



## **Biora Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full-Year 2022 Financial Results**

March 30, 2023

*Biora initiating preclinical testing with pharma collaborator's molecule following recent data exceeding the company's target bioavailability levels for systemic therapeutics platform*

*No adverse events indicated in 14-day tox study for targeted therapeutics program*

*Announcing new brand names for Biora's therapeutics platforms: the NaviCap™ targeted oral delivery platform and the BioJet™ systemic oral delivery platform*

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

SAN DIEGO, March 30, 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 fourth quarter and full year ended December 31, 2022.

Today, the company launched new brand names for its two therapeutics platforms. Its targeted therapeutics platform, previously called the Drug Delivery System (DDS), will now be known as the [NaviCap™ targeted oral delivery platform](#). The NaviCap capsule uses autolocation technology to navigate through the GI tract and deliver drug to a targeted location.

Biora's systemic therapeutics platform, previously called the Oral Biotherapeutic Delivery System (OBDS), is now the [BioJet™ systemic oral delivery platform](#). The BioJet device uses liquid jet injection to deliver biotherapeutics into the small intestine for uptake into systemic circulation. Biora is also taking this opportunity to update its program numbers, replacing PGN with BT, for Biora Therapeutics. A guide to the new platform names and program numbers is available in the [Investor Q&A on Biora's website](#).

Biora recently completed execution of its 14-day toxicology study for its BT-600 program (formerly PGN-600). All planned doses were administered, and the company observed no adverse events or safety signals. The company is completing data analysis and reporting for the study, including analysis of device performance data for the over 600 devices administered during the study.

Biora also recently shared topline results from preclinical studies with two drugs using its BioJet systemic oral delivery platform, in which it achieved more than double its target bioavailability of 15% using an endoscopically placed and activated next-gen device. The company observed an average bioavailability of 37% with semaglutide, a GLP-1 receptor agonist, and an average bioavailability of 51% with adalimumab, a monoclonal antibody. These results significantly exceeded the 15% bioavailability target set by Biora and its pharma collaborators for progression of further development and testing using the platform.

"We are extremely pleased with our recent progress in development of our next-generation BioJet systemic delivery device. The excellent bioavailability results that we observed have enabled us to move forward with preclinical studies with one of our collaborator's molecules, and we are on track for our goal to progress our other collaborations and potential partnerships this year," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "For the NaviCap targeted delivery platform, we achieved an important milestone with the administration of over 600 devices during our 14-day toxicology study for BT-600, which is far more devices than we would expect to administer as part of a phase 1 study. We have some additional work to do to analyze the device performance as part of this animal study, and we look forward to sharing that data with the FDA as we move toward filing our IND for BT-600 later this year," continued Adi Mohanty.

### **Fourth Quarter and Full Year 2022 and Other Recent Corporate Highlights**

- Launched new brands to support the company's two therapeutics platforms: the [NaviCap targeted oral delivery platform](#) and the [BioJet systemic oral delivery platform](#).
- Announced topline preclinical results with two drugs using the BioJet systemic oral delivery platform, achieving 37% average bioavailability for a GLP-1 receptor agonist and 51% average bioavailability for a variant of adalimumab.
- Preparing to initiate preclinical studies with pharma collaborator's molecule based on the compelling bioavailability data generated recently.
- Presented [detailed results from a device function study](#) of the NaviCap platform at the Crohn's & Colitis Congress, demonstrating minimal effect of food upon device performance in healthy patients.
- Completed execution of a 14-day toxicology study for the BT-600 program with initial results indicating no adverse events or safety signals; device performance analysis is ongoing.

- Completed out-license of [the Preecludia™ rule-out test for preeclampsia for commercial](#) development.
- Raised \$12.9 million in gross proceeds during the first quarter through the company's ATM program.

