# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 8-K

## CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): May 15, 2023**

# Biora Therapeutics, Inc.

**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-39334** | **27-3950390** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **4330 La Jolla Village Drive, Suite 300** | |
| **San Diego, California** | **92122** |
| **(Address of Principal Executive Offices)** | **(Zip Code)** |

**Registrant's Telephone Number, Including Area Code: (833) 727-2841**

**N/A**
**(Former Name or Former Address, if Changed Since Last Report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Securities registered pursuant to Section 12(b) of the Act:**

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, par value $0.001 per share | BIOR | The Nasdaq Global Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).
Emerging growth company
☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.
☐

**Item 2.02 Results of Operations and Financial Condition.**

On May 15, 2023, Biora Therapeutics, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2023. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

*As provided in General Instruction B.2 of Form 8-K, the information in this Item 2.02 and Exhibit 99.1 incorporated herein shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall such information or Exhibit 99.1 be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.*

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits.**

| | |
|---|---|
| 99.1 | Press release, dated May 15, 2023 |
| 104 | Cover Page Interactive Data File (embedded with the Inline XBRL document) |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Biora Therapeutics, Inc.

Date: May 15, 2023

By: /s/ Aditya P. Mohanty

Aditya P. Mohanty
Chief Executive Officer

**Exhibit 99.1**

**Biora Therapeutics Provides Corporate Update and Reports First Quarter 2023 Financial Results**

*Completed execution of toxicology study for NaviCap™ BT-600 program with no adverse events indicated in preliminary data; on track to file IND in Q3 2023*

*Preclinical testing for the BioJet™ platform is advancing both internally and with pharma collaborator's molecule*

*Data from preclinical study of the BioJet platform with GLP-1 receptor agonist was accepted as a late-breaking abstract for presentation at upcoming scientific meeting*

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

SAN DIEGO, May 15, 2023 – Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutic delivery, today provided a corporate update and reported financial results for the first quarter ended March 31, 2023.

During the first quarter of 2023, Biora completed execution of the toxicology study for its BT-600 program, a liquid formulation of tofacitinib delivered via the NaviCap™ targeted delivery platform for the treatment of ulcerative colitis, during which over 600 drug-device combinations were administered in animals. While results are still being analyzed, the company has received the majority of the data and has observed no adverse events or safety signals. Biora anticipates receiving the final audited report in the coming weeks.

“For our NaviCap platform, the preliminary results from our BT-600 toxicology study show that peak drug levels in blood were approximately one-quarter of what would be expected using traditional oral administration, and we saw levels in tissue that suggest the drug does not accumulate after repeat doses, which is a robust sign of safety,” said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. “In addition to the toxicology study, we are tracking well on progress with other aspects of the program, and we remain on schedule for our planned IND filing in the third quarter of 2023,” continued Mr. Mohanty.

"With our BioJet™ systemic delivery platform, we recently conducted a round of preclinical testing with one of our collaborators, for which we are awaiting results. We are also continuing our internal testing and are on track to generate data during the second quarter that could enable us to progress our other pharma collaborations,” said Mr. Mohanty.

For its BioJet™ systemic delivery platform, Biora previously announced topline results from preclinical studies with two drugs, adalimumab, a monoclonal antibody, and semaglutide, a peptide and GLP-1 receptor agonist. The BioJet platform is designed to orally deliver large

molecules through a needle-free injection in the small intestine for systemic uptake. In the preclinical study with semaglutide, the company achieved more than double its target bioavailability of 15% using an endoscopically placed and activated version of the next-generation BioJet device.

**First Quarter 2023 and Other Recent Corporate Highlights**

- Completed execution of toxicology study for NaviCap BT-600 program with no adverse events indicated in preliminary data; on schedule to file IND in Q3.
- Announced the appointment of Dr. Ariella Kelman as Chief Medical Officer, strengthening the Biora clinical team as the NaviCap platform advances toward the clinic.
- Performed preclinical testing using the BioJet platform and a collaborator's molecule. The company is awaiting results and will share findings at the appropriate time.
- Continued preclinical testing with an autonomous BioJet device; the company is on track to generate data in Q2 that could enable its other pharma collaborators to initiate testing the BioJet platform with their molecules.
- Data from Biora’s preclinical study of the BioJet platform with semaglutide, a GLP-1 receptor agonist, was accepted as a late-breaking abstract; detailed results will be presented at an important scientific conference focused on diabetes in June 2023.

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**First Quarter 2023 Financial Results**

***Comparison of Three Months Ended March 31, 2023 and December 31, 2022***

Operating expenses were $15.5 million for the three months ended March 31, 2023, compared to $13.8 million for the three months ended December 31, 2022, an increase of $1.7 million primarily driven by higher investment in device development and pre-clinical activities.

