BioCryst Reports Fourth Quarter and Full Year 2022 Financial Results and Upcoming Key Milestones

February 21, 2023

—ORLADEYO net revenue of $70.7 million for Q4 2022 and $251.6 million for FY 2022—

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

—ORLADEYO peak sales expected to be $1 billion—

RESEARCH TRIANGLE PARK, N.C., Feb. 21, 2023 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today reported financial results for the fourth quarter and full year ended December 31, 2022, and provided a corporate update.

“It has been exciting to build on our strong initial launch by doubling ORLADEYO revenues in our second year, and to see the expanding global reach of an oral, once-daily therapy that is changing the lives of patients with HAE and their families,” 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 2022 was $70.7 million.
- New patient demand for ORLADEYO was strong in the fourth quarter, consistent with the steady growth trajectory observed since launch.
- The ORLADEYO prescriber base continues to grow significantly, with approximately half of new prescriptions in the fourth quarter coming from the top 500 prescribers.
- The total number of patients on ORLADEYO at year-end 2022 was consistent with the company’s expectations.
- The company expects patient growth in Q1 2023 to remain strong. Because of typical first quarter requirements from payors for prescription reauthorization of specialty products, like ORLADEYO, that can temporarily move patients from paid drug to free product, copayment assistance and Medicare D cost sharing dynamics, the company expects ORLADEYO net revenue in Q1 2023 to be similar to, or slightly less than, Q4 2022. The company has accounted for this expected Q1 impact in its expectation that full year 2023 ORLADEYO global net revenues will grow to no less than $320 million.
- The Canadian Agency for Drugs and Technologies in Health Canadian Drug Expert Committee has recently issued a final draft positive recommendation for ORLADEYO to be reimbursed for the routine prevention of HAE attacks in adults and pediatric patients 12 years of age and older.

“Underlying demand from patients and physicians for ORLADEYO continues to be strong and consistent in the U.S. and our initial European launches are gaining traction with ORLADEYO now commercially available in 15 countries. All of this enables more and more patients to benefit from ORLADEYO, which is on a trajectory to achieve $1 billion in peak sales,” said Charlie Gayer, chief commercial officer of BioCryst.

Complement Inhibitor Program

- In January 2023, the company announced that initial data from ongoing phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) trials in healthy volunteers showed rapid, sustained and >97 percent suppression of the alternative pathway (AP) of the complement system 24 hours following a single 110 mg dose, and that BCX10013 has been safe and generally well-tolerated at all doses studied to date. Recent dose-related observations in an ongoing BCX10013 nonclinical study will delay the clinical program.
- In addition to BCX10013, which targets Factor D in the alternative pathway of complement, BioCryst also announced that the company 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.

Fourth Quarter 2022 Financial Results

For the three months ended December 31, 2022, total revenues were $79.5 million, compared to $47.2 million in the fourth quarter of 2021 (+68 percent year-over-year). The increase was primarily due to $70.7 million in ORLADEYO net revenue in the fourth quarter of 2022, in addition to $8.7 million of net revenue from Rapivab related sales.

Research and development (R&D) expenses for the fourth quarter of 2022 increased to $73.2 million from $63.5 million in the fourth quarter of 2021 (+15 percent year-over-year), primarily due to increased investment in our complement inhibitor program, including accelerated expenses related to the termination of BCX9930.

Selling, general and administrative (SG&A) expenses for the fourth quarter of 2022 increased to $50.2 million, compared to $35.4 million in the fourth quarter of 2021 (+42 percent year-over-year). The increase was primarily due to increased investment to support the U.S. commercial launch of ORLADEYO and expanded international operations.

Interest expense was $26.5 million in the fourth quarter of 2022, compared to $18.8 million in the fourth quarter of 2021. The increase was due to service on the company's royalty and debt financing agreements.

Net loss for the fourth quarter of 2022 was $71.5 million, or $0.38 per share, compared to a net loss of $17.8 million, or $0.10 per share, for the fourth quarter of 2021. Non-GAAP net loss for the fourth quarter of 2021 was $73.6 million, or $0.40 per share when excluding the one-time non-cash gain of $55.8 million related to the extinguishment of the non-recourse PhaRMA notes. A reconciliation between GAAP and non-GAAP net loss is provided in the table below.

Cash, cash equivalents, restricted cash and investments totaled $443.9 million as of December 31, 2022, compared to $517.8 million as of December 31, 2021. Operating cash use for the fourth quarter of 2022 was $18.8 million.

Full Year 2022 Financial Results

For the full year ended December 31, 2022, total revenues were $270.8 million, compared to $157.2 million in the full year ended December 31, 2021 (+72 percent year-over-year). The increase was primarily due to $251.6 million of ORLADEYO net revenue in 2022.

R&D expenses in full year 2022 increased to $253.3 million from $208.8 million in full year 2021 (+21 percent year-over-year), primarily due to increased investment in our compliment inhibitor program, and an increase in other research, preclinical and development activities.

