BioCryst Reports Second Quarter 2023 Financial Results and Provides Business Update

August 3, 2023

— Q2 2023 ORLADEYO net revenue of $81.0 million (+24 percent y-o-y)—

— On-track to achieve ≥ $320 million in full year 2023 ORLADEYO revenue and $1 billion in peak ORLADEYO revenue—

— Q2 2023 GAAP EPS of ($0.40), non-GAAP EPS of ($0.24), excluding one-time debt extinguishment fee of $29 million—

— BCX10013, once-daily, oral Factor D inhibitor, clinical trial in patients expected to begin enrollment by end of year—

—Company to host R&D day on Friday, November 3rd to introduce additional pipeline assets and programs—

RESEARCH TRIANGLE PARK, N.C., Aug. 03, 2023 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today reported financial results for the second quarter ended June 30, 2023, and provided a corporate update.

“Our strong second quarter keeps us firmly on track to achieve no less than $320 million in ORLADEYO revenue this year, as our base of patients grows larger and larger every quarter. While ORLADEYO revenues continue to grow, we are also excited to host an R&D day in November to introduce new molecules and programs from our discovery platform that have the potential to replicate or exceed the success of ORLADEYO,” 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 significant step-up in revenue we expected and achieved in the second quarter reflects the continued strong growth in patients taking ORLADEYO, the normal seasonality in revenue that follows first quarter prescription reauthorizations, and our steady improvement in helping patients get to reimbursed therapy. We recently attended the HAEA summit, attended by 1,200 patients and family members. Their strong interest and enthusiasm gave us even more confidence in our expectations for sustained long-term demand for ORLADEYO in the U.S. and globally,” said Charlie Gayer, chief commercial officer of BioCryst.

- ORLADEYO net revenue in the second quarter of 2023 was $81.0 million (+24.2 percent year-over-year (y-o-y)).
- Total growth in patients taking ORLADEYO continued on a strong, linear trajectory.
- The percentage of U.S. ORLADEYO patients receiving paid drug improved in the second quarter as the company made progress converting commercially-insured patients who had been receiving long-term free product, and as patients who received temporary free product during the first quarter prescription re-authorization process returned to reimbursed product in the second quarter.
- Sales from outside the U.S. contributed 10.1 percent of global ORLADEYO net revenues in the second quarter.
- The ongoing APeX-P trial in pediatric HAE patients who are 2 to <12 years of age continues to enroll as expected.

BCX10013—Oral Factor D Inhibitor

“Our goal with BCX10013 is to bring a best-in-class molecule to physicians and patients. That means a safe, highly effective, once-daily oral therapy, and we are now focused on preparing for enrollment in our dose-ranging trial in patients,” said Dr. Helen Thackray, chief research and development officer.

- The company has begun opening clinical trial sites for a dose-ranging trial in patients with paroxysmal nocturnal hemoglobinuria (PNH) and expects to begin patient enrollment (in countries without other approved therapies) by the end of the year. The trial is designed to identify a safe, effective, once-daily dose that BioCryst can advance into a pivotal program in renal complement-mediated diseases.
- The company also plans to complete an additional cohort of its multiple ascending dose trial (MAD) of BCX10013, at a higher dose (160 mg QD), in healthy volunteers to provide further information to the pharmacokinetic model.

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 Research Center of Excellence in Birmingham, AL (the event also will be webcast live). At the R&D day, the company plans to introduce additional assets from its pipeline targeting rare diseases.

Second Quarter 2023 Financial Results

For the three months ended June 30, 2023, total revenues were $82.5 million, compared to $65.5 million in the second quarter of 2022 (+25.9 percent year-over-year (y-o-y)). The increase was primarily due to $81.0 million in ORLADEYO net revenue in the second quarter of 2023, compared to $65.2 million in ORLADEYO net revenue in the second quarter of 2022 (+24.2 percent y-o-y).

