



Biora Therapeutics Provides Corporate Update and Reports Third Quarter 2023 Financial Results

November 13, 2023

NaviCap™ Targeted Oral Delivery platform advancing toward initiation of phase 1 clinical trial by year end

Pharma collaborations accelerate for the BioJet™ Systemic Oral Delivery platform, which shows potential for liver-targeted delivery of large molecules

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

SAN DIEGO, Nov. 13, 2023 (GLOBE NEWSWIRE) -- Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutic delivery, today provided a corporate update and reported financial results for the third quarter ended September 30, 2023.

"We took a big step in advancing our NaviCap platform toward the clinic, with the filing of our IND and a planned phase 1 trial for BT-600 on track for initiation in December," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "We're excited about the NaviCap platform's potential to improve outcomes for ulcerative colitis patients who still have significant unmet needs. With our proprietary technology, we have unique potential to achieve higher drug levels in the diseased tissue without systemic toxicity," continued Mr. Mohanty.

"The third quarter was also marked by accelerating development of our BioJet™ platform. We progressed our three existing pharma collaborations during the quarter and are actively negotiating with a potential fourth pharma collaborator. The BioJet platform has demonstrated not only category-leading bioavailability, but the potential to enable liver-targeted, oral delivery of large molecules," stated Mr. Mohanty.

Third Quarter 2023 and Other Recent Highlights

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

- **BT-600 IND Filing.** Biora filed an IND application with the FDA for BT-600 in September 2023. The company responded to agency questions and filed an updated IND in late October to provide additional time for regulatory review.
- **NaviCap Patent for Targeted Delivery of JAK Inhibitors to the GI Tract.** The USPTO recently allowed a new patent regarding the novel treatment paradigm of the BT-600 program, which provides targeted delivery of a JAK inhibitor to the GI tract.

BioJet™ Systemic Oral Delivery Platform preclinical development

- **EASD Presentation of BioJet 2 Data.** New data was presented at the European Association for the Study of Diabetes, demonstrating that the BioJet 2 device met its performance targets. Across three studies in a porcine model, 96% of animals showed semaglutide in systemic circulation at clinically relevant levels, and oral bioavailability averaged 20.5%.
- **Liver-Targeted Delivery of Large Molecules.** Early collaborator data indicates the BioJet platform could provide a unique advantage for liver-targeted, oral delivery of large molecules through its proprietary liquid jet injection into the small intestine, where the hepatic portal system provides optimal delivery to the liver.
- **BioJet Research Collaborations.** Biora received data analysis from animal studies with one pharma collaborator; completed studies with a second collaborator and awaits sample analysis; and is initiating new studies with a third collaborator. Active negotiations are underway with a fourth potential pharma collaborator.

Capital Markets

- **Optimization of Capital Structure.** Biora materially reduced its convertible notes balance by \$50 million through a notes exchange agreement during the third quarter and raised more than \$5.5 million through various sources including monetization of legacy business assets and direct capital investments.

Anticipated Milestones

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

- FDA response to IND application for BT-600 is anticipated, with Phase 1 trial initiation expected before the end of 2023, followed by execution in Q1 2024, and final data assessment in Q2 2024

BioJet™ Systemic Oral Delivery Platform development

- Potential new collaboration and progress with existing collaborators

- Ongoing preclinical data generation through animal studies with multiple collaborators' molecules anticipated during Q4 2024

Third Quarter 2023 Financial Results

Comparison of Three Months Ended September 30, 2023 and June 30, 2023

Operating expenses were \$23.3 million for the three months ended September 30, 2023, compared to \$14.9 million for the three months ended June 30, 2023. The increase was primarily attributable to a one-time stock-based compensation non-cash charge of approximately \$9.0 million related to vesting of employees' restricted stock units (RSUs).

Net loss was \$73.5 million and net loss per share was \$4.89 for the three months ended September 30, 2023, 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. This includes non-cash charges to stock-based compensation expense of \$9.0 million noted above and a non-cash charge of \$53.2 million attributable to the convertible notes exchange implemented by the company in September 2023.

Comparison of Three Months Ended September 30, 2023 and 2022

Operating expenses were \$23.3 million for the three months ended September 30, 2023, compared to \$14.0 million for the three months ended September 30, 2022. The increase was primarily attributable to a \$9.0 million one-time stock-based compensation non-cash charge related to vesting of employees' RSUs.

