



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

August 14, 2023

NaviCap™ targeted oral delivery platform on track for September IND filing; achieved successful device function study results in humans with phase 1-ready device

BioJet™ systemic oral delivery platform device development achieved function targets while continuing to exceed bioavailability targets

The company strengthened its intellectual property position with additional patents for both platforms

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

SAN DIEGO, Aug. 14, 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 second quarter ended June 30, 2023.

Biora recently announced preliminary results from a device function study in humans with the phase 1-ready device for its NaviCap™ targeted oral delivery platform. The company subsequently completed the study as planned with a total of sixteen healthy volunteers participating in the study. The NaviCap device accurately identified entry into the colon, triggered release of its non-drug payload, and achieved distribution throughout the colon in 15 out of 16 subjects.

"In this fourth human functional study, we once again demonstrated the robustness of our NaviCap platform, which performed as designed across a range of expected differences in GI motility among study participants," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "We remain on track for IND filing in September for our BT-600 program. We believe the NaviCap platform can address the large unmet need for ulcerative colitis patients by solving one of the primary treatment gaps, which is the inability to achieve high enough drug levels in the diseased tissue without systemic toxicity," continued Mr. Mohanty.

"During the second quarter, we continued development of our BioJet™ platform, which has shown category-leading oral bioavailability of large molecules. We successfully tested the autonomously triggered version of our next-gen device, achieving our device function targets while continuing to exceed our performance target of 15% average bioavailability," said Mr. Mohanty.

Also during the second quarter, Biora presented data at the American Diabetes Association assessing the delivery of semaglutide via the BioJet device in an animal model. In two studies, the company achieved more than double its target average bioavailability. Biora will be presenting additional data from the BioJet platform at the European Association for the Study of Diabetes annual meeting in Hamburg, Germany, October 2-6, 2023.

In addition, Biora recently further strengthened its intellectual property position for both platforms. The company was awarded a group of US and European patents related to additional therapeutic targets for its NaviCap targeted oral delivery platform, which could help the company broaden its NaviCap pipeline in the future. Biora also recently announced additional patents covering key features of the proprietary liquid jet injection technology used in its BioJet platform. The company's recent patents are part of its larger corporate portfolio consisting of 73 patent families, including approximately 167 issued patents and 143 pending applications in major jurisdictions around the world.

Second Quarter 2023 and Other Recent Corporate Highlights

- Biora achieved successful device function study results in humans with its phase 1-ready NaviCap device.
- The company remains on track for a September 2023 IND filing for the BT-600 program.
- Biora presented data from its BioJet systemic oral delivery platform at the American Diabetes Association Scientific Sessions assessing the bioavailability of semaglutide delivered via the BioJet device in an animal model.
- The company continued development of its autonomously triggered next-gen BioJet device, successfully achieving its device function targets, while continuing to achieve bioavailability similar to subcutaneous injection. Confirmatory studies are underway.
- Biora will be presenting additional data from the BioJet platform at the European Association for the Study of Diabetes annual meeting in Hamburg, Germany, October 2-6, 2023.
- The company was awarded a group of US and European patents related to the use of its NaviCap targeted oral delivery platform to deliver well-known IBD therapeutics at the site of disease in the colon.
- Biora also recently announced additional patents covering key features of the proprietary liquid jet injection technology, a core component of its BioJet platform.
- The company raised \$8 million in gross proceeds via a registered direct offering during the second quarter, funding the majority of its Q2 operating expenses.

Second Quarter 2023 Financial Results

Comparison of Three Months Ended June 30, 2023 and March 31, 2023

Operating expenses were \$14.9 million for the three months ended June 30, 2023, compared to \$15.5 million for the three months ended March 31, 2023.

Net loss was \$17.8 million and net loss per share was \$1.47 for the three months ended June 30, 2023, compared to a net loss of \$17.4 million and net loss per share of \$1.59 for the for the three months ended March 31, 2023.

