Biora Therapeutics Provides Corporate Update and Reports Second Quarter 2024 Financial Results

August 12, 2024

Phase 1 clinical trial results for BT-600 demonstrate precise drug delivery to the colon with low systemic exposure, supporting clinical development plan

Company secures up to $16M funding from existing investors supported by BT-600 results and progress toward BioJet™ partnership

Management will host conference call and webcast today at 4:30 PM Eastern / 1:30 PM Pacific

SAN DIEGO, Aug. 12, 2024 (GLOBE NEWSWIRE) -- Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company reimagining therapeutic delivery, today provided a corporate update and reported financial results for the second quarter ended June 30, 2024.

“Research shows that ulcerative colitis patients with higher drug exposure in the colon tissue have significantly better responses to therapy,” said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. “Our Phase 1 clinical trial demonstrated the NaviCap platform’s ability to achieve higher tissue drug exposure by direct, topical delivery to the colon, and we are thrilled to have met all our study objectives. Everything we have seen indicates that our approach should lead to improved response and reduced toxicity for UC patients, and we are eager to continue with clinical development to prove that out.”

“Our goal for the BioJet™ platform last quarter was to achieve a critical mass of data and to have partner-stated interest confirmed by mid year. We met that goal, and we’re currently in active partnership discussions with more than one large pharma company and anticipate bringing at least one of these through to completion in the near term. This progress has also been recognized by several of our institutional investors, who are stepping up to support our operations while we conclude our partnership process,” continued Mr. Mohanty.

Second Quarter 2024 and Recent Highlights

NaviCap™ Targeted Oral Delivery Platform and BT-600 in ulcerative colitis

- **Completion of Phase 1 Clinical Trial for BT-600.** All trial objectives were met, with results demonstrating precise drug delivery to the colon with limited systemic exposure. Results demonstrated a pharmacokinetic (PK) profile consistent with drug delivery and absorption in the colon for both single and multiple ascending dose (SAD/MAD) cohorts:
    - First evidence of systemic absorption of tofacitinib was at six hours, consistent with colonic (vs. upper gastrointestinal) delivery. Maximal levels in the trial occurred at eight to ten hours vs. 30 minutes for conventional oral tofacitinib in other trials.
    - Maximal systemic drug exposure was three to four times lower than that seen with conventional oral tofacitinib in other trials, demonstrating the NaviCap platform’s ability to deliver locally to the colon and limit systemic drug exposure.
- The distribution of colon tissue exposure suggests that pan-colonic delivery of tofacitinib was achieved:
    - Biopsy results provided evidence of drug exposure extending to sites in the distal colon, following delivery of tofacitinib in the proximal colon, with concentrations above the IC50 level for all three locations.
    - Modeling projects tissue levels at or above the estimated IC90 through at least 16 hours after dosing.
    - Post-retrieval device analysis further confirmed that NaviCap devices accurately delivered drug in the colon, with no early release, and with >95% of devices detecting colon entry.
- NaviCap devices were well tolerated by participants in both the SAD and MAD cohorts:
    - No serious adverse events occurred; all AEs were consistent with those expected in a healthy population.
    - No evidence of device or drug colon toxicity was observed; colon tissue histology was within normal limits.
    - There were no notable changes or differences in safety laboratory parameters between groups.

BioJet™ Systemic Oral Delivery Platform Preclinical Development

- **BioJet Research Collaborations.** Biora completed additional animal studies during the first quarter that demonstrated performance advances in consistency and bioavailability for the company's peptide candidate, semaglutide, and its antibody candidate, adalimumab, as well as collaborator molecules. The platform continues to exceed its performance targets, with over 40% bioavailability compared to IV administration demonstrated across multiple molecule types.

Capital Markets

- **Access to Capital Markets.** Biora today announced up to $16 million in funding from existing investors, demonstrating continued institutional support for Biora’s programs.

Anticipated Milestones

NaviCap™ Targeted Oral Delivery Platform and BT-600 in ulcerative colitis

- Biora will present Phase 1 clinical trial data from the BT-600 program at the American College of Gastroenterology annual meeting in October, 2024.
- Initiation of a Phase 1B clinical study in active ulcerative colitis patients is anticipated toward the end of 2024.

BioJet™ Systemic Oral Delivery Platform development

- Biora is in active partnership discussions with large pharma and anticipates concluding at least one partnership agreement for the BioJet platform in the near term, with others anticipated later in 2024.

Second Quarter 2024 Financial Results

Comparison of Three Months Ended June 30, 2024 and March 31, 2024

Operating expenses were $16.1 million for the three months ended June 30, 2024, including $1.6 million in non-cash stock-based compensation expenses, compared to $16.1 million for the three months ended March 31, 2024 including $1.5 million in non-cash stock-based compensation expenses.

Net income was $6.5 million, including non-cash items of $22.8 million attributable to the change in fair value of warrant and derivative liabilities, while diluted net loss per share was $0.04 for the three months ended June 30, 2024, compared to a net loss of $4.2 million, net of non-cash items of $14.3 million attributable to the change in fair value of warrant and derivative liabilities, while net loss per share was $0.14 for the three months ended March 31, 2024.

Comparison of Three Months Ended June 30, 2024 and 2023

Operating expenses were $16.1 million for the three months ended June 30, 2024, including $1.6 million in non-cash stock-based compensation expenses, compared to $14.9 million for the three months ended June 30, 2023, including $2.0 million in non-cash stock-based compensation expenses.

