BioCryst Reports Fourth Quarter and Full Year 2023 Financial Results and Upcoming Key Milestones

February 26, 2024

—ORLADEYO net revenue of $90.9 million for Q4 2023 and $326.0 million for FY 2023 (+30 percent y-o-y) —

—2024 ORLADEYO net revenue expected to be between $380-$400 million—

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

RESEARCH TRIANGLE PARK, N.C., Feb. 26, 2024 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today reported financial results for the fourth quarter and full year ended December 31, 2023, and provided a corporate update.

“The impressive growth we are seeing with ORLADEYO has put us in a position to accelerate our path to profitability while continuing to invest in our diverse pipeline of first-in-class or best-in-class molecules that we believe will deliver our next marketed product,” 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

- ORLADEYO net revenue in the fourth quarter of 2023 was $90.9 million.
- The total number of U.S. patients on paid or long-term free product reached 1,104 at the end of the fourth quarter (+30 percent y-o-y) with 71.5 percent of those patients on paid product.
- Net U.S. patient growth totaled 321 in 2023, including new patients still on short-term quick start product at the end of the quarter.
- The number of new ORLADEYO prescribers in the fourth quarter of 2023 (Q4 2023) was the largest number of new prescribers of any quarter in 2023.
- Real-world data presented at the American Academy of Allergy, Asthma & Immunology (AAAAI) annual meeting reinforced prior data showing patients switching to ORLADEYO experience sustained attack reduction regardless of baseline attack rate or prior HAE prophylaxis treatment.
- Access to ORLADEYO continues to expand to more HAE patients around the world. In Q4 2023, ORLADEYO was approved in Argentina, launched in Spain, and granted final pricing approval in Austria. In the first quarter of 2024, ORLADEYO secured final reimbursement in Italy.

“As the real-world evidence with ORLADEYO consistently underscores, patients are switching to ORLADEYO because they can achieve outstanding HAE attack control and tolerability with an oral, once-daily therapy, leading to life-changing results,” said Charlie Gayer, chief commercial officer of BioCryst.

Fourth Quarter 2023 Financial Results

For the three months ended December 31, 2023, total revenues were $93.4 million, compared to $79.5 million in the fourth quarter of 2022. The increase was primarily due to $90.9 million in ORLADEYO net revenue in the fourth quarter of 2023, compared to $70.7 million in the fourth quarter of 2022. Revenue in the fourth quarter of 2023 also included $2.3 million of net revenue from RAPIVAB related sales, compared to $8.7 million in the fourth quarter of 2022.

Research and development (R&D) expenses for the fourth quarter of 2023 decreased to $70.1 million from $73.2 million in the fourth quarter of 2022 (-4 percent year-over-year), primarily due to the discontinuation of the BCX9930 and BCX9250 programs announced in December 2022 and November 2022, respectively. These reductions were partially offset by increased investment in BCX17725 and our other early-stage programs, including the $5 million upfront payment to Clearside Biomedical related to avoralstat, and ORLADEYO label expansion and life cycle investments, such as our ongoing ORLADEYO pediatric trial.

Selling, general and administrative (SG&A) expenses for the fourth quarter of 2023 increased to $64.4 million, compared to $50.2 million in the fourth quarter of 2022 (+28 percent year-over-year). The increase was primarily due to increased investment to expand and enhance the U.S. commercial team and international operations.

Interest expense was $24.6 million in the fourth quarter of 2023, compared to $26.5 million in the fourth quarter of 2022. 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 Pharmakon debt refinancing secured in April 2023.

Net loss for the fourth quarter of 2023 was $61.7 million, or $0.31 per share, compared to a net loss of $71.5 million, or $0.38 per share, for the fourth quarter of 2022. Non-GAAP net loss for the fourth quarter of 2023 was $56.4 million, or $0.28 per share when excluding one-time costs associated with the R&D restructuring and the postponement of the expansion at our Discovery Center in Alabama, totaling $5.4 million. A reconciliation between GAAP and non-GAAP net loss is provided in the table below.

Cash, cash equivalents, restricted cash and investments totaled $390.8 million as of December 31, 2023, compared to $443.9 million as of December 31, 2022. Net cash utilization for the fourth quarter of 2023 was $8.6 million.

Full Year 2023 Financial Results

For the full year ended December 31, 2023, total revenues were $331.4 million, compared to $270.8 million in the full year ended December 31, 2022. The increase was primarily due to $326.0 million of ORLADEYO net revenue in 2023, compared to $251.6 million in 2022. The increase in ORLADEYO net revenue was partially offset by a decrease in other net revenues of $13.8 million, primarily due to RAPIVAB stockpiling sales to complete the U.S. Department of Health and Human Services procurement contract during the year ended December 31, 2022.

