



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

August 15, 2022

Successfully completed PM-602 human study for its targeted therapeutics platform demonstrating promising device performance in active ulcerative colitis patients

Successfully completed PM-611 human study for its targeted therapeutics platform in healthy volunteers showing promising performance regardless of feeding schedule

Confirmed planned phase 1 IND filing in Q1 based on FDA feedback on PGN-600 program in ulcerative colitis

Strengthened patent position for both targeted and systemic therapeutics platforms

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

SAN DIEGO, Aug. 15, 2022 (GLOBE NEWSWIRE) -- [Biora Therapeutics, Inc.](https://www.bioratherapeutics.com) (Nasdaq: BIOR), the biotech company that is reimagining therapeutics, today provided a corporate update and reported financial results for the second quarter ended June 30, 2022.

During the second quarter, the company completed its PM-611 device function study which assessed whether the autonomous location functionality of the ingestible devices designed for targeted drug delivery was impacted by a fed state as compared to a fasted state. The study demonstrated that all analyzed capsules indicated entry to the colon, activation, and deployment, regardless of fasted or fed schedule, with no failure modes observed in the analyzed devices. These study results suggest that the Drug Delivery System (DDS) capsule could be the first ingestible therapeutic delivery device that does not require fasting or other food restriction for use, which may be an important consideration for patients who need frequent dosing in chronic diseases like ulcerative colitis.

The company also recently announced topline results from its PM-602 device function study that assessed the safety and performance of the targeted delivery device in active ulcerative colitis patients. The study demonstrated that the device was well tolerated, and that the device performed as intended in active ulcerative colitis (UC) patients. In all seven patients, the device accurately identified entry into the colon, triggered release of a non-drug liquid payload, and achieved distribution across the entire colon. The company is not aware of any other oral drug delivery technology that accurately detects colon entry, especially in the environment of inflammation, blood and highly variable motility seen in active ulcerative colitis.

In the second quarter the company submitted a Type C filing to the United States Food and Drug Administration (FDA) asking for feedback on its proposed PGN-600 clinical development plan related to its targeted therapeutics platform. In a constructive response received recently, the FDA generally agreed with the proposed clinical trial design and provided helpful feedback on protocols. The FDA also reviewed the proposed supporting data package and confirmed the anticipated need for additional toxicology data. The company believes it will be in a position to file an IND in Q1 2023 to support the initiation of its Phase 1 clinical study.

Finally, Biora strengthened its intellectual property (IP) portfolio during the second quarter with a newly issued US patent and the allowance of two additional US patent applications. The issued US patent (No. 11,363,964) is directed to the company's targeted delivery localization technology used in the DDS device which enables detection of device entry into the colon. This builds on the company's proprietary localization technology portfolio, which includes 29 issued patents worldwide, including multiple patents issued in both the US and Europe. Related to the company's systemic therapeutics platform, the company was pleased to receive a Notice of Allowance for a US patent application covering liquid jet delivery of GLP-1 receptor agonists to the small intestine for the treatment of any disease, including Type 2 diabetes.

"We've continued to generate important human safety and performance data in support of our targeted therapeutics platform, where so far we have demonstrated that our DDS capsule functions as intended in humans, and especially in UC patients. After receiving constructive feedback from the FDA, we are now preparing to initiate our clinical program for PGN-600," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "This is an important step for this program, and we are very excited about the opportunity to improve treatment for patients with ulcerative colitis. We also continue to strengthen our IP portfolio, illustrating the innovative and proprietary aspects of our technology and platforms for both systemic and targeted drug delivery."

Second Quarter 2022 and Recent Corporate Highlights

- Completed the PM-611 device function study of the Drug Delivery System (DDS) capsule, which demonstrated that performance of the DDS device in healthy volunteers is not affected by food.
- Completed the PM-602 device function study of the DDS capsule, where the device accurately identified entry into the colon, triggered release of a non-drug liquid payload, and achieved distribution across the entire lower colon as confirmed by an independent scintigraphy imaging method.
- Received constructive feedback from the FDA on PGN-600 trial design, which will enable initiation of the Phase 1 clinical trial for PGN-600, which is now planned for Q1 2023.
- Announced a new patent issuance and allowed applications related to the company's targeted and systemic therapeutic

platforms including an issued U.S. patent with claims covering the localization technology used in the targeted delivery DDS devices which enable detection of colon entry; and related to the systemic delivery platform, an allowed U.S. patent application covering delivery of a liquid formulation of any GLP-1 receptor agonist using any method of liquid jet delivery in the small intestine for any indication.

Second Quarter 2022 Financial Results

Comparison of Three Months Ended June 30, 2022, and March 31, 2022

The company generated \$0.9 million in revenues during the second quarter, out of which \$0.8 million came from discontinued operations. The company generated \$1.4 million in revenues during the first quarter, out of which \$1.3 million came from discontinued operations. Operating expenses were \$14.3 million for the three months ended June 30, 2022, compared to \$20.0 million for the three months ended March 31, 2022.

