	$ (164,808)
Basic and diluted net loss per common share	$ (0.07)	$ (0.19)	$ (0.30)	$ (0.87)
Weighted average shares outstanding	206,905	189,644	206,466	189,095

Balance Sheet Data (in thousands)

	September 30, 2024 (unaudited)	December 31, 2023 (Note 1)
Cash, cash equivalents and investments	$ 349,439	$ 388,987
Restricted cash	2,223	1,804
Receivables	72,456	56,950
Total assets	491,254	516,960
Secured term loan	314,333	303,231
Royalty financing obligation	514,775	531,599
Accumulated deficit	(1,743,245)	(1,681,159)
Stockholders' deficit	(468,563)	(455,528)
Shares of common stock outstanding	207,119	205,771

Note 1: Derived from audited financial statements.

Reconciliation of Adjusted Net Loss and Adjusted Diluted Earnings Per Share (in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
GAAP net loss	$ (14,033)	$ (36,149)	$ (62,086)	$ (164,808)
Less: One-time R&D restructuring expense	—	—	(1,264)	—
Less: One-time loss on extinguishment of Athyrium term loans	—	—	—	(29,019)
Adjusted net loss	$ (14,033)	$ (36,149)	$ (60,822)	$ (135,789)
GAAP basic and diluted net loss per common share	$ (0.07)	$ (0.19)	$ (0.30)	$ (0.87)
Adjusted basic and diluted net loss per common share	$ (0.07)	$ (0.19)	$ (0.29)	$ (0.72)

Reconciliation of Adjusted Income (Loss) from Operations (in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
GAAP income (loss) from operations	$ 7,692	$ (11,921)	$ 1,965	$ (61,039)
Less: Stock-based compensation expense	(17,249)	(12,279)	(44,074)	(39,127)
Adjusted income (loss) from operations	$ 24,941	$ 358	$ 46,039	$ (21,912)