BioCryst Reports Second Quarter 2022 Financial Results and Upcoming Key Milestones

August 4, 2022

—Q2 2022 ORLADEYO net revenue of $65.2 million—

—FY 2022 ORLADEYO net revenue expected to be between $255 million and $265 million—

RESEARCH TRIANGLE PARK, N.C., Aug. 04, 2022 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today reported financial results for the second quarter ended June 30, 2022, and provided a corporate update.

“With ORLADEYO firmly established in the marketplace as it steadily grows each quarter towards $1 billion in peak sales, our pipeline of other oral drugs for rare diseases and a balance sheet of nearly $500 million alongside our product revenues, BioCryst is uniquely positioned to bring multiple oral medicines for rare diseases to patients,” 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

U.S. Launch

- ORLADEYO net revenue in the second quarter of 2022 was $65.2 million.
- In the second quarter, more new physicians prescribed ORLADEYO than any quarter since the third quarter of 2021.
- Prescribing from the top 500 HAE treaters increased in the second quarter with 60 percent of those physicians now having prescribed ORLADEYO. These top 500 physicians accounted for two-thirds of new patient prescriptions in the quarter.
- The majority of patients continue to be well controlled on ORLADEYO. Even as the patient base has continued to grow steadily, discontinuations in the second quarter declined to their smallest number since the third quarter of 2021.
- Patients continue to have broad and rapid access to ORLADEYO with the median time for a patient to receive reimbursed product following a prescription now under three weeks.
- Based on the strong performance of ORLADEYO in the first half of 2022, and the steady quarterly ORLADEYO net revenue growth the company expects in the second half of 2022, the company now expects full year 2022 ORLADEYO net revenue to be between $255 million and $265 million. The company expects peak global net ORLADEYO sales of $1 billion.

“More than a year and a half into the launch of ORLADEYO, we see steady growth and strong momentum, which we expect to continue. The majority of HAE patients are very satisfied with their experience using oral, once-daily ORLADEYO and physicians continue to consistently express their strong intent for future prescribing, which we see translating directly to our growing patient numbers quarter after quarter,” said Charlie Gayer, chief commercial officer of BioCryst.

ORLADEYO: Global Updates

- In the second quarter, ORLADEYO was approved in Canada and Switzerland. The company expects approvals and launches in additional countries throughout the year.
- Also in the second quarter, pricing was finalized in Germany, France and Switzerland.
- On June 9, 2022, the company announced it had selected Pint Pharma as its commercial partner for ORLADEYO in Latin America.

Complement Oral Factor D Inhibitor Program – BCX9930

- On August 4, 2022, the company announced that the U.S. Food and Drug Administration (FDA) has lifted its partial clinical hold on the BCX9930 program. The company will resume enrollment in global clinical trials under revised protocols at a reduced dose of 400 mg twice daily of BCX9930. This includes the REDEEM-1 and REDEEM-2 pivotal trials in patients with paroxysmal nocturnal hemoglobinuria (PNH) and the RENEW proof-of-concept trial in patients with C3 glomerulopathy

(C3G), immunoglobulin A nephropathy (IgAN) and primary membranous nephropathy (PMN).

- Clinical evidence and recent laboratory studies have informed the company's hypothesis that crystals form in the kidneys of some patients. The company believes that lowering the dose to 400 mg and ensuring adequate hydration will dilute the concentration of drug in the urine below the threshold where crystals can form.

- The company's goal is to find a safe and effective dose for BCX9930. The company expects this can be accomplished in a reasonable time frame after resuming enrollment, in a relatively small number of patients given the rate and timing of the serum creatinine rises in patients prior to the enrollment pause.

- If successful, the company plans to invest more significantly in BCX9930 to tap the full potential of reaching many patients suffering from a number of alternative pathway diseases, and, if not successful, the company will stop investment in BCX9930 and move on to other molecules in the pipeline.

Additional Updates

- On April 27, 2022, the company announced the European Medicines Agency (EMA) had granted PRIME designation to BioCryst's ALK-2 inhibitor, BCX9250, for the treatment of fibrodysplasia ossificans progressiva.

- The EMA also has recently granted orphan drug designation and the FDA has granted fast track status for BCX9250.

Second Quarter 2022 Financial Results

For the three months ended June 30, 2022, total revenues were $65.5 million, compared to $50.0 million in the second quarter of 2021 (+31 percent year-over-year (y-o-y)). The increase was primarily due to $65.2 million in ORLADEYO net revenue in the second quarter of 2022, compared to $28.5 million in ORLADEYO net revenue in the second quarter of 2021 (+129 percent y-o-y). The $65.2 million of ORLADEYO net revenue in the second quarter of 2022 included approximately $2.2 million of non-repeating reimbursement related accrual releases.

