BioCryst Reports Fourth Quarter and Full Year 2024 Financial Results and Upcoming Key Milestones

February 24, 2025

—ORLADEYO net revenue of $124.2 million for Q4 2024 (+36.6 percent y-o-y) and $437.7 million for FY 2024 (+34.3 percent y-o-y)—

—FY 2025 ORLADEYO net revenue guidance increased to between $535-$550 million (previously $515-$535 million)—

—GAAP operating loss for full year 2024 was $2.5 million; company achieved $62.9 million non-GAAP operating profit in full year 2024 (not including stock-based compensation), expects to approach positive EPS and positive cash flow in 2H 2025—

—Initial clinical data from BCX17725 in Netherton syndrome and avoralstat in diabetic macular edema targeted by end of year—

—Company expects to expand ORLADEYO label to children with HAE aged 2 to 11 using oral granule formulation; NDA submission planned this year—

RESEARCH TRIANGLE PARK, N.C., Feb. 24, 2025 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today reported financial results for the fourth quarter and full year ended December 31, 2024, and provided a corporate update.

"We ended 2024 with the strongest execution and performance in the company's history, and this year is off to a fantastic start, with ORLADEYO revenue already exceeding our initial expectations, the first clinical data from both the BCX17725 and avoralstat programs, and our pediatric label expansion for ORLADEYO anticipated later this year," 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

"We are seeing favorable early signs that many more Medicare patients taking ORLADEYO are able to afford therapy because their copayments are lower under the Inflation Reduction Act. New prescription demand also remained strong in the fourth quarter and into the early part of this year and we have increased our guidance for ORLADEYO revenue in 2025," said Charlie Gayer, chief commercial officer of BioCryst.

- ORLADEYO net revenue in the fourth quarter of 2024 was $124.2 million (+36.6 percent y-o-y).
- 73.5 percent of U.S. patients were on paid product at the end of the fourth quarter (up from 71.4 percent at the end of 2023).
- Sales from outside the U.S. contributed 13.9 percent of global ORLADEYO net revenues in the fourth quarter and 11.8 percent for full year 2024.
- The company has received final reimbursement for ORLADEYO in Portugal. ORLADEYO is now reimbursed in all major countries in Western Europe, except the Netherlands, which is expected in 1H 2025.
- A new market tracking survey of 60 HAE treaters showed that 97 percent are considering prescribing ORLADEYO and 59 percent (up from 26 percent 18 months prior) of current prescribers indicate they are extremely likely to prescribe for more of their patients.

Rare Disease Pipeline

"There is a tremendous unmet need for an oral option for children with HAE, so we are excited to bring ORLADEYO to children as young as two years old. In parallel, we look forward to dosing the first patient with DME in our avoralstat clinical program and continuing our ongoing clinical program with BCX17725, the potential first disease-modifying therapy for Netherton syndrome. Both of these programs could produce initial clinical data in 2025," said Dr. Helen Thackray, chief R&D officer of BioCryst.

The goal with our pipeline is to build on our success with ORLADEYO by bringing additional selected, highly differentiated rare disease products to patients.

- The company is on track to submit a new drug application (NDA) in 2025 to the U.S. Food and Drug Administration (FDA) to expand the ORLADEYO label to children with HAE aged 2 to 11 using an oral granule formulation. Additional regulatory filings are planned in global territories, including Europe, Japan and Canada. ORLADEYO would be the first targeted oral prophylactic therapy for children with HAE.
    - Earlier today, the company announced positive results from an interim analysis of the ongoing APeX-P clinical trial

evaluating ORLADEYO in children with HAE aged 2 to 11. The results will be presented in a late-breaking abstract at the 2025 American Academy of Allergy, Asthma & Immunology (AAAAI) / World Allergy Organization (WAO) Joint Congress on Sunday, March 2.

- 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, severe food 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 of fluid from the blood vessels in the retina. While current treatments focus on vascular endothelial growth factor (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, 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.

