BioCryst Reports First Quarter 2024 Financial Results and Provides Business Update

May 6, 2024

—Q1 2024 ORLADEYO net revenue grows 30 percent y-o-y to $88.9 million—

—Full-year 2024 ORLADEYO revenue guidance adjusted to $390-$400 million (top end of prior guidance range) —

—Pipeline programs, including BCX17725 for Netherton syndrome and avoralstat for DME, advancing on schedule into clinical trials—

RESEARCH TRIANGLE PARK, N.C., May 06, 2024 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today reported financial results for the first quarter ended March 31, 2024, and provided a corporate update.

“We are off to a fantastic start to the year with outstanding ORLADEYO revenue growth and our prioritized pipeline programs advancing on schedule. We are focused on continuing this momentum as we see strong patient demand for ORLADEYO and more pipeline programs advancing into the clinic, starting later this year,” 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 first quarter of 2024 was $88.9 million (+30 percent year-over-year (y-o-y)).
- In the first quarter, the U.S. commercial team accelerated patients going through annual reimbursement reauthorization from free drug to paid drug faster than in previous years, generating higher than expected ORLADEYO revenue.
- New patient growth remained strong, with the past two quarters having the most new prescriptions in the United States since the first two quarters of the launch.
- Sales from outside the U.S. contributed 10 percent of global ORLADEYO net revenues in the first quarter, as the number of patients treated with ORLADEYO continued to grow strongly and consistently in new and existing markets.
- New real-world evidence showing significant reductions in healthcare resource utilization among patients with HAE following ORLADEYO initiation to be presented in a poster on May 8 at the 2024 International Society for Pharmacoeconomics and Outcomes Research conference (ISPOR).

“Our team made exceptional efficiency improvements in the U.S. prescription reauthorization process, and new prescriptions remained very strong as physicians and patients increasingly understand that ORLADEYO provides excellent efficacy and convenience. These two successes helped us exceed our revenue projections for the quarter and, as a result, we are increasing our revenue guidance for 2024,” 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. Milestones in the next 18 months include:

- The ongoing proof-of-concept trial with BCX10013, an oral Factor D inhibitor, remains on track. The company expects to partner or discontinue the program later this year.
- Enrollment is complete in the APeX-P pediatric trial. Data from the trial will support a regulatory filing in 2025 to expand the ORLADEYO label to enable children as young as two years of age to receive ORLADEYO. ORLADEYO would be the first oral prophylactic therapy for children with HAE.
- 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 rare, lifelong genetic disorder that often presents in neonates or infancy with red, scaly and inflamed skin and susceptibility to recurrent skin infections. 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 the most common cause of vision loss in individuals with diabetes and at least one-third of patients have persistent DME despite anti-VEGF therapies, which are administered via monthly injection. By delivering avoralstat with Clearside's SCS microinjector ® directly into the suprachoroidal space of the eye in the clinical trial, avoralstat could inhibit plasma kallikrein at the sites of edema formation in DME disease, the retinal and choroidal vascular endothelium. With its low solubility, the drug could persist in the eye at the site of disease for a long duration, resulting in less frequent injections.

"It is very exciting to be advancing our pipeline of first-in-class/best-in-class molecules into the clinic to generate proof-of-concept data across multiple programs and diseases, and to be so close to delivering the first oral prophylactic option to children with HAE," said Dr. Helen Thackray, chief research and development officer of BioCryst.

First Quarter 2024 Financial Results

For the three months ended March 31, 2024, total revenues were $92.8 million, compared to $68.8 million in the first quarter of 2023 (+34.9 percent y-o-y). The increase was primarily due to $88.9 million in ORLADEYO net revenue in the first quarter of 2024, compared to $68.4 million in ORLADEYO net revenue in the first quarter of 2023 (+30 percent y-o-y).

Research and development (R&D) expenses for the first quarter of 2024 decreased to $46.5 million from $48.4 million in the first quarter of 2023 (-3.9 percent y-o-y), primarily due to decreased spending on BCX10013 due to our plan to either out-license or discontinue late-stage development and commercialization, which was announced in January 2024, as well as the discontinuation of the BCX9930 program, which was announced in December 2022. These reductions were partially offset by increased investment in BCX17725 and other discovery programs, and ORLADEYO label expansion and life cycle investments, such as our ongoing ORLADEYO pediatric trial.