#### **Fourth Quarter and Full-Year 2022 Financial Results**

##### ***Comparison of Three Months Ended December 31, 2022 and September 30, 2022***

Operating expenses were \$13.8 million for the three months ended December 31, 2022, compared to \$14.0 million for the three months ended September 30, 2022.

Net loss was \$13.7 million and net loss per share was \$1.64 for the three months ended December 31, 2022, compared to net loss of \$5.1 million and net loss per share of \$0.68 for the three months ended September 30, 2022.

Net loss from discontinued operations was \$0.3 million and net loss per share was \$0.03 for the three months ended December 31, 2022, compared to net gain from discontinued operations of \$9.8 million and net gain per share of \$1.31 for the three months ended September 30, 2022.

##### ***Comparison of Three Months Ended December 31, 2022 and 2021***

Operating expenses were \$13.8 million for the three months ended December 31, 2022, compared to \$20.6 million for the three months ended December 31, 2021.

Net loss was \$13.7 million and net loss per share was \$1.64 for the three months ended December 31, 2022, compared to net loss of \$92.9 million and net loss per share of \$13.98 for the three months ended December 31, 2021.

Net loss from discontinued operations was \$0.3 million and net loss per share was \$0.03 for the three months ended December 31, 2022, compared to net loss from discontinued operations of \$10.1 million and net loss per share of \$1.52 for the three months ended December 31, 2021.

##### ***Comparison of Full Year Ended December 31, 2022 and 2021***

The company generated \$12.2 million in revenues for the year ended December 31, 2022, out of which \$11.8 million came from discontinued operations, primarily due to a partial reversal of prior period accruals. The company generated \$60.6 million in revenues for the year ended December 31, 2021, out of which \$59.4 million came from discontinued operations. Operating expenses were \$62.1 million for the year ended December 31, 2022, compared to \$119.1 million for the year ended December 31, 2021.

Net loss was \$38.2 million and net loss per share was \$5.00 for the year ended December 31, 2022, compared to net loss of \$247.4 million and net loss per share of \$64.33 for the year ended December 31, 2021.

Net gain from discontinued operations was \$10.7 million and net gain per share was \$1.40 for the year ended December 31, 2022, compared to net loss from discontinued operations of \$68.9 million and net loss per share of \$17.91 for the year ended December 31, 2021.

#### **Webcast and Conference Call Information**

Biora Therapeutics will host a webcast and conference call to discuss the fourth quarter and full year 2022 financial results and answer investment community questions today, Thursday, March 30, 2023 at 4:30 PM Eastern time / 1:30 PM Pacific time.

The live call may be accessed by dialing 1-855-327-6837 (domestic) or 1-631-891-4304 (international) and entering the conference code: 10021548. 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](http://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, 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.

**Investor Contact**

Chuck Padala  
 Managing Director, LifeSci Advisors  
[IR@bioratherapeutics.com](mailto:IR@bioratherapeutics.com)  
 (646) 627-8390

**Media Contact**

[media@bioratherapeutics.com](mailto:media@bioratherapeutics.com)

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

	<b>Three Months Ended</b>	
	<b>December 31, 2022</b>	<b>September 30, 2022</b>
Revenues	\$ 14	\$ 80
Operating expenses:		
Research and development	5,767	5,820
Selling, general and administrative	8,023	8,147
Total operating expenses	<u>13,790</u>	<u>13,967</u>
Loss from operations	(13,776)	(13,887)
Interest expense, net	(2,685)	(2,773)
Gain on warrant liabilities	5,458	2,044
Other expense, net	(2,207)	(100)
Loss before income taxes	(13,210)	(14,716)
Income tax expense	259	158
Loss from continuing operations	(13,469)	(14,874)
(Loss) gain from discontinued operations	(253)	9,760
Net loss	<u>\$ (13,722)</u>	<u>\$ (5,114)</u>
Net loss per share from continuing operations, basic and diluted	<u>\$ (1.61)</u>	<u>\$ (1.99)</u>
Net (loss) gain per share from discontinued operations, basic and diluted	<u>\$ (0.03)</u>	<u>\$ 1.31</u>
Net loss per share, basic and diluted	<u>\$ (1.64)</u>	<u>\$ (0.68)</u>
Weighted average shares outstanding, basic and diluted	<u>8,349,844</u>	<u>7,478,149</u>

