BioCryst Reports Second Quarter 2024 Financial Results and Provides Business Update

August 5, 2024

—Q2 2024 ORLADEYO net revenue grows 34 percent y-o-y to $108.3 million—

—Full-year 2024 ORLADEYO revenue guidance increased to $420-$435 million (previously $390-$400 million)—

—Company generates GAAP operating profit of $8.8 million in second quarter ($21.9 million non-GAAP operating profit)—

—Pipeline continues to advance—

RESEARCH TRIANGLE PARK, N.C., Aug. 05, 2024 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today reported financial results for the second quarter ended June 30, 2024, and provided a corporate update.

“The first half of 2024 has been outstanding for BioCryst due to the success we are having in the marketplace with ORLADEYO. As a result, we are increasing our full year guidance for ORLADEYO, advancing multiple programs toward the clinic in the next 18 months and moving the company closer to profitability,” said Jon Stonehouse, president and chief executive officer of BioCryst.

ORLADEYO® (berotralstat): Oral, Once-daily Treatment for Prevention of Hereditary Angioedema (HAE) Attacks

- ORLADEYO net revenue in the second quarter of 2024 was $108.3 million (+34 percent year-over-year (y-o-y)).
- Operational improvements drove revenue above expectations for the second quarter. This included a three percent increase in the overall rate of paid patients relative to the end of 2023, which now stands at 74.4 percent.
- New patient starts continued at the same high rate seen in the prior two quarters, matching the new patient demand seen in the first three quarters of the launch in 2021, and patient retention remained strong. We continue to see more than 60 percent of patients on paid therapy staying on for at least a year.
- A recent market research study showed that 52 percent of allergist/immunologists are extremely likely to prescribe ORLADEYO to more patients, up from 29 percent in early 2023.
- With additional recent approvals and reimbursement authorizations in Europe and Latin America, ORLADEYO is now commercially available to patients in more than 20 countries. Ex-U.S. ORLADEYO revenue in the second quarter increased 51 percent y-o-y and accounted for 11 percent of global ORLADEYO net revenues.

“Our second quarter revenue growth and increased full year guidance for ORLADEYO reflect strong underlying demand and favorable patient outcomes, combined with our continuing focus on improving patient services and market access operations. The real-world experience of patients who respond to ORLADEYO is consistent with the 91 percent reduction in attacks from baseline that we saw in long-term clinical trials. The potential for patients to have that high level of HAE attack control in a once-daily pill is a major differentiator in the marketplace that makes ORLADEYO’s trajectory toward $1 billion in peak sales increasingly clear,” said Charlie Gayer, chief commercial officer of BioCryst.

Rare Disease Pipeline

The goal with our pipeline is to build on our success with ORLADEYO by bringing additional selected, highly differentiated rare disease products to patients.

- The company remains on track to submit a regulatory filing in 2025 to expand the ORLADEYO label to enable children as young as two years of age to receive an oral granule formulation of ORLADEYO. ORLADEYO would be the first oral prophylactic therapy for children with HAE.
- The company has completed its clinical evaluation of its oral Factor D inhibitor, BCX10013. The drug was safe and well tolerated at all doses studied, however the level of clinical activity observed was less than other therapies on the market and potential partners have declined to make the additional investment required to evaluate higher doses. BioCryst plans to discontinue development, consistent with its previously announced plans.
- The company expects to advance BCX17725, its KLK-5 inhibitor for the treatment of Netherton syndrome, into the clinic by the end of 2024.

- Netherton syndrome is a serious, rare, lifelong genetic disorder affecting the skin, hair and immune system. People with Netherton syndrome often have red, scaly, inflamed skin, fragile hair, and are more likely to develop skin infections, allergies, asthma and eczema. Netherton syndrome can be life threatening, especially during infancy when patients are vulnerable to dehydration and recurrent infections. Currently, there is no approved treatment for Netherton syndrome.

- In 2025, the company plans to advance avoralstat, a plasma kallikrein inhibitor, into a clinical trial of patients with diabetic macular edema (DME).