Net loss was $17.4 million and net loss per share was $1.59 for the three months ended March 31, 2023, compared to net loss of $13.7 million and net loss per share of $1.64 for the for the three months ended December 31, 2022.

The company successfully raised $12.9 million in gross proceeds from its ATM program during the first quarter, leading to a stable cash balance of $30.5 million as of March 31, 2023.

***Comparison of Three Months Ended March 31, 2023 and 2022***

Operating expenses were $15.5 million for the three months ended March 31, 2023, compared to $20.0 million for the three months ended March 31, 2022.

Net loss was $17.4 million and net loss per share was $1.59 for the three months ended March 31, 2023, compared to net loss of $13.8 million and net loss per share of $1.88 for the three months ended March 31, 2022.

**Webcast and Conference Call Information**

Biora Therapeutics will host a webcast and conference call to discuss the first quarter financial results and provide a corporate update today, Monday, May 15, 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: 13738101. 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 future expectations, goals, and plans related to our research and development efforts, preclinical studies and clinical trials and programs, the safety and efficacy profiles of our product candidates, expectations regarding the timing of any IND filings, expectations regarding data generation and opportunities with pharma collaborators, 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, 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 | |
|---|---|---|
| | **March 31, 2023** | **December 31, 2022** |
| Revenues | $ 2 | $ 14 |
| Operating expenses: | | |
| Research and development | 7,190 | 5,767 |
| Selling, general and administrative | 8,356 | 8,023 |
| Total operating expenses | 15,546 | 13,790 |
| Loss from operations | (15,544) | (13,776) |
| Interest expense, net | (2,680) | (2,685) |
| Gain on warrant liabilities | 864 | 5,458 |
| Other expense, net | (81) | (2,207) |
| Loss before income taxes | (17,441) | (13,210) |
| Income tax expense | — | 259 |
| Loss from continuing operations | (17,441) | (13,469) |
| Loss from discontinued operations | — | (253) |
| Net loss | $ (17,441) | $ (13,722) |
| Net loss per share from continuing operations, basic and diluted | $ (1.59) | $ (1.61) |
| Net loss per share from discontinued operations, basic and diluted | $ — | $ (0.03) |
| Net loss per share, basic and diluted | $ (1.59) | $ (1.64) |
| Weighted average shares outstanding, basic and diluted | 10,970,583 | 8,349,844 |

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | **2022** |
| Revenues | $ 2 | $ 107 |
| Operating expenses: | | |
| Research and development | 7,190 | 6,558 |
| Selling, general and administrative | 8,356 | 13,457 |
| Total operating expenses | 15,546 | 20,015 |
| Loss from operations | (15,544) | (19,908) |
| Interest expense, net | (2,680) | (2,760) |
| Gain on warrant liabilities | 864 | 8,989 |
| Other expense, net | (81) | (811) |
| Loss from continuing operations | (17,441) | (14,490) |
| Gain from discontinued operations | — | 682 |
| Net loss | $ (17,441) | $ (13,808) |
| Net loss per share from continuing operations, basic and diluted | $ (1.59) | $ (1.97) |
| Net gain per share from discontinued operations, basic and diluted | $ — | $ 0.09 |
| Net loss per share, basic and diluted | $ (1.59) | $ (1.88) |
| Weighted average shares outstanding, basic and diluted | 10,970,583 | 7,328,067 |

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

| | March 31, 2023 | December 31, 2022 (1) |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 30,463 | $ 30,486 |
| Income tax receivable | 828 | 828 |
| Prepaid expenses and other current assets | 3,368 | 4,199 |
| Current assets of disposal group held for sale | 2,509 | 2,603 |
| Total current assets | 37,168 | 38,116 |
| Property and equipment, net | 1,498 | 1,654 |
| Right-of-use assets | 2,246 | 1,482 |
| Other assets | 6,259 | 6,201 |
| Goodwill | 6,072 | 6,072 |
| Total assets | $ 53,243 | $ 53,525 |
| **Liabilities and Stockholders' Deficit** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,422 | $ 3,606 |
| Accrued expenses and other current liabilities | 18,987 | 16,161 |
| Warrant liabilities | 2,674 | 3,538 |
| Total current liabilities | 25,083 | 23,305 |
| Convertible notes, net | 128,185 | 127,811 |
| Other long-term liabilities | 4,973 | 4,696 |
| Total liabilities | $ 158,241 | $ 155,812 |
| Stockholders' deficit: | | |
| Common stock | 11 | 8 |
| Additional paid-in capital | 758,353 | 743,626 |
| Accumulated deficit | (844,284) | (826,843) |
| Treasury stock | (19,078) | (19,078) |
| Total stockholders' deficit | (104,998) | (102,287) |
| Total liabilities and stockholders' deficit | $ 53,243 | $ 53,525 |

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