Net income was $6.5 million, including non-cash items of $22.8 million attributable to the change in fair value of warrant and derivative liabilities, while diluted net loss per share was $0.04 for the three months ended June 30, 2024, compared to a net loss of $17.8 million and net loss per share of $1.47 for the three months ended June 30, 2023.

Conference Call and Webcast Information

Date:	Wednesday, August 12, 2024
Time:	4:30 PM Eastern time / 1:30 PM Pacific time
Conference Call:	Domestic 1-877-423-9813 International 1-201-689-8573 Conference ID 13747616 Call me for instant telephone access
Webcast:	https://investors.bioratherapeutics.com/events-presentations

About Biora Therapeutics

Biora Therapeutics is a clinical-stage biotech developing two smart pill-based therapeutics platforms: the NaviCap™ platform for colon-targeted treatment of IBD, designed to improve patient outcomes through treatment at the site of disease in the gastrointestinal tract, and the BioJet™ platform for oral delivery of large molecules, designed to replace injection with needle-free delivery for better management of chronic diseases.

For more information, visit bioratherapeutics.com or follow the company on LinkedIn or Twitter.

Safe Harbor Statement or Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this press release, including statements concerning the progress and future expectations and goals of our research and development, preclinical and clinical trial activities, including those involving BT-600 and our NaviCap platform and model-based data projections for the BT-600 program, and partnering and collaboration efforts with third parties, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “envision,” “may,” “might,” “will,” “objective,” “intend,” “should,” “could,” “can,” “would,” “expect,” “anticipate,” “forward,” “believe,” “design,” “estimate,” “predict,” “projects,” “projecting,” “potential,” “plan,” “goal(s),” “target,” or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements reflect our plans, estimates, and expectations, as of the date of this press release. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this press release. Such risks, uncertainties, and other factors include, among others, our ability to innovate in the field of therapeutics, our ability to make future FDA filings and initiate and execute clinical trials on expected timelines or at all, our ability to obtain and maintain regulatory approval or clearance of our products on expected timelines or at all, our plans to research, develop, and commercialize new products, the unpredictable relationship between preclinical study results and clinical study results, our expectations regarding allowed patents or intended grants to result in issued or granted patents, our expectations regarding opportunities with current

or future pharmaceutical collaborators or partners, our ability to raise sufficient capital to achieve our business objectives, our ability to maintain our listing on the Nasdaq Global Market, and those risks described in “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission (SEC) and other subsequent documents, including Quarterly Reports on Form 10-Q, that we file with the SEC. Biora Therapeutics expressly disclaims any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

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Biora Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended	
	June 30, 2024	**March 31, 2024**
Revenues	$ 318	$ 542
Operating expenses:		
Research and development	7,704	7,005
Selling, general and administrative	8,400	9,053
Total operating expenses	16,104	16,058
Loss from operations	(15,786)	(15,516)
Interest expense, net	(711)	(2,757)
Gain on warrant liabilities	13,003	13,915
Other income, net	9,892	217
Gain (loss) before income taxes	6,398	(4,141)
Income tax (benefit) expense	(67)	48
Net income (loss)	$ 6,465	$ (4,189)
Net income (loss) per share:		
Basic	$ 0.18	$ (0.14)
Diluted	$ (0.04)	$ (0.14)
Weighted average shares outstanding:		
Basic	35,720,168	29,296,767
Diluted	74,215,969	29,296,767

Biora Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,	
	2024	**2023**
Revenues	$ 318	$ 2
Operating expenses:		
Research and development	7,704	5,983
Selling, general and administrative	8,400	8,953
Total operating expenses	16,104	14,936
Loss from operations	(15,786)	(14,934)
Interest expense, net	(711)	(2,703)
Gain (loss) on warrant liabilities	13,003	(161)

Other income (expense), net	9,892	(5)
Gain (loss) before income taxes	6,398	(17,803)
Income tax (benefit) expense	(67)	4
Net income (loss)	$ 6,465	$ (17,807)
Net income (loss) per share:		
Basic	$ 0.18	$ (1.47)
Diluted	$ (0.04)	$ (1.47)
Weighted average shares outstanding:		
Basic	35,720,168	12,143,108
Diluted	74,215,969	12,143,108

Biora Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	June 30, 2024	December 31, 2023 (1)
Assets		
Current assets:		
Cash, cash equivalents and restricted cash	$ 5,325	$ 15,211
Income tax receivable	822	830
Prepaid expenses and other current assets	3,054	3,030
Total current assets	9,201	19,071
Property and equipment, net	1,268	1,156
Right-of-use assets	1,217	1,614
Other assets	505	3,302
Goodwill	6,072	6,072
Total assets	$ 18,263	$ 31,215
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 7,512	$ 2,843
Accrued expenses and other current liabilities	19,568	17,319
Warrant liabilities	17,001	40,834
Related party senior secured convertible notes, current portion	1,912	1,976
Total current liabilities	45,993	62,972
Convertible notes, net	4,512	9,966
Senior secured convertible notes, net	19,842	14,591
Related party senior secured convertible notes, net	19,411	19,179
Derivative liabilities	17,246	22,899
Other long-term liabilities	581	3,029
Total liabilities	$ 107,585	$ 132,636
Stockholders' deficit:		
Common stock	34	25
Additional paid-in capital	878,405	868,591
Accumulated deficit	(948,682)	(950,958)
Treasury stock	(19,079)	(19,079)
Total stockholders' deficit	(89,322)	(101,421)
Total liabilities and stockholders' deficit	$ 18,263	$ 31,215

(1) The condensed consolidated balance sheet data as of December 31, 2023 has been derived from the audited consolidated financial statements