  - DME is an important cause of vision loss in diabetes and is due to leakage from the blood vessels in the retina. While current treatments focus on VEGF inhibition, DME can develop from other mechanisms, such as the kallikrein-bradykinin pathway. This is supported by observations that many DME patients have an incomplete response to intravitreal anti-VEGF therapies that are administered every four to eight weeks. Avoralstat targets the kallikrein-bradykinin system on the retinal vascular endothelial cells and may result in less vascular leakage and less edema. Avoralstat, delivered to the suprachoroidal space as a depot formulation, is designed to provide high dose levels to the retinal vessels with long-lasting exposure, which could result in less frequent injections and a reduced burden on patients and the healthcare system.

Second Quarter 2024 Financial Results

For the three months ended June 30, 2024, total revenues were $109.3 million, compared to $82.5 million in the second quarter of 2023 (+32.5 percent year-over-year (y-o-y)). The increase was primarily due to $108.3 million in ORLADEYO net revenue in the second quarter of 2024, compared to $81.0 million in ORLADEYO net revenue in the second quarter of 2023 (+33.7 percent y-o-y).

R&D expenses for the second quarter of 2024 decreased to $37.6 million from $51.2 million in the second quarter of 2023 (-26.6 percent y-o-y), primarily due to decreased spending on BCX10013 and the discontinuation of the BCX9930 program. These reductions were partially offset by increased investment in BCX17725, avoralstat and other discovery programs, and our ongoing ORLADEYO pediatric trial.

Selling, general and administrative expenses for the second quarter of 2024 increased to $61.2 million, compared to $51.0 million in the second quarter of 2023 (+20.0 percent y-o-y), primarily due to an increase in commercial expenses to support growing revenue, newly launched regions and expanded international operations. In addition, there was an increase in general and administrative expenses, primarily related to an increase in resourcing to support our accounting and IT functions.

Total operating expenses were $100.6 million for the second quarter of 2024, compared to $103.2 million in the second quarter of 2023 (-2.5 percent y-o-y). Non-cash stock compensation was $13.2 million for the second quarter of 2024. Total operating expenses, not including non-cash stock compensation for the second quarter of 2024 were $87.4 million, compared to $90.4 million in the second quarter of 2023 (-3.3 percent y-o-y).

The company generated a GAAP operating profit of $8.8 million in the second quarter of 2024. This compares to a GAAP operating loss of $20.7 million in the second quarter of 2023. Adjusted for non-cash stock compensation, the non-GAAP operating profit was $21.9 million in the second quarter of 2024, compared to a non-GAAP operating loss of $7.9 million in the second quarter of 2023.

Interest expense was $24.7 million in the second quarter of 2024, compared to $28.9 million in the second quarter of 2023 (-14.5 percent y-o-y). The decrease was primarily due to a decrease in the amortization of interest associated with our royalty financing obligations.

Net loss for the second quarter of 2024 was $12.7 million, or $0.06 per share, compared to a net loss of $75.3 million, or $0.40 per share, for the second quarter of 2023. In the second quarter of 2023, 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 $338.1 million at June 30, 2024, compared to $415.7 million at June 30, 2023. Operating cash use for the second quarter of 2024 was $0.2 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 and second quarter 2024 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, operating profit 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. Our reference to our second quarter 2024 and first six months 2024 “non-GAAP pro forma” financial measure of non-GAAP operating profit constitutes a non-GAAP financial measure. It refers to our GAAP results, adjusted to show the results without including non-cash stock compensation expense.

Financial Outlook for 2024

Based on the operational improvements and strong patient and physician demand for ORLADEYO seen in the first half of 2024, the company is raising

its outlook for full year 2024 global net ORLADEYO revenue to be between $420 million and $435 million (previously $390 million to $400 million).

The company maintains its prior operating expense outlook, and expects full year 2024 operating expenses to be between $365 million and $375 million, flat to full year 2023 operating expenses.

This operating expense outlook does not reflect non-cash stock compensation expense, or one-time expenses related to the previously announced workforce reduction implemented in the first quarter of 2024.

Based on the company's disciplined approach to capital allocation, and the increased revenue guidance for ORLADEYO, the company is confident that it will achieve a full-year operating profit in 2024 (not including non-cash stock compensation), be approaching quarterly positive earnings per share (EPS) and positive cash flow in the second half of 2025 (not including non-cash stock compensation) and be profitable on an EPS basis, with positive cash flow, for full year 2026. The company expects it can achieve these financial milestones without raising additional funds and does not intend to draw the additional $150 million of debt available to it from Pharmakon.