Fourth Quarter 2024 Financial Results

“The strong start to 2025 has enabled us to raise our revenue guidance, further increasing our confidence in achieving our profitability goals. With revenue growth significantly outpacing operating expenses over the next few years, we expect to achieve meaningful and sustainable profitability, adding hundreds of millions in cash to the balance sheet,” said Anthony Doyle, chief financial officer of BioCryst.

For the three months ended December 31, 2024, total revenues were $131.5 million, compared to $93.4 million in the fourth quarter of 2023 (+40.8 percent y-o-y). The increase was primarily due to $124.2 million in ORLADEYO net revenue in the fourth quarter of 2024, compared to $90.9 million in the fourth quarter of 2023 (+36.6 percent y-o-y). Revenue in the fourth quarter of 2024 also included $7.3 million of net revenue from RAPIVAB related sales, compared to $2.3 million in the fourth quarter of 2023.

Research and development (R&D) expenses for the fourth quarter of 2024 decreased to $49.4 million from $70.1 million in the fourth quarter of 2023 (-29.5 percent y-o-y), primarily due to decreased expenses driven by the discontinuation and close-out of BCX10013 and BCX9930. These reductions were partially offset by increased investment in BCX17725, avoralstat, and our other early-phase pipeline programs, primarily due to investigational new drug application-enabling activities and the initiation of the Phase 1 trial evaluating BCX17725.

Selling, general and administrative (SG&A) expenses for the fourth quarter of 2024 increased to $80.5 million, compared to $64.4 million in the fourth quarter of 2023 (+25.0 percent y-o-y). The increase was primarily due to increased commercial investment to support our growing ORLADEYO revenue, our newly launched regions, expanded international operations and global commercial support activities. Additionally, there was an increase to general and administrative expenses, and an offsetting reduction to research and development expenses, due to a decrease in the general and administrative expense allocations in 2024.

Interest expense was $24.4 million in the fourth quarter of 2024, compared to $24.6 million in the fourth quarter of 2023.

GAAP operating loss for the fourth quarter of 2024 was $4.5 million, compared to $42.7 million for the fourth quarter of 2023. Non-GAAP operating profit, excluding stock-based compensation expense, was $16.8 million for the fourth quarter of 2024, compared to a non-GAAP operating loss of $26.2 million for the fourth quarter of 2023.

Net loss for the fourth quarter of 2024 was $26.8 million, or $0.13 per share, compared to a net loss of $61.7 million, or $0.31 per share, for the fourth quarter of 2023. In the fourth quarter of 2023, there was a one-time cost associated with the R&D restructuring and the postponement of the expansion at our Discovery Center in Alabama, totaling $5.4 million. Excluding this one-time event, non-GAAP net loss for the fourth quarter of 2023 was $56.4 million, or $0.28 per share. A reconciliation between GAAP and non-GAAP net loss is provided in the table below.

Cash, cash equivalents, restricted cash and investments totaled $342.8 million as of December 31, 2024, compared to $390.8 million as of December 31, 2023. Operating cash use for the fourth quarter of 2024 was $8.4 million.

Full Year 2024 Financial Results

For the full year ended December 31, 2024, total revenues were $450.7 million, compared to $331.4 million in the full year ended December 31, 2023 (+36.0 percent y-o-y). The increase was primarily due to $437.7 million of ORLADEYO net revenue in 2024, compared to $326.0 million in 2023 (+34.3 percent y-o-y). Revenue for the full year 2024 also included $13.0 million of net revenue from RAPIVAB related sales, compared to $5.1 million for the full year 2023.

R&D expenses for the full year 2024 decreased to $174.6 million from $216.6 million for the full year 2023 (-19.4 percent y-o-y), primarily due to decreased expenses driven by the discontinuation and close-out of the Factor D programs, BCX10013 and BCX9930. These reductions were partially

offset by increased investment in BCX17725, avoralstat, and our other early-phase pipeline programs, primarily due to investigational new drug application-enabling activities and the initiation of the Phase 1 trial evaluating BCX17725.

