BioCryst Reports First Quarter 2023 Financial Results and Provides Business Update

May 3, 2023

—Q1 2023 ORLADEYO net revenue grows 38 percent y-o-y to $68.4 million—

—Strong ORLADEYO new patient growth in Q1: 46 percent increase in patients on therapy y-o-y, including eight percent growth q-o-q—

—Over 1,000 U.S. patients on ORLADEYO therapy—

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

RESEARCH TRIANGLE PARK, N.C., May 03, 2023 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today reported financial results for the first quarter ended March 31, 2023, and provided a corporate update.

“The strong new patient growth in the first quarter, building on our large patient base with ORLADEYO, positions us very well to achieve our expectations for 2023, and advances us on a trajectory to peak sales of $1 billion. This growing revenue stream, alongside our robust balance sheet, has dramatically reduced our reliance on the capital markets as we drive value with continued commercial execution and disciplined investment in our pipeline,” 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

- ORLADEYO net revenue in the first quarter of 2023 was $68.4 million (+37.6 percent year-over-year (y-o-y)).
- The number of U.S. patients on drug at the end of Q1 2023 increased by 46 percent compared to the end of Q1 2022 and increased by eight percent compared to the end of Q4 2022.
- The launch has recently surpassed the milestone of 1,000 patients in the U.S. on ORLADEYO therapy.
- New patient growth remained strong, with a 20 percent increase in U.S. patient start forms in the first quarter of 2023 compared to the first quarter of 2022. There were more new U.S. patient start forms in the first quarter of 2023 than in three of the four quarters in 2022.
- The launch of ORLADEYO outside the U.S. continues to accelerate. Sales from outside the U.S. contributed 11.1 percent of global ORLADEYO net revenues in the first quarter.
- As expected, the percentage of U.S. ORLADEYO patients receiving free drug in the first quarter increased, primarily because many patients went through the annual re-authorization process with payors.

“As we enter our third year on the market, 1,000 of 7,500 U.S. HAE patients are already benefitting from ORLADEYO. Demand is very strong in the U.S. and in international markets and our market data from patients and physicians tells us that ORLADEYO is still in the early stages of its growth trajectory,” said Charlie Gayer, chief commercial officer of BioCryst.

Rare Disease Pipeline

The goal with our pipeline is to continue bringing selected, highly differentiated rare disease products to the market, and to reproduce the commercial success we have delivered with ORLADEYO. We are investing to expand the ORLADEYO label with our ongoing pediatric trial (APeX-P); and pursuing BCX10013, a potential best-in-class once-daily, oral Factor D inhibitor, an oral C2 inhibitor in lead optimization, and other discovery programs targeting multiple complement and non-complement pathways.

Debt Refinancing

On April 17, 2023, the company entered into a $450 million loan agreement with Pharmakon which provided for an initial term loan of $300 million. The remaining $150 million can be drawn at the company’s option until September 2024. The initial proceeds were used to repay the outstanding indebtedness with Athyrium and provided approximately $26 million for other general corporate purposes.

First Quarter 2023 Financial Results

For the three months ended March 31, 2023, total revenues were $68.8 million, compared to $49.9 million in the first quarter of 2022 (+37.8 percent y-o-y). The increase was primarily due to $68.4 million in ORLADEYO net revenue in the first quarter of 2023, compared to $49.7 million in ORLADEYO net revenue in the first quarter of 2022 (+37.6 percent y-o-y).

Research and development (R&D) expenses for the first quarter of 2023 decreased to $48.4 million from $65.4 million in the first quarter of 2022 (-26.0 percent y-o-y), primarily due to reduced R&D investment following the discontinuation of the BCX9930 and BCX9250 programs.

Selling, general and administrative (SG&A) expenses for the first quarter of 2023 increased to $47.9 million, compared to $34.3 million in the first quarter of 2022 (+39.6 percent y-o-y). The increase was primarily due to increased investment to expand and enhance the U.S. commercial team and expanded international operations.

Interest expense was $27.4 million in the first quarter of 2023, compared to $23.8 million in the first quarter of 2022 (+14.9 percent y-o-y). The increase was due to service on the company's royalty and debt financing agreements. $7.1 million was paid in cash following the expiration of the payment-in-kind (PIK) interest period under the Athyrium agreement.

Net loss for the first quarter of 2023 was $53.3 million, or $0.28 per share, compared to a net loss of $74.2 million, or $0.40 per share, for the first quarter of 2022.

Cash, cash equivalents, restricted cash and investments totaled $403.1 million at March 31, 2023, compared to $446.8 million at March 31, 2022. Operating cash use for the first quarter of 2023 was $40.8 million. Following the completion of the debt refinancing with Pharmakon announced in April 2023, net proceeds of the agreement of $26 million brought pro forma cash to approximately $429 million.

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.

BCRXW

Contact:
John Bluth
+1 919 859 7910
jbluth@biocryst.com

BIOCRYST PHARMACEUTICALS, INC.
CONSOLIDATED FINANCIAL SUMMARY
(in thousands, except per share)

Statements of Operations (Unaudited)

	Three Months Ended March 31,	
	2023	2022
Revenues:		
ORLADEYO	$ 68,414	$ 49,704
Other	364	219
Total revenues	68,778	49,923
Expenses:		
Cost of product sales	931	236
Research and development	48,388	65,360
Selling, general and administrative	47,867	34,282
Royalty	7	2
Total operating expenses	97,193	99,880
Loss from operations	(28,415)	(49,957)
Interest and other income	3,378	54
Interest expense	(27,396)	(23,837)
Foreign currency (losses) gains, net	(229)	(177)
Loss before income taxes	(52,662)	(73,917)
Income tax expense	671	279
Net loss	$ (53,333)	$ (74,196)
Basic and diluted net loss per common share	$ (0.28)	$ (0.40)
Weighted average shares outstanding	188,509	184,898

Balance Sheet Data (in thousands)

	March 31, 2023 (Unaudited)	December 31, 2022 (Note 1)
Cash, cash equivalents and investments	$ 401,590	$ 442,387
Restricted cash	1,463	1,472
Receivables	48,639	50,599
Total assets	509,737	550,000
Secured term loan	232,522	231,624
Royalty financing obligation	514,411	501,655
Accumulated deficit	(1,507,953)	(1,454,620)
Stockholders' deficit	(328,287)	(294,597)
Shares of common stock outstanding	188,883	187,906

Note 1: Derived from audited financial statements.