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 1-844-481-2942 for domestic callers and 1-412-317-1866 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 is a global biotechnology company with a deep commitment to improving the lives of people living with complement-mediated and other rare diseases. BioCryst leverages its expertise in structure-guided drug design to develop first-in-class or best-in-class oral small-molecule and protein therapeutics to target difficult-to-treat diseases. BioCryst has commercialized ORLADEYO® (berotralstat), the first oral, once-daily plasma kallikrein inhibitor, and is advancing a pipeline of small-molecule and protein therapies. For more information, please visit www.biocryst.com or follow us on LinkedIn.

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: BioCryst's ability to successfully implement or maintain its commercialization plans for ORLADEYO; risks related to the planned discontinuation of the development of BCX10013; BioCryst's ability to successfully progress its pipeline development plans as described herein; risks related to the reduction in size of BioCryst's R&D organization; 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 sustained market acceptance; ongoing and future preclinical and clinical development of product candidates may take longer than expected and may not have positive results; 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; BioCryst's ability to successfully manage its growth and compete effectively; risks related to the international expansion of BioCryst's business; timing for achieving profitability and positive cash flow may not meet management's expectations; statements and projections regarding financial guidance and goals and the attainment of such goals may differ from actual results based on market factors and BioCryst's ability to execute its operational and budget plans; 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,	
	2024	2023	2024	2023
Revenues:				
ORLADEYO	$ 108,288	$ 81,009	$ 197,155	$ 149,423
Other	1,044	1,482	4,938	1,846

Total revenues	109,332	82,491	202,093	151,269
Expenses:				
Cost of product sales	1,699	894	2,964	1,825
Research and development	37,623	51,247	84,116	99,635
Selling, general and administrative	61,214	50,997	120,578	98,864
Royalty	35	56	162	63
Total operating expenses	100,571	103,194	207,820	200,387
Income (loss) from operations	8,761	(20,703)	(5,727)	(49,118)
Interest income	3,554	3,750	7,585	7,128
Interest expense	(24,733)	(28,915)	(49,239)	(56,311)
Foreign currency (losses) gains, net	(84)	301	(135)	72
Loss on extinguishment of debt	—	(29,019)	—	(29,019)
Loss before income taxes	$ (12,502)	$ (74,586)	$ (47,516)	$ (127,248)
Income tax expense	172	740	537	1,411
Net loss	$ (12,674)	$ (75,326)	$ (48,053)	$ (128,659)
Basic and diluted net loss per common share	$ (0.06)	$ (0.40)	$ (0.23)	$ (0.68)
Weighted average shares outstanding	206,425	189,118	206,244	188,815

Balance Sheet Data (in thousands)

	June 30, 2024 (unaudited)	December 31, 2023 (Note 1)
Cash, cash equivalents and investments	$ 336,344	$ 388,987
Restricted cash	1,795	1,804
Receivables	68,759	56,950
Total assets	472,419	516,960
Secured term loan	313,822	303,231
Royalty financing obligation	523,633	531,599
Accumulated deficit	(1,729,212)	(1,681,159)
Stockholders' deficit	(475,606)	(455,528)
Shares of common stock outstanding	206,629	205,771

Note 1: Derived from audited financial statements.

Reconciliation of Adjusted Net Loss and Adjusted Diluted Earnings Per Share (in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
GAAP net loss	$ (12,674)	$ (75,326)	$ (48,053)	$ (128,659)
Less: One-time R&D restructuring expense	—	—	(1,264)	—
Less: One-time loss on extinguishment of Athyrium term loans	—	(29,019)	—	(29,019)
Adjusted net loss	$ (12,674)	$ (46,307)	$ (46,789)	$ (99,640)
GAAP basic and diluted net loss per common share	$ (0.06)	$ (0.40)	$ (0.23)	$ (0.68)
Adjusted basic and diluted net loss per common share	$ (0.06)	$ (0.24)	$ (0.23)	$ (0.53)

Reconciliation of Adjusted Income (Loss) from Operations (in thousands)

	Three Months Ended June 30,	Six Months Ended June 30,

	2024	2023	2024	2023
GAAP income (loss) from operations	$ 8,761	$ (20,703)	$ (5,727)	$ (49,118)
Less: Stock-based compensation expense	(13,173)	(12,841)	(26,825)	(26,848)
Adjusted income (loss) from operations	$ 21,934	$ (7,862)	$ 21,098	$ (22,270)