R&D expenses in full year 2023 decreased to $216.6 million from $253.3 million in full year 2022 (-14 percent year-over-year), primarily due to the discontinuation of the BCX9930 and BCX9250 programs announced in December 2022 and November 2022, respectively. These reductions were partially offset by increased investment in BCX17725, increased investment in our other early-stage discovery programs, including the $5 million upfront payment to Clearside Biomedical related to avoralstat, ORLADEYO label expansion and life cycle investments, such as our ongoing ORLADEYO pediatric trial, and an increase in indirect costs to support our programs.

SG&A expenses in full year 2023 increased to $213.9 million, compared to $159.4 million in full year 2022 (+34 percent year-over-year). The increase was primarily due to increased investment in order to expand and enhance the U.S. commercial team and expanded international operations.

Interest expense was $108.2 million in full year 2023, compared to $99.1 million in full year 2022. The increase in interest expense was primarily associated with the interest accrued on the Tranche A Loan of $300.0 million under the Pharmakon Loan Agreement.

Other expense was comprised primarily of a loss on extinguishment of debt of $29.0 million on the repayment of the term loans under the Athyrium Credit Agreement and net foreign currency losses of $1.0 million, partially offset by interest income of $15.8 million for the year ended December 31, 2023. Other income was comprised of interest income of $5.1 million, partially offset by net foreign currency losses of $2.0 million for the year ended December 31, 2022.

Net loss for full year 2023 was $226.5 million, or $1.18 per share, compared to a net loss of $247.1 million, or $1.33 per share, for full year 2022. 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 the 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.

Non-GAAP Pro forma Financial Measures

The information furnished in this release includes non-GAAP pro forma 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 pro forma results with these items adjusted, is valuable and useful since they allow the company and investors to better understand the company’s financial performance in the absence of these one-time events and allowed investors to more accurately understand our 2023 results and more easily compare them to future results. These non-GAAP pro forma measures also correspond with the way we expect investors and financial analysts to compare our results. Our non-GAAP pro forma 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 “non-GAAP pro forma” 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 debt extinguishment on the repayment of the term loans under the Athyrium Credit Agreement, as well as the R&D restructuring and the postponement of previously planned capital expenditures at our Discovery Center in Alabama. A reconciliation between GAAP and non-GAAP net loss is provided in the table below.

Financial Outlook for 2024

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.

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 between $20 million and $30 million versus 2023. 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 previously announced workforce reduction implemented 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.

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 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 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 its commercialization plans for ORLADEYO, which could take longer or be more expensive than planned; 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; ongoing and future preclinical and clinical development of product candidates may take longer than expected and may not have positive results; 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 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,	
	2023	2022	2023	2022
Revenues:				
ORLADEYO	$ 90,883	$ 70,735	$ 325,990	$ 251,633
Other	2,518	8,810	5,422	19,194
Total revenues	93,401	79,545	331,412	270,827
Expenses:				
Cost of product sales	1,557	2,383	4,481	6,408
Research and development	70,052	73,207	216,566	253,297
Selling, general and administrative	64,382	50,153	213,894	159,371
Royalty	80	113	180	186
Total operating expenses	136,071	125,856	435,121	419,262

Loss from operations	(42,670)	(46,311)	(103,709)	(148,435)
Interest and other income	4,465	2,704	15,777	5,127
Interest expense	(24,583)	(26,458)	(108,239)	(99,092)
Loss on extinguishment of debt	—	—	(29,019)	—
Foreign currency losses, net	(374)	(1,400)	(1,039)	(1,983)
Loss before income taxes	$ (63,162)	$ (71,465)	$ (226,229)	$ (244,383)
Income tax (benefit) expense	(1,431)	76	310	2,733
Net loss	$ (61,731)	$ (71,541)	$ (226,539)	$ (247,116)
Basic and diluted net loss per common share	$ (0.31)	$ (0.38)	$ (1.18)	$ (1.33)
Weighted average shares outstanding	201,409	186,922	192,198	185,908

Balance Sheet Data (in thousands)

	December 31, 2023 (unaudited)	December 31, 2022 (Note 1)
Cash, cash equivalents and investments	$ 388,987	$ 442,387
Restricted cash	1,804	1,472
Receivables	56,950	50,599
Total assets	516,960	550,000
Secured term loan	303,231	231,624
Royalty financing obligation	531,599	501,655
Accumulated deficit	(1,681,159)	(1,454,620)
Stockholders' deficit	(455,528)	(294,597)
Shares of common stock outstanding	205,771	187,906

Note 1: Derived from audited financial statements

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
GAAP net loss	**$ (61,731)**	**$ (71,541)**	**$ (226,539)**	**$ (247,116)**
Less: One-time loss on extinguishment of Athyrium term loans	—	—	(29,019)	—
Less: One-time R&D restructuring expense	(3,380)	—	(3,380)	—
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	**$ (56,363)**	**$ (71,541)**	**$ (192,152)**	**$ (247,116)**
GAAP basic and diluted net loss per common share	**$ (0.31)**	**$ (0.38)**	**$ (1.18)**	**$ (1.33)**
Adjusted basic and diluted net loss per common share	**$ (0.28)**	**$ (0.38)**	**$ (1.00)**	**$ (1.33)**