Net loss was \$73.5 million and net loss per share was \$4.89 for the three months ended September 30, 2023, compared to a net loss of \$5.1 million and net loss per share of \$0.68 for the three months ended September 30, 2022. This includes non-cash charges to stock-based compensation expense of \$9.0 million noted above and a non-cash charge of \$53.2 million attributable to the convertible note exchange implemented by the company in September 2023.

Conference Call and Webcast Information

Date: Monday, November 13, 2023
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 13741259
[Call me](#) for instant telephone access
Webcast: <https://investors.bioratherapeutics.com/events-presentations>

About Biora Therapeutics

Biora Therapeutics is reimagining therapeutic delivery. By creating innovative smart pills designed for targeted drug delivery to the GI tract, and systemic, needle-free delivery of biotherapeutics, the company is developing therapies to improve patients' lives.

Biora is focused on development of two therapeutics platforms: the [NaviCap™ targeted oral delivery platform](#) which is designed to improve outcomes for patients with inflammatory bowel disease through treatment at the site of disease in the gastrointestinal tract, and the [BioJet™ systemic oral delivery platform](#), which is designed to replace injection for better management of chronic diseases through needle-free, oral delivery of large molecules.

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 and clinical efforts including phase 1 trial readiness and execution timeline, FDA acceptance, and trial commencement, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan," "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 filings and initiate 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, our ability to raise sufficient capital to achieve our business objectives, 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, 2022 filed with the SEC and other subsequent documents, including Quarterly Reports, 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	
	September 30, 2023	June 30, 2023
Revenues	\$ —	\$ 2
Operating expenses:		
Research and development	10,547	5,983
Selling, general and administrative	12,774	8,953
Total operating expenses	23,321	14,936
Loss from operations	(23,321)	(14,934)
Interest expense, net	(2,592)	(2,703)
Gain (loss) on warrant liabilities	4,568	(161)
Other expense, net	(52,108)	(5)
Loss before income taxes	(73,453)	(17,803)
Income tax expense	1	4
Net loss	\$ (73,454)	\$ (17,807)
Net loss per share, basic and diluted	\$ (4.89)	\$ (1.47)
Weighted average shares outstanding, basic and diluted	15,024,726	12,143,108

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

	Three Months Ended	
	September 30,	
	2023	2022
Revenues	\$ —	\$ 80
Operating expenses:		
Research and development	10,547	5,820
Selling, general and administrative	12,774	8,147
Total operating expenses	23,321	13,967
Loss from operations	(23,321)	(13,887)
Interest expense, net	(2,592)	(2,773)
Gain on warrant liabilities	4,568	2,044
Other expense, net	(52,108)	(100)
Loss before income taxes	(73,453)	(14,716)
Income tax expense	1	158
Loss from continuing operations	(73,454)	(14,874)
Gain from discontinued operations	—	9,760
Net loss	\$ (73,454)	\$ (5,114)
Net loss per share from continuing operations, basic and diluted	\$ (4.89)	\$ (1.99)
Net gain per share from discontinued operations, basic and diluted	\$ —	\$ 1.30
Net loss per share, basic and diluted	\$ (4.89)	\$ (0.68)
Weighted average shares outstanding, basic and diluted	15,024,726	7,478,150

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

	September 30, 2023	December 31, 2022
		(1)
Assets		
Current assets:		
Cash, cash equivalents and restricted cash	\$ 12,569	\$ 30,486
Income tax receivable	818	828
Prepaid expenses and other current assets	3,351	4,199
Current assets of disposal group held for sale	2,509	2,603
Total current assets	<u>19,247</u>	<u>38,116</u>
Property and equipment, net	1,236	1,654
Right-of-use assets	1,834	1,482
Other assets	6,314	6,201
Goodwill	6,072	6,072
Total assets	<u>\$ 34,703</u>	<u>\$ 53,525</u>
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 3,905	\$ 3,606
Accrued expenses and other current liabilities	24,314	16,161
Warrant liabilities	41,325	3,538
Total current liabilities	<u>69,544</u>	<u>23,305</u>
Convertible notes, net	80,378	127,811
Other long-term liabilities	3,567	4,696
Total liabilities	<u>\$ 153,489</u>	<u>\$ 155,812</u>
Stockholders' deficit:		
Common stock	21	8
Additional paid-in capital	835,817	743,626
Accumulated deficit	(935,545)	(826,843)
Treasury stock	(19,079)	(19,078)
Total stockholders' deficit	<u>(118,786)</u>	<u>(102,287)</u>
Total liabilities and stockholders' deficit	<u>\$ 34,703</u>	<u>\$ 53,525</u>

(1) The condensed consolidated balance sheet data as of December 31, 2022 has been derived from the audited consolidated financial statements