



Biora Therapeutics Provides Corporate Update and Reports Third Quarter 2022 Financial Results

November 14, 2022

Presented results of human study at the American College of Gastroenterology annual meeting, demonstrating promising device performance in active ulcerative colitis patients

Executed a registered direct capital raise of \$9.75 million

Presented preclinical results demonstrating the possibilities for systemic delivery of large molecules using the company's systemic delivery platform

Received key patent for oral delivery of GLP-1 receptor agonist

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

SAN DIEGO, Nov. 14, 2022 (GLOBE NEWSWIRE) -- [Biora Therapeutics, Inc.](https://www.bioratherapeutics.com) (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, 2022.

During the third quarter, the company shared the results of its PM-602 device function study, which assessed the safety and performance of the company's targeted delivery device in active ulcerative colitis patients, at the American College of Gastroenterology annual meeting. In the study, the device accurately identified entry into the colon, triggered release of a non-drug liquid payload, and achieved distribution across the entire colon in seven patients. These results demonstrate the potential of the targeted therapeutics platform to transform management of ulcerative colitis by improving efficacy through increased drug concentration in the colon, while potentially minimizing the harmful side effects associated with high systemic drug uptake.

Additionally, the company recently announced a registered direct financing raising \$9.75 million in total, with \$6 million in gross proceeds from an existing investor and \$3.75 million reinvested by Athyrium from the interest on convertible notes held by the firm, demonstrating continued commitment by existing investors to support Biora's key programs. These funds, combined with cash on hand, will help the company work toward important clinical milestones coming up in 2023.

Biora also shared preclinical results from its systemic therapeutics program, demonstrating promising device performance using liquid jet injection to the small intestine in animal models. The company successfully demonstrated $\geq 83\%$ deployment accuracy in the canine small intestine and average bioavailability of 22% (up to 55%) for a variant of adalimumab in swine where drug was detected in blood. Results were presented at the Controlled Release Society Annual Meeting, the Parenteral Drug Association Universe of Pre-Filled Syringes and Injection Devices Conference, and the American College of Gastroenterology Annual Scientific Meeting.

Biora continued to strengthen its intellectual property portfolio during the third quarter with a newly-issued patent covering jet delivery of any glucagon-like peptide-1 (GLP-1) receptor agonist formulation to the small intestine for treatment of any disease, including type 2 diabetes. According to leading analytics firm GlobalData, the GLP-1 receptor agonist market is forecasted to be well over \$20 billion by 2025.

"We are extremely pleased with the ongoing development of our targeted drug delivery platform and have demonstrated that our device functions as intended in ulcerative colitis patients, which is a key step in advancing our PGN-600 program. We are on track to initiate clinical studies for our drug-device combination early next year," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "We are very excited about the opportunity to improve treatment for patients with ulcerative colitis. We also continue to progress our systemic therapeutics platform, strengthen our IP portfolio, and seek to find ways to monetize legacy assets to generate value for our investors."

Third Quarter 2022 and Recent Corporate Highlights

- Presented results of the company's PM-602 study for its targeted therapeutics platform at the American College of Gastroenterology annual meeting, demonstrating successful device performance in active ulcerative colitis patients
- Executed a registered direct financing raise of \$9.75 million
- Presented results of preclinical studies for the company's systemic therapeutics platform, demonstrating promising bioavailability and device performance in animal models
- Received a key patent for oral delivery of any GLP-1 receptor agonist for the systemic therapeutics platform
- Announced sale of patent rights related to methods for determining the origin of cell-free DNA to Roche Diagnostics, as Biora continues generating value from legacy assets

Third Quarter 2022 Financial Results

Comparison of Three Months Ended September 30, 2022 and June 30, 2022

The company generated \$10.0 million in revenues during the third quarter, out of which \$9.9 million came from discontinued operations, primarily due to a partial reversal of prior period accruals. The company generated \$0.9 million in revenues during the second quarter, out of which \$0.8 million came from discontinued operations. Operating expenses were \$14.1 million for the three months ended September 30, 2022, compared to \$14.6 million for the three months ended June 30, 2022, out of which \$0.2 million and \$0.3 million, respectively came from discontinued operations.

Net loss was \$5.1 million and net loss per share was \$0.03 for the three months ended September 30, 2022, compared to net loss of \$5.5 million and net loss per share of \$0.03 for the three months ended June 30, 2022.

Net gain from discontinued operations was \$9.8 million and net gain per share was \$0.05 for the three months ended September 30, 2022, compared to net gain from discontinued operations of \$0.5 million with no impact to loss per share for the three months ended June 30, 2022.

Comparison of Three Months Ended September 30, 2022 and 2021

The company generated \$10.0 million in revenues for three months ended September 30, 2022, out of which \$9.9 million came from discontinued operations primarily due to a partial reversal of prior period accruals. The company generated \$9.7 million in revenues for the three months ended September 30, 2021, out of which \$9.5 million came from discontinued operations. Operating expenses were \$14.1 million for the three months ended September 30, 2022, compared to \$37.0 million for the three months ended September 30, 2021, out of which \$0.2 million and \$6.3 million, respectively, came from discontinued operations.