Selling, general and administrative (SG&A) expenses for the first quarter of 2024 increased to $59.4 million, compared to $47.9 million in the first quarter of 2023 (+24.0 percent y-o-y). The increase was primarily due to increased investment to expand and enhance the U.S. commercial team and expand and support international operations.

Operating loss for the first quarter was $14.5 million, adjusted to $0.8 million excluding non-cash stock compensation.

Interest expense was $24.5 million in the first quarter of 2024, compared to $27.4 million in the first quarter of 2023 (-10.6 percent y-o-y). The decrease was primarily due to a decrease in the amortization of interest associated with our royalty financing obligations, partially offset by an increase in interest expense associated with the Pharmakon debt refinancing secured in April 2023.

Net loss for the first quarter of 2024 was $35.4 million, or $0.17 per share, compared to a net loss of $53.3 million, or $0.28 per share, for the first quarter of 2023. Non-GAAP net loss for the first quarter of 2024 was $34.1 million, or $0.17 per share when excluding one-time costs associated with the R&D restructuring, totaling $1.3 million. A reconciliation between GAAP and non-GAAP net loss is provided in the table below.

Cash, cash equivalents, restricted cash and investments totaled $338.4 million at March 31, 2024, compared to $403.1 million at March 31, 2023. Net cash utilization for the first quarter of 2024 was $52.4 million, which was driven by debt service, royalty payments and one-time first quarter compensation expense. We expect, as in previous years, that the first quarter will be the highest quarter of operating cash use for the year, and that operating cash use for the remaining quarters of 2024 will normalize around $10-$12 million per quarter. We expect that total cash at the end of 2024 will be above $300 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 allowed investors to more accurately understand our current period results and more easily compare them to future results. These non-GAAP pro forma measures also correspond with the way we expect investors and financial 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 first quarter 2024 "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 costs associated with the R&D restructuring. A reconciliation between GAAP and non-GAAP net loss is provided in the table below.

Financial Outlook for 2024

Based on the team's success in accelerating ORLADEYO patients through the U.S. reauthorization process faster than anticipated, the company is adjusting its outlook for full year 2024 global net ORLADEYO revenue to be between $390 million and $400 million, the top end of its prior guidance range.

The company 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 adjusted revenue guidance for ORLADEYO, the company is even more 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 its commercialization plans for ORLADEYO, which could take longer or be more expensive than planned; BioCryst's ability to successfully implement its plans for BCX10013, including that the results of the ongoing proof-of-concept trial may differ from BioCryst's expectations and that BioCryst may not be able to successfully out-license the late-stage development and commercialization 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 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 March 31,	
	2024	2023
Revenues:		
ORLADEYO	$ 88,867	$ 68,414
Other	3,894	364
Total revenues	92,761	68,778
Expenses:		
Cost of product sales	1,265	931
Research and development	46,493	48,388
Selling, general and administrative	59,364	47,867
Royalty	127	7
Total operating expenses	107,249	97,193

Loss from operations	(14,488)	(28,415)
Interest income	4,031	3,378
Interest expense	(24,506)	(27,396)
Foreign currency losses, net	(51)	(229)
Loss before income taxes	$ (35,014)	$ (52,662)
Income tax expense	365	671
Net loss	$ (35,379)	$ (53,333)
Basic and diluted net loss per common share	$ (0.17)	$ (0.28)
Weighted average shares outstanding	206,064	188,509

Balance Sheet Data (in thousands)

	March 31, 2023 (unaudited)	December 31, 2023 (Note 1)
Cash, cash equivalents and investments	$ 336,554	$ 388,987
Restricted cash	1,798	1,804
Receivables	60,586	56,950
Total assets	467,892	516,960
Secured term loan	308,484	303,231
Royalty financing obligation	530,574	531,599
Accumulated deficit	(1,716,538)	(1,681,159)
Stockholders' deficit	(476,167)	(455,528)
Shares of common stock outstanding	206,347	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 March 31,	
	2024	**2023**
GAAP net loss	**$ (35,379)**	**$ (53,333)**
Less: One-time R&D restructuring expense	(1,264)	—
Adjusted net loss	**$ (34,115)**	**$ (53,333)**
GAAP basic and diluted net loss per common share	**$ (0.17)**	**$ (0.28)**
Adjusted basic and diluted net loss per common share	**$ (0.17)**	**$ (0.28)**