R&D expenses for the second quarter of 2023 decreased to $51.2 million from $62.0 million in the second quarter of 2022 (-17.3 percent y-o-y), primarily due to decreased investment in both the BCX9250 and complement programs, partially offset by increased investment in the early-stage pipeline.

Selling, general and administrative expenses for the second quarter of 2023 increased to $51.0 million, compared to $38.0 million in the second quarter of 2022 (+34.1 percent y-o-y). The increase was primarily due to increased investment to support the commercial launch of ORLADEYO and expanded international operations.

Interest expense was $28.9 million in the second quarter of 2023, compared to $24.0 million in the second quarter of 2022 (+20.4 percent y-o-y). The increase is primarily driven by additional interest to service the Pharmakon debt secured in April 2023.

Net loss for the second quarter of 2023 was $75.3 million, or $0.40 per share, compared to a net loss of $58.9 million, or $0.32 per share, for the second quarter of 2022. There was a $29.0 million one-time debt extinguishment fee related to the close-out of the Athyrium debt facility. Excluding this one-time event, non-GAAP net loss for the second quarter of 2023 was $0.24 per share.

Cash, cash equivalents, restricted cash and investments totaled $415.7 million at June 30, 2023, compared to $418.9 million at June 30, 2022. Operating cash use for the second quarter of 2023 was $13.5 million.

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 second quarter 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 second quarter 2023 and first six months 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.

Financial Outlook for 2023

The company expects full year 2023 global net ORLADEYO revenue to be no less than $320 million. 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 BCX10013 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 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.

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
ORLADEYO	$ 81,009	$ 65,223	$ 149,423	$ 114,927
Other	1,482	309	1,846	528
Total revenues	82,491	65,532	151,269	115,455
Expenses:				
Cost of product sales	894	246	1,825	482
Research and development	51,247	61,990	99,635	127,350
Selling, general and administrative	50,997	38,017	98,864	72,299
Royalty	56	1	63	3
Total operating expenses	103,194	100,254	200,387	200,134
Loss from operations	(20,703)	(34,722)	(49,118)	(84,679)
Interest and other income	3,750	609	7,128	663
Interest expense	(28,915)	(24,022)	(56,311)	(47,859)
Foreign currency gains (losses), net	301	132	72	(45)
Loss on extinguishment of debt	(29,019)	-	(29,019)	-
Loss before income taxes	(74,586)	(58,003)	(127,248)	(131,920)
Income tax expense	740	856	1,411	1,135
Net loss	$ (75,326)	$ (58,859)	$ (128,659)	$ (133,055)
Basic and diluted net loss per common share	$ (0.40)	$ (0.32)	$ (0.68)	$ (0.72)
Weighted average shares outstanding	189,118	185,605	188,815	185,253

Balance Sheet Data (in thousands)

	June 30, 2023 (Unaudited)	December 31, 2022 (Note 1)
Cash, cash equivalents and investments	$ 414,115	$ 442,387
Restricted cash	1,574	1,472
Receivables	57,667	50,599

Total assets	529,885	550,000
Secured term loan	293,176	231,624
Royalty financing obligation	526,121	501,655
Accumulated deficit	(1,583,279)	(1,454,620)
Stockholders' deficit	(388,713)	(294,597)
Shares of common stock outstanding	189,491	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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
GAAP net loss	**$ (75,326)**	**$ (58,859)**	**$ (128,659)**	**$ (133,055)**
Less : One-time loss on extinguishment of Athyrium term loans	(29,019)	-	(29,019)	-
Adjusted net loss	**$ (46,307)**	**$ (58,859)**	**$ (99,640)**	**$ (133,055)**
GAAP basic and diluted net loss per common share	**$ (0.40)**	**$ (0.32)**	**$ (0.68)**	**$ (0.72)**
Adjusted basic and diluted net loss per common share	**$ (0.24)**	**$ (0.32)**	**$ (0.53)**	**$ (0.72)**