Research and development expenses for the second quarter of 2022 increased to $62.0 million from $52.9 million in the second quarter of 2021 (+17 percent y-o-y), primarily due to increased investment in the development of our Factor D program, including BCX9930, as well as other research, preclinical and development costs.

Selling, general and administrative expenses for the second quarter of 2022 increased to $38.0 million, compared to $26.3 million in the second quarter of 2021 (+44 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 $24.0 million in the second quarter of 2022, compared to $13.5 million in the second quarter of 2021 (+78 percent y-o-y). The increase was due to service on the royalty financings, which were completed in November 2021.

Net loss for the second quarter of 2022 was $58.9 million, or $0.32 per share, compared to a net loss of $43.2 million, or $0.24 per share, for the second quarter of 2021.

Cash, cash equivalents, restricted cash and investments totaled $418.9 million at June 30, 2022, compared to $222.8 million at June 30, 2021. Operating cash use for the second quarter of 2022 was $27.9 million.

Additionally, on July 29, 2022, having achieved all required revenue-based milestones, the company drew the available $75 million tranche under its existing credit facility from Athyrium Capital Management. On a pro-forma basis, net of fees, this results in pro-forma cash of approximately $492 million.

Financial Outlook for 2022

Based on the strength of the ORLADEYO launch through the first half of 2022, and the continued steady growth from new patient demand the company expects for the remainder of the year, the company expects full year 2022 net ORLADEYO revenue to be between $255 million and $265 million.

Based on the reduced spending on the BCX9930 program in the first half of the year, and lower than projected spending on the program for the remainder of the year, the company now expects operating expenses for full year 2022, not including non-cash stock compensation, to be between $390 million and $400 million.

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 866-374-5140 for domestic callers and 404-400-0571 for international callers and using conference ID 68509725#. A live webcast of the call and any slides will be available online at the investors section of the company website at www.biocryst.com. A replay of the call will be available on the company website.

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 multiple global markets. BioCryst has several ongoing development programs including BCX9930, an oral Factor D inhibitor for the treatment of complement-mediated diseases, BCX9250, an ALK-2 inhibitor for the treatment of fibrodysplasia ossificans progressiva, and galidesivir, a potential

treatment for Marburg virus disease and yellow fever. 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 BCX9930, BCX9250 and galidesivir 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, all of which identify important factors that could cause the 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,	
	2022	2021	2022	2021
Revenues:				
Product sales	$ 64,888	$ 33,430	$ 114,434	$ 51,301
Royalty revenue	540	128	887	(769)
Milestone revenue	-	15,000	-	15,000
Collaborative and other research and development	104	1,401	134	3,486
Total revenues	65,532	49,959	115,455	69,018
Expenses:				
Cost of product sales	246	297	482	6,220
Research and development	61,990	52,873	127,350	95,308
Selling, general and administrative	38,017	26,325	72,299	48,439
Royalty	1	46	3	10
Total operating expenses	100,254	79,541	200,134	149,977

Loss from operations	(34,722)	(29,582)	(84,679)	(80,959)
Interest and other income	609	13	663	39
Interest expense	(24,022)	(13,495)	(47,859)	(26,399)
Foreign currency gains (losses), net	132	(134)	(45)	(163)
Loss before income taxes	(58,003)	(43,198)	(131,920)	(107,482)
Income tax expense	856	-	1,135	-
Net loss	$ (58,859)	$ (43,198)	$ (133,055)	$ (107,482)
Basic and diluted net loss per common share	$ (0.32)	$ (0.24)	$ (0.72)	$ (0.60)
Weighted average shares outstanding	185,605	178,127	185,253	177,737

Balance Sheet Data (in thousands)

	June 30, 2022 (Unaudited)	December 31, 2021 (Note 1)
Cash, cash equivalents and investments	$ 417,483	$ 514,430
Restricted cash	1,448	3,345
Receivables	41,491	29,413
Total assets	510,538	588,151
Secured term loan	144,516	136,082
Royalty financing obligation	477,666	449,375
Accumulated deficit	(1,340,559)	(1,207,504)
Stockholders' deficit	(213,232)	(106,986)
Shares of common stock outstanding	185,876	184,350

Note 1: Derived from audited financial statements.