Comparison of Three Months Ended June 30, 2023 and 2022

Operating expenses were \$14.9 million for the three months ended June 30, 2023, compared to \$14.3 million for the three months ended June 30, 2022.

Net loss was \$17.8 million and net loss per share was \$1.47 for the three months ended June 30, 2023, compared to a net loss of \$5.5 million and net loss per share of \$0.75 for the three months ended June 30, 2022.

Webcast and Conference Call Information

Biora Therapeutics will host a webcast and conference call to discuss the second quarter financial results and provide a corporate update today, Monday, August 14, 2023 at 4:30 PM Eastern time / 1:30 PM Pacific time.

The live call may be accessed by dialing 1-877-423-9813 (domestic) or 1-201-689-8573 (international) and entering the conference code: 13740025. A live webcast will be available via the [investors section of the company website](#), with a replay available online for 60 days following the call.

About Biora Therapeutics

Biora Therapeutics is the biotech company that 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, and phase 1 readiness, 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	
	June 30, 2023	March 31, 2023
Revenues	\$ 2	\$ 2
Operating expenses:		
Research and development	5,983	7,190
Selling, general and administrative	8,953	8,356
Total operating expenses	14,936	15,546
Loss from operations	(14,934)	(15,544)
Interest expense, net	(2,703)	(2,680)
(Loss) gain on warrant liabilities	(161)	864
Other expense, net	(5)	(81)
Loss before income taxes	(17,803)	(17,441)
Income tax expense	4	—
Net loss	\$ (17,807)	\$ (17,441)
Net loss per share, basic and diluted	\$ (1.47)	\$ (1.59)
Weighted average shares outstanding, basic and diluted	12,143,108	10,970,583

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

	Three Months Ended June 30,	
	2023	2022
Revenues	\$ 2	\$ 104
Operating expenses:		
Research and development	5,983	5,904
Selling, general and administrative	8,953	8,410
Total operating expenses	14,936	14,314
Loss from operations	(14,934)	(14,210)
Interest expense, net	(2,703)	(2,772)
(Loss) gain on warrant liabilities	(161)	4,413
Other (expense) income, net	(5)	5,735
Loss before income taxes	(17,803)	(6,834)
Income tax expense (benefit)	4	(837)
Loss from continuing operations	(17,807)	(5,997)
Gain from discontinued operations	—	484
Net loss	\$ (17,807)	\$ (5,513)
Net loss per share from continuing operations, basic and diluted	\$ (1.47)	\$ (0.81)
Net gain per share from discontinued operations, basic and diluted	\$ —	\$ 0.06
Net loss per share, basic and diluted	\$ (1.47)	\$ (0.75)
Weighted average shares outstanding, basic and diluted	12,143,108	7,374,865

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

	June 30, 2023	December 31, 2022
Assets		(1)
Current assets:		
Cash, cash equivalents and restricted cash	\$ 26,452	\$ 30,486
Income tax receivable	819	828
Prepaid expenses and other current assets	4,105	4,199
Current assets of disposal group held for sale	2,509	2,603

Total current assets	33,885	38,116
Property and equipment, net	1,351	1,654
Right-of-use assets	1,887	1,482
Other assets	6,478	6,201
Goodwill	6,072	6,072
Total assets	<u>\$ 49,673</u>	<u>\$ 53,525</u>
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 5,042	\$ 3,606
Accrued expenses and other current liabilities	21,791	16,161
Warrant liabilities	10,835	3,538
Total current liabilities	<u>37,668</u>	<u>23,305</u>
Convertible notes, net	128,568	127,811
Other long-term liabilities	4,318	4,696
Total liabilities	<u>\$ 170,554</u>	<u>\$ 155,812</u>
Stockholders' deficit:		
Common stock	11	8
Additional paid-in capital	760,277	743,626
Accumulated deficit	(862,091)	(826,843)
Treasury stock	(19,078)	(19,078)
Total stockholders' deficit	<u>(120,881)</u>	<u>(102,287)</u>
Total liabilities and stockholders' deficit	<u>\$ 49,673</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.