SG&A expenses in full year 2022 increased to $159.4 million, compared to $118.8 million in full year 2021 (+34 percent year-over-year). The increase was primarily due to increased investment to support the U.S. commercial launch of ORLADEYO and expanded international operations.

Interest and other income was $5.1 million in full year 2022, compared to $0.1 million in full year 2021. The increase was primarily due to increased interest income, driven by interest rate increases over the course of the year.

Interest expense was $99.1 million in full year 2022, compared to $59.3 million in full year 2021. The increase was due to service on the company's royalty and debt financing agreements.

A one-time non-cash gain of $55.8 million on extinguishment of debt was recognized in full year 2021 related to the write-off of the non-recourse PhaRMA notes and related accrued interest payable.

Net loss for full year 2022 was $247.1 million, or $1.33 per share, compared to a net loss of $184.1 million, or $1.03 per share, for full year 2021. Non-GAAP net loss for full year 2021 was $239.9 million, or $1.34 per share when excluding the one-time gain on the extinguishment of the non-recourse PhaRMA notes. 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 2021 results and more easily compare them to future results. These non-GAAP pro forma measures also correspond with the way we expected Wall Street 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 2021 and full year 2021 "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 gain realized by the extinguishment of the debt from our PhaRMA notes.

Financial Outlook for 2023

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 ORLADEYO net revenue in the first quarter of 2023 to be similar to, or slightly less than, ORLADEYO net revenue in the fourth quarter of 2022.

Operating expenses for full year 2023, not including non-cash stock compensation, are expected to be flat to 2022 at approximately $375 million. While flat year over year, we expect reductions in R&D spending in 2023 following the discontinuation of the BCX9930 and BCX9250 programs in 2022 and the delay in the 10013 clinical program, offset by increases in SG&A to support the U.S. launch and global expansion of ORLADEYO.

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 1-866-777-2509 for domestic callers and 1-412-317-5413 for international callers. A live webcast and replay

of the call will be available online at the investors section of the company website at 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 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; 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; ongoing and future preclinical and clinical development of BCX10013 and other 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, 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 PHARMACEUTICALS, INC.
CONSOLIDATED FINANCIAL SUMMARY
(in thousands, except per share)

Statements of Operations (Unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Revenues:				
Product sales, net	$ 78,063	$ 45,908	$ 267,710	$ 136,350
Royalty revenue	1,416	347	2,903	(100)
Milestone revenue	-	-	-	15,000
Collaborative and other research and development	66	903	214	5,920
Total revenues	79,545	47,158	270,827	157,170
Expenses:				
Cost of product sales	2,383	418	6,408	7,229

Research and development	73,207	63,529	253,297	208,808
Selling, general and administrative	50,153	35,387	159,371	118,818
Royalty	113	1	186	35
Total operating expenses	125,856	99,335	419,262	334,890
Loss from operations	(46,311)	(52,177)	(148,435)	(177,720)
Interest and other income	2,704	14	5,127	62
Interest expense	(26,458)	(18,780)	(99,092)	(59,294)
Gain (loss) on extinguishment of debt	-	55,838	-	55,838
Foreign currency losses, net	(1,401)	(421)	(1,984)	(695)
Loss before income taxes	$ (71,466)	$ (15,526)	$ (244,384)	$ (181,809)
Income tax expense	76	2,253	2,733	2,253
Net loss	$ (71,542)	$ (17,779)	$ (247,117)	$ (184,062)
Basic and diluted net loss per common share	$ (0.38)	$ (0.10)	$ (1.33)	$ (1.03)
Weighted average shares outstanding	186,922	181,843	185,908	179,117

Balance Sheet Data (in thousands)

	December 31, 2022 (Unaudited)	December 31, 2021 (Note 1)
Cash, cash equivalents and investments	$ 442,387	$ 514,430
Restricted cash	1,472	3,345
Receivables	50,599	29,413
Total assets	550,000	588,151
Secured term loan	231,625	136,082
Royalty financing oblgation	501,655	449,375
Accumulated deficit	(1,454,621)	(1,207,504)
Stockholders' deficit	(294,597)	(106,986)
Shares of common stock outstanding	187,906	184,350

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,	
	2022	2021	2022	2021
GAAP net loss	**$ (71,542)**	**$ (17,779)**	**$ (247,117)**	**$ (184,062)**
Less : One-time Gain on extinguishment of PhaRMA notes	-	55,838	-	55,838
Adjusted net loss	**$ (71,542)**	**$ (73,617)**	**$ (247,117)**	**$ (239,900)**
GAAP basic and diluted net loss per common share	**$ (0.38)**	**$ (0.10)**	**$ (1.33)**	**$ (1.03)**
Adjusted basic and diluted net loss per common share	**$ (0.38)**	**$ (0.40)**	**$ (1.33)**	**$ (1.34)**