Net loss was \$5.1 million and net loss per share was \$0.03 for the three months ended September 30, 2022, compared to net loss of \$43.7 million and net loss per share of \$0.46 for the three months ended September 30, 2021.

Net gain from discontinued operations was \$9.8 million and net gain per share was \$0.05 for the three months ended September 30, 2022, compared to net loss from discontinued operations of \$6.9 million and net loss per share of \$0.07 for the three months ended September 30, 2021.

Webcast and Conference Call Information

Biora Therapeutics will host a webcast and conference call to discuss the third quarter financial results and answer investment community questions today, Monday, November 14, 2022 at 4:30 p.m. Eastern / 1:30 p.m. Pacific.

The live call may be accessed by dialing 1-877-423-9813 (domestic) or 1-201-689-8573 (international) and entering the conference code: 13731511. 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 envisions a world where patients have access to needle-free drug delivery and better therapeutic outcomes.

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 future expectations of our research and development efforts and clinical trials and programs, the safety and efficacy profiles of our product candidates, our goals and plans regarding our IP portfolio and legacy assets and potential addressable market size, 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" 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 precision medicine and develop our drug-device combinations, 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 future revenue generating opportunities with current or future pharmaceutical collaborators, our ability to raise sufficient capital to achieve our business objectives, the ongoing COVID-19 pandemic, 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, 2021 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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(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended	
	September 30, 2022	June 30, 2022
Revenues	\$ 80	\$ 104
Operating expenses:		
Research and development	5,820	5,904
Selling, general and administrative	8,147	8,410
Total operating expenses	<u>13,967</u>	<u>14,314</u>
Loss from operations	(13,887)	(14,210)
Interest expense, net	(2,773)	(2,772)
Gain on warrant liability	2,044	4,413
Other (expense) income, net	(100)	5,735
Loss before income taxes	(14,716)	(6,834)
Income tax (expense) benefit	(158)	837
Loss from continuing operations	(14,874)	(5,997)
Gain from discontinued operations	9,760	484
Net loss	<u>\$ (5,114)</u>	<u>\$ (5,513)</u>
Net loss per share from continuing operations, basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.03)</u>
Net gain per share from discontinued operations, basic and diluted	<u>\$ 0.05</u>	<u>\$ —</u>
Net loss per share, basic and diluted	<u>\$ (0.03)</u>	<u>\$ (0.03)</u>
Weighted average shares outstanding, basic and diluted	<u>186,953,741</u>	<u>184,371,626</u>

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

	Three Months Ended	
	September 30,	
	2022	2021
Revenues	\$ 80	\$ 182
Operating expenses:		
Research and development	5,820	12,226
Selling, general and administrative	8,147	18,517
Total operating expenses	<u>13,967</u>	<u>30,743</u>
Loss from operations	(13,887)	(30,561)
Interest expense, net	(2,773)	(3,458)
Gain (loss) on warrant liability	2,044	(3,322)
Other (expense) income, net	(100)	467
Loss before income taxes	(14,716)	(36,874)
Income tax (expense) benefit	(158)	—
Loss from continuing operations	(14,874)	(36,874)
Gain (loss) from discontinued operations	9,760	(6,870)
Net loss	<u>\$ (5,114)</u>	<u>\$ (43,744)</u>
Net loss per share from continuing operations, basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.38)</u>
Net gain (loss) per share from discontinued operations, basic and diluted	<u>\$ 0.05</u>	<u>\$ (0.07)</u>
Net loss per share, basic and diluted	<u>\$ (0.03)</u>	<u>\$ (0.46)</u>
Weighted average shares outstanding, basic and diluted	<u>186,953,741</u>	<u>95,846,672</u>

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

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
		(1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 37,060	\$ 88,397
Accounts receivable, net	—	653
Income tax receivable	828	—
Prepaid expenses and other current assets	6,259	7,232
Current assets of disposal group held for sale	<u>2,213</u>	<u>2,147</u>
Total current assets	46,360	98,429
Property and equipment, net	2,112	4,012
Right-of-use assets	1,843	—
Other assets	6,227	326
Goodwill	6,072	6,072
Total assets	<u>\$ 62,614</u>	<u>\$ 108,839</u>
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 2,356	\$ 8,709
Accrued expenses and other current liabilities	21,750	34,157
Warrant liability	3,285	18,731
Current portion of capital lease obligations	<u>—</u>	<u>12</u>
Total current liabilities	27,391	61,609
Convertible notes, net	127,445	126,392
Other long-term liabilities	<u>5,221</u>	<u>5,814</u>
Total liabilities	<u>\$ 160,057</u>	<u>\$ 193,815</u>
Stockholders' deficit:		
Common stock	153	146
Additional paid-in capital	734,607	722,646
Accumulated deficit	(813,121)	(788,686)
Treasury stock	<u>(19,082)</u>	<u>(19,082)</u>
Total stockholders' deficit	<u>(97,443)</u>	<u>(84,976)</u>
Total liabilities and stockholders' deficit	<u>\$ 62,614</u>	<u>\$ 108,839</u>

(1) The condensed consolidated balance sheet data as of December 31, 2021 has been derived from the audited consolidated financial statements