SG&A expenses for the full year 2024 increased to $266.1 million, compared to $213.9 million for the full year 2023 (+24.4 percent y-o-y). The increase was primarily due to increased commercial investment to support our growing ORLADEYO revenue, our newly launched regions, expanded international operations, and global commercial support activities. Additionally, there was an increase to general and administrative expenses, and an offsetting reduction to research and development expenses, due to a decrease in the general and administrative expense allocations in 2024.

Interest expense was $98.5 million in full year 2024, compared to $108.2 million in full year 2023. The decrease was primarily due to a decrease in the amortization of interest associated with our royalty financing obligations, partially offset by an increase in interest expense associated with the interest accrued on the Tranche A Loan of $300.0 million under the Pharmakon Loan Agreement.

GAAP operating loss for the full year 2024 was $2.5 million, compared to $103.7 million for the full year 2023. Non-GAAP operating profit, excluding stock-based compensation expense, was $62.9 million for the full year 2024 compared to a non-GAAP operating loss of $48.1 million for the full year 2023.

Net loss for the full year 2024 was $88.9 million, or $0.43 per share, compared to a net loss of $226.5 million, or $1.18 per share, for the full year 2023. Non-GAAP net loss for the full year 2024 was $87.6 million, or $0.42 per share, when excluding one-time costs associated with the R&D restructuring recognized in the first quarter of 2024, totaling $1.3 million. Non-GAAP net loss for full year 2023 was $192.2 million, or $1.00 per share, when excluding the one-time loss on debt extinguishment of $29.0 million on the repayment of the term loans under the Athyrium Credit Agreement recognized in the second quarter of 2023, as well as R&D restructuring and the postponement of previously planned capital expenditures at our Discovery Center in Alabama recognized in the fourth quarter of 2023, totaling $5.4 million. A reconciliation between GAAP and non-GAAP net loss is provided in the table below.

Financial Outlook for 2025

Based on the early signs we are seeing that many more of our Medicare patients are able to afford paid therapy in 2025, and the strong patient demand for ORLADEYO to start the year, the company has increased its full year 2025 outlook for global net ORLADEYO revenue to between $535 million and $550 million (previously $515 million to $535 million). The company now expects full year 2025 total revenue (including RAPIVAB® (peramivir injection)) will be between $560 million and $575 million (previously $540 million to $560 million).

The increased guidance for ORLADEYO revenues in 2025 also results in an increase in related operating expenses, primarily related to cost of goods sold, distribution costs and higher incentive compensation. The company reiterates the previously provided 2025 non-GAAP operating expense outlook range of $425 million to $435 million (not including stock-based compensation). The revenue related operating expense increases are captured at the higher end of this range.

Profitability Outlook

In 2024, revenue growth significantly exceeded operating expense growth. The company expects this pattern to continue, and over the next three years the company expects an annual CAGR for revenue of around 20 percent, compared to a projected annual operating expense CAGR of closer to five percent over the same period.

Building on the $62.9 million non-GAAP operating profit the company achieved in 2024 (not including stock-based compensation), the company expects to approach quarterly positive EPS and positive cash flow in the second half of 2025, and to be profitable on an EPS basis, with positive cash flow, for full year 2026.

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 2023 and 2024 results and more easily compare them to future results. These non-GAAP measures also correspond with the way we expect 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 fourth quarter 2023 and full year 2023 and 2024 “non-GAAP” financial measures of non-GAAP net loss and non-GAAP earnings per share constitute non-GAAP financial measures. For 2023, they refer to our GAAP results, adjusted to show the results without the one-time loss on the extinguishment of the Athyrium term loans, as well as the R&D restructuring and the postponement of previously planned capital expenditures at our Discovery Center in Alabama. For 2024, they refer to our GAAP results, adjusted to show the results without the one-time R&D restructuring expense. Our reference to our fourth quarter 2023 and 2024 and full year 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.