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

	<b>Three Months Ended</b>		<b>Year Ended December 31,</b>	
	<b>December 31, 2022</b>	<b>2021</b>	<b>2022</b>	<b>2021</b>
Revenues	\$ 14	435	\$ 305	\$ 1,247
Operating expenses:				
Research and development	5,767	8,485	24,049	45,785
Selling, general and administrative	8,023	12,109	38,037	73,299
Total operating expenses	<u>13,790</u>	<u>20,594</u>	<u>62,086</u>	<u>119,084</u>
Loss from operations	(13,776)	(20,159)	(61,781)	(117,837)
Interest expense, net	(2,685)	(2,186)	(10,990)	(12,636)
Gain (loss) on warrant liabilities	5,458	(48,339)	20,904	(54,157)
Other (expense) income, net	(2,207)	(12,222)	2,617	5,990
Loss before income taxes	(13,210)	(82,906)	(49,250)	(178,640)
Income tax expense (benefit)	259	(119)	(420)	(119)
Loss from continuing operations	(13,469)	(82,787)	(48,830)	(178,521)
(Loss) gain from discontinued operations	(253)	(10,087)	10,673	(68,891)
Net loss	<u>(13,722)</u>	<u>(92,874)</u>	<u>(38,157)</u>	<u>(247,412)</u>

Net loss per share from continuing operations, basic and diluted	\$ <u>(1.61)</u>	\$ <u>(12.46)</u>	\$ <u>(6.40)</u>	\$ <u>(46.42)</u>
Net (loss) gain per share from discontinued operations, basic and diluted	\$ <u>(0.03)</u>	\$ <u>(1.52)</u>	\$ <u>1.40</u>	\$ <u>(17.91)</u>
Net loss per share, basic and diluted	\$ <u>(1.64)</u>	\$ <u>(13.98)</u>	\$ <u>(5.00)</u>	\$ <u>(64.33)</u>
Weighted average shares outstanding, basic and diluted	<u>8,349,844</u>	<u>6,642,888</u>	<u>7,635,107</u>	<u>3,846,187</u>

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

	<u>December 31,</u>	
	<u>2022</u>	<u>2021</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 30,486	\$ 88,397
Accounts receivable, net	—	653
Income tax receivable	828	—
Prepaid expenses and other current assets	4,199	7,232
Current assets of disposal group held for sale	2,603	2,493
Total current assets	<u>38,116</u>	<u>98,775</u>
Property and equipment, net	1,654	3,666
Right-of-use assets	1,482	—
Other assets	6,201	326
Goodwill	6,072	6,072
Total assets	<u>\$ 53,525</u>	<u>\$ 108,839</u>
<b>Liabilities and Stockholders' Deficit</b>		
Current liabilities:		
Accounts payable	\$ 3,606	\$ 8,709
Accrued expenses and other current liabilities	16,161	34,157
Warrant liabilities	3,538	18,731
Current portion of capital lease obligations	—	12
Total current liabilities	<u>23,305</u>	<u>61,609</u>
Convertible notes, net	127,811	126,392
Other long-term liabilities	4,696	5,814
Total liabilities	<u>\$ 155,812</u>	<u>\$ 193,815</u>
Stockholders' deficit:		
Common stock	8	6
Additional paid-in capital	743,626	722,782
Accumulated deficit	(826,843)	(788,686)
Treasury stock	(19,078)	(19,078)
Total stockholders' deficit	<u>(102,287)</u>	<u>(84,976)</u>
Total liabilities and stockholders' deficit	<u>\$ 53,525</u>	<u>\$ 108,839</u>