Net loss was \$5.5 million and net loss per share was \$0.03 for the three months ended June 30, 2022, compared to net loss of \$13.8 million and net loss per share of \$0.08 for the three months ended March 31, 2022.

Net gain from discontinued operations was \$0.5 million for the three months ended June 30, 2022, with no impact to loss per share, compared to net gain from discontinued operations of \$0.7 million with no impact to loss per share for the three months ended March 31, 2022.

Comparison of Three Months Ended June 30, 2022, and 2021

Operating expenses were \$14.3 million for the three months ended June 30, 2022, compared to \$36.1 million for the three months ended June 30, 2021.

Net loss was \$5.5 million and net loss per share was \$0.03 for the three months ended June 30, 2022, compared to net loss of \$78.5 million and net loss per share of \$1.23 for the three months ended June 30, 2021.

Net gain from discontinued operations was \$0.5 million for the three months ended June 30, 2022, with no impact to loss per share, compared to net loss from discontinued operations of \$37.1 million and net loss per share for discontinued operations of \$0.58 for the three months ended June 30, 2021.

Webcast and Conference Call Information

Biora Therapeutics will host a webcast and conference call to discuss the second quarter financial results and answer investment community questions today, Monday, August 15, 2022, at 4:30 PM Eastern / 1:30 PM 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 therapeutics. 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, 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, 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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Biora Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended	
	June 30, 2022	March 31, 2022
Revenues	\$ 104	\$ 107
Operating expenses:		
Research and development	5,904	6,558
Selling, general and administrative	8,410	13,457
Total operating expenses	<u>14,314</u>	<u>20,015</u>
Loss from operations	(14,210)	(19,908)
Interest expense, net	(2,772)	(2,760)
Gain on warrant liability	4,413	8,989
Other income (expense), net	5,735	(811)
Loss before income taxes	(6,834)	(14,490)
Income tax benefit	(837)	—
Loss from continuing operations	(5,997)	(14,490)
Gain from discontinued operations	484	682
Net loss	<u>\$ (5,513)</u>	<u>\$ (13,808)</u>
Net loss per share from continuing operations, basic and diluted	<u>\$ (0.03)</u>	<u>\$ (0.08)</u>
Net loss per share from discontinued operations, basic and diluted	<u>\$ —</u>	<u>\$ —</u>
Net loss per share, basic and diluted	<u>\$ (0.03)</u>	<u>\$ (0.08)</u>
Weighted average shares outstanding, basic and diluted	<u>184,371,626</u>	<u>183,201,663</u>

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

	Three Months Ended	
	June 30,	
	2022	2021
Revenues	\$ 104	\$ 463
Operating expenses:		
Research and development	5,904	13,401
Selling, general and administrative	8,410	22,715
Total operating expenses	<u>14,314</u>	<u>36,116</u>
Loss from operations	(14,210)	(35,653)
Interest expense, net	(2,772)	(3,502)
Gain (loss) on warrant liability	4,413	(5,146)
Other income, net	5,735	2,901
Loss before income taxes	(6,834)	(41,400)
Income tax benefit	(837)	—
Loss from continuing operations	(5,997)	(41,400)
Gain (loss) from discontinued operations	484	(37,131)
Net loss	<u>\$ (5,513)</u>	<u>\$ (78,531)</u>
Net loss per share from continuing operations, basic and diluted	<u>\$ (0.03)</u>	<u>\$ (0.65)</u>
Net loss per share from discontinued operations, basic and diluted	<u>\$ —</u>	<u>\$ (0.58)</u>
Net loss per share, basic and diluted	<u>\$ (0.03)</u>	<u>\$ (1.23)</u>
Weighted average shares outstanding, basic and diluted	<u>184,371,626</u>	<u>63,942,298</u>

(Unaudited)
(In thousands)

	June 30, 2022	December 31, 2021
		(1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 48,506	\$ 88,397
Accounts receivable, net	—	653
Income tax receivable	817	—
Prepaid expenses and other current assets	8,675	7,232
Current assets of disposal group held for sale	2,147	2,147
Total current assets	60,145	98,429
Property and equipment, net	2,454	4,012
Right-of-use assets	2,203	—
Other assets	6,227	326
Goodwill	6,072	6,072
Total assets	\$ 77,101	\$ 108,839
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 4,315	\$ 8,709
Accrued expenses and other current liabilities	30,940	34,157
Warrant liability	5,329	18,731
Current portion of capital lease obligations	—	12
Total current liabilities	40,584	61,609
Convertible notes, net	127,086	126,392
Other long-term liabilities	5,537	5,814
Total liabilities	\$ 173,207	\$ 193,815
Stockholders' deficit:		
Common stock	150	146
Additional paid-in capital	730,833	722,646
Accumulated deficit	(808,007)	(788,686)
Treasury stock	(19,082)	(19,082)
Total stockholders' deficit	(96,106)	(84,976)
Total liabilities and stockholders' deficit	\$ 77,101	\$ 108,839

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