We also provide our non-GAAP operating expense outlook for full year 2025, which refers to our expected GAAP operating expense, excluding stock-based compensation expense. We have not provided a reconciliation against the comparable forward-looking GAAP measure because we are unable to predict with reasonable certainty the full amount of stock-based compensation expense for full year 2025 without unreasonable effort. Stock-based compensation expense is uncertain and depends on various factors, including our future hiring and retention needs, as well as the future fair market value of our common stock, which is difficult to predict and subject to change. The actual amount of stock-based compensation expense for the full year 2025 could have a material impact on GAAP reported results for the guidance period.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding future results, performance or achievements, and expectations regarding pipeline development timing. These statements involve known and unknown risks, uncertainties and other factors which may cause BioCryst's actual results, performance, achievements or pipeline development timing to be materially different from any future results, performance, achievements, or timing 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; BioCryst's ability to successfully progress its pipeline development plans as described herein, including meeting the expected timelines; 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; the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final 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 not review regulatory filings on our expected timeline, 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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BIOCRYST PHARMACEUTICALS, INC.
CONSOLIDATED FINANCIAL SUMMARY
(In thousands, except per share)

Statements of Operations (unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
Revenues:				
ORLADEYO	$ 124,186	$ 90,883	$ 437,660	$ 325,990
Other	7,348	2,518	13,052	5,422
Total revenues	131,534	93,401	450,712	331,412
Expenses:				
Cost of product sales	6,094	1,557	12,269	4,481
Research and development	49,441	70,052	174,638	216,566
Selling, general and administrative	80,470	64,382	266,132	213,894
Royalty	37	80	216	180
Total operating expenses	136,042	136,071	453,255	435,121

Loss from operations	(4,508)	(42,670)	(2,543)	(103,709)
Other (expense) income:				
Interest income	3,570	4,465	14,746	15,777
Interest expense	(24,449)	(24,583)	(98,516)	(108,239)
Loss on extinguishment of debt	—	—	—	(29,019)
Foreign currency losses, net	(604)	(374)	(641)	(1,039)
Total other expense	(21,483)	(20,492)	(84,411)	(122,520)
Loss before income taxes	(25,991)	(63,162)	(86,954)	(226,229)
Income tax expense (benefit)	804	(1,431)	1,927	310
Net loss	$ (26,795)	$ (61,731)	$ (88,881)	$ (226,539)
Basic and diluted net loss per common share	$ (0.13)	$ (0.31)	$ (0.43)	$ (1.18)
Weighted average shares outstanding	207,381	201,409	206,696	192,198

Balance Sheet Data (in thousands)

	December 31,	
	2024 (unaudited)	2023 (Note 1)
Cash, cash equivalents and investments	$ 341,173	$ 388,987
Restricted cash	1,610	1,804
Receivables	79,069	56,950
Total assets	490,420	516,960
Secured term loan	314,869	303,231
Royalty financing obligation	513,729	531,599
Accumulated deficit	(1,770,040)	(1,681,159)
Stockholders' deficit	(475,934)	(455,528)
Shares of common stock outstanding	208,543	205,771

Note 1: Derived from audited financial statements.

Reconciliation of Adjusted Net Loss and Adjusted Diluted Earnings Per Share (in thousands, except per share)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
GAAP net loss	$ (26,795)	$ (61,731)	$ (88,881)	$ (226,539)
Less: One-time R&D restructuring expense	—	(3,380)	(1,264)	(3,380)
Less: One-time loss on extinguishment of Athyrium term loans	—	—	—	(29,019)
Less: One-time cost associated with expensing previously capitalized costs due to postponement of Discovery Center (AL) expansion	—	(1,988)	—	(1,988)
Adjusted net loss	$ (26,795)	$ (56,363)	$ (87,617)	$ (192,152)
GAAP basic and diluted net loss per common share	$ (0.13)	$ (0.31)	$ (0.43)	$ (1.18)
Adjusted basic and diluted net loss per common share	$ (0.13)	$ (0.28)	$ (0.42)	$ (1.00)

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
GAAP loss from operations	$ (4,508)	$ (42,670)	$ (2,543)	$ (103,709)
Less: Stock-based compensation expense	(21,339)	(16,488)	(65,413)	(55,615)

Adjusted income (loss) from operations	$ 16,831	$ (26,182)	$ 62,870	$ (48,094)