BioCryst Reports Third Quarter 2023 Financial Results and Provides Business Update

November 2, 2023

- Q3 2023 ORLADEYO net revenue of $85.7 million (+29.8 percent y-o-y) --

- Company expects to achieve no less than $320 million in full year 2023 ORLADEYO revenue and $1 billion in peak ORLADEYO revenue -

- Net cash utilization of $16.5 million in Q3 2023 (-43.9 percent y-o-y) -

- Company to host R&D Day on Friday, November 3rd to introduce additional therapies from its pipeline -

RESEARCH TRIANGLE PARK, N.C., Nov. 02, 2023 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today reported financial results for the third quarter ended September 30, 2023, and provided a corporate update.

“With nearly three years of launch data, we have excellent visibility into the pattern of growth for ORLADEYO and we remain on track to achieve the no less than $320 million in ORLADEYO revenues we have expected for 2023. Our solid base and the consistent addition of new patients each quarter, combined with the ongoing improvement in our percentage of paid patients and launches in new global markets, are all driving peak revenues to $1 billion,” 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

“Strong, steady new patient switches continue to fuel the growth in ORLADEYO as more and more patients want to experience the benefits of the only oral, once-daily therapy to prevent HAE attacks,” said Charlie Gayer, chief commercial officer of BioCryst.

- ORLADEYO net revenue in the third quarter of 2023 was $85.7 million (+29.8 percent year-over-year (y-o-y)).
- Total growth in patients taking ORLADEYO continued on a strong, linear trajectory.
- The ongoing APeX-P trial in pediatric HAE patients who are 2 to <12 years of age continues to enroll as expected.
- Sales from outside the U.S. contributed 12.2 percent of global ORLADEYO net revenues in the third quarter.
- Austria has approved the reimbursement of ORLADEYO for the targeted prophylaxis of hereditary angioedema (HAE) in patients 12 years of age or older.

Upcoming R&D Day—November 3, 2023

BioCryst will host a Research and Development (R&D) Day at 1:00p ET on Friday, November 3 at its Discovery Center of Excellence in Birmingham, AL. At the R&D Day, the company plans to describe its drug discovery process and introduce additional therapies from its pipeline. The live webcast and replay of the R&D Day will be available online in the investors section of the company website at www.biocryst.com.

Third Quarter 2023 Financial Results

For the three months ended September 30, 2023, total revenues were $86.7 million, compared to $75.8 million in the third quarter of 2022 (+14.4 percent y-o-y). The increase was primarily due to an increase in ORLADEYO net revenue of $19.7 million, partially offset by a reduction in RAPIVAB® (peramivir injection) revenue of $8.8 million, compared to the third quarter of 2022.

Research and development expenses for the third quarter of 2023 decreased to $46.9 million from $52.7 million in the third quarter of 2022 (-11.0 percent y-o-y), primarily due to the discontinuations of the BCX9930 and BCX9250 programs, partially offset by additional investment in BCX10013 and pipeline programs.

Selling, general and administrative expenses for the third quarter of 2023 increased to $50.7 million, compared to $36.9 million in the third quarter of 2022 (+37.1 percent y-o-y). The increase was primarily due to increased investment to support the commercial launch of ORLADEYO.

Interest expense was $27.3 million in the third quarter of 2023, compared to $24.8 million in the third quarter of 2022 (+10.1 percent y-o-y). The increase was due to additional interest to service the Pharmakon debt secured in April 2023.

Net loss for the third quarter of 2023 was $36.1 million, or $0.19 per share, compared to a net loss of $42.5 million, or $0.23 per share, for the third quarter of 2022.

Cash, cash equivalents, restricted cash and investments totaled $399.2 million at September 30, 2023, compared to $462.6 million at September 30, 2022. Operating cash use for the third quarter of 2023 was $16.5 million (-43.9 percent y-o-y).

Financial Outlook for 2023

The company expects full year 2023 global net ORLADEYO revenue to be no less than $320 million. The company continues to be disciplined in its approach to capital allocation and is reducing its outlook for operating expenses for full year 2023, not including non-cash stock compensation, to between $365 million and $375 million, reflecting an expected decline from 2022 operating expenses.

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 in 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.

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 allow investors to more accurately understand our nine months ended September 2023 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 nine months ended September 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 the extinguishment of the Athyrium term loans, which occurred in the second quarter of 2023.

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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
ORLADEYO	$ 85,684	$ 65,972	$ 235,107	$ 180,899
Other	1,058	9,855	2,904	10,383
Total revenues	86,742	75,827	238,011	191,282
Expenses:				
Cost of product sales	1,099	3,543	2,924	4,025
Research and development	46,879	52,740	146,514	180,090
Selling, general and administrative	50,648	36,919	149,512	109,218
Royalty	37	70	100	73
Total operating expenses	98,663	93,272	299,050	293,406
Loss from operations	(11,921)	(17,445)	(61,039)	(102,124)
Interest and other income	4,184	1,760	11,312	2,423
Interest expense	(27,345)	(24,775)	(83,656)	(72,634)
Foreign currency gains (losses), net	(737)	(538)	(665)	(583)
Loss on extinguishment of debt	-	-	(29,019)	-
Loss before income taxes	(35,819)	(40,998)	(163,067)	(172,918)
Income tax expense	330	1,522	1,741	2,657
Net loss	$ (36,149)	$ (42,520)	$ (164,808)	$ (175,575)
Basic and diluted net loss per common share	$ (0.19)	$ (0.23)	$ (0.87)	$ (0.95)
Weighted average shares outstanding	189,644	186,180	189,095	185,566

Balance Sheet Data (in thousands)

	September 30, 2023 (Unaudited)	December 31, 2022 (Note 1)
Cash, cash equivalents and investments	$ 397,590	$ 442,387
Restricted cash	1,584	1,472
Receivables	53,646	50,599
Total assets	522,924	550,000
Secured term loan	297,995	231,624
Royalty financing obligation	535,186	501,655
Accumulated deficit	(1,619,428)	(1,454,620)
Stockholders' deficit	(410,986)	(294,597)
Shares of common stock outstanding	189,803	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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
GAAP net loss	**$ (36,149)**	**$ (42,520)**	**$ (164,808)**	**$ (175,575)**
Less : One-time loss on extinguishment of Athyrium term loans	**-**	-	**(29,019)**	-

Adjusted net loss	**$ (36,149)**	**$ (42,520)**	**$ (135,789)**	**$ (175,575)**
GAAP basic and diluted net loss per common share	**$ (0.19)**	**$ (0.23)**	**$ (0.87)**	**$ (0.95)**
Adjusted basic and diluted net loss per common share	**$ (0.19)**	**$ (0.23)**	**$ (0.72)**	**$ (0.95)**