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): March 26, 2024

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 March 26, 2024, Biora Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and year ended December 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 8.01 Other Events.

Results from SAD Portion of Phase 1 Clinical Trial of BT-600

On March 26, 2024, the Company announced the results from the single-ascending dose ("SAD") portion of its Phase 1 clinical trial of BT-600 in ulcerative colitis. Results from this portion of the trial were consistent with desired performance targets:

- NaviCap devices were well tolerated by study subjects in the SAD cohort.
- All participants who received devices containing active drug showed systemic drug absorption, indicating that all NaviCap devices released and delivered drug as intended.
- Measurable tofacitnib in blood was first observed at approximately six hours, with maximal concentrations at approximately eight hours post ingestion, which is indicative of drug delivery and absorption in the colon, as intended.
- Plasma levels of tofacitinib were approximately 3-4 times lower than what is observed with conventional oral tofacitinib at the same doses, which is a positive sign, consistent with passage of drug through the colonic tissue and into systemic circulation.
- Dose-proportional pharmacokinetics were also observed, with consistently lower plasma drug concentrations with the 5 mg dose than the 10 mg dose.

Settlement of IPO Litigation

In March 2024, the Company and plaintiffs agreed to settle the litigation related to the Company's IPO, subject to negotiation and entry into definitive and binding agreements and court approval, for an amount of $1.0 million. The Company has accrued this amount in accrued expenses in the balance sheet as of December 31, 2023. For more information regarding the IPO litigation, see Note 9, "Commitments and Contingencies" to the condensed consolidated financial statements included in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press release dated March 26, 2024
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: March 26, 2024

By: /s/ Aditya P. Mohanty

Aditya P. Mohanty
Chief Executive Officer

Exhibit 99.1

Biora Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full-Year 2023 Financial Results

All performance targets achieved in single-ascending dose (SAD) cohorts of BT-600 clinical trial

Results demonstrated targeted drug delivery and absorption in the colon, with 3-4 times lower drug levels in blood

Remainder of BT-600 clinical trial progressing well and on schedule

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

SAN DIEGO, March 26, 2024 – 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 year ended December 31, 2023.

“We are thrilled by the results from the single ascending dose (SAD) portion of our clinical trial for BT-600. The data indicate exactly what we had hoped: NaviCap devices consistently delivered tofacitinib directly to the colon, resulting in systemic drug levels three to four times lower than conventional oral delivery. This demonstrates the NaviCap platform’s unique ability for targeted delivery to the colon, and is consistent with potentially higher drug levels in colon tissue at the site of the disease,” said Adi Mohanty, Chief Executive Officer of Biora Therapeutics.

“We eagerly anticipate the conclusion of the multiple ascending dose (MAD) portion of the trial during the second quarter of 2024, which will provide additional insight into the performance of BT-600. We are working to create a new treatment paradigm that leads to better outcomes for patients suffering from ulcerative colitis, and we are encouraged by the data so far,” stated Mr. Mohanty.

“Meanwhile, our BioJet platform is progressing well. We just completed animal studies with another collaborator molecule, and we remain focused on our planned goal of progressing to partnerships this year,” continued Mr. Mohanty.

Fourth Quarter and Full-Year 2023 and Recent Highlights

NaviCap™ Targeted Oral Delivery Platform and BT-600 in ulcerative colitis

- **Completion of SAD Portion of Phase 1 Clinical Trial for BT-600.** Results from the single-ascending dose (SAD) portion of the trial were consistent with desired performance targets:
  - NaviCap devices were well tolerated by study subjects in the SAD cohort.
  - All participants who received devices containing active drug showed systemic drug absorption, indicating that the NaviCap devices released and delivered drug as intended.

- Measurable tofacitinib in blood was first observed at approximately six hours, with maximal concentrations at approximately eight hours post ingestion, which is indicative of drug delivery and absorption in the colon, as intended.
- Plasma levels of tofacitinib were approximately 3-4 times lower than what is observed with conventional oral tofacitinib at the same doses, which is a positive sign consistent with passage of drug through the colonic tissue and into systemic circulation.
- Dose-proportional pharmacokinetics were also observed, with consistently lower plasma drug concentrations with the 5 mg dose than the 10 mg dose.

BioJet™ Systemic Oral Delivery Platform preclinical development

- **BioJet Research Collaborations.** Biora has now successfully performed animal studies with peptides, antibodies, and nucleic acids, exceeding its performance target of 15% bioavailability compared to IV administration, and achieving 30-40% bioavailability with its most recent studies. The company recently completed animal studies with another large pharma research collaborator; final study data is anticipated during Q2.

Capital Markets

- **Optimization of Capital Structure.** During 2023, Biora reduced its outstanding notes by more than $80 million, resulting in a 75% reduction in net debt. With an additional note exchange in March 2024, the company has brought in a total of $19.8 million in new investment through these transactions, demonstrating continued support from institutional investors.
- **Resolution of Legacy Matters.** Biora recently monetized its investment in Enumera Molecular, Inc., generating $3 million in non-dilutive capital, and also reached an agreement in principle to resolve a legacy securities litigation matter. The company believes that remaining legacy issues will have minimal impact on Biora going forward.

Anticipated Milestones

NaviCap™ Targeted Oral Delivery Platform and BT-600 in ulcerative colitis

- Conclusion of the Phase 1 clinical trial of BT-600 is anticipated. The company expects to receive final SAD/MAD data, including colon tissue biopsy results, during Q2 2024 and plans to present topline data from the trial shortly afterward.
- A clinical study in active ulcerative colitis patients is planned during the second half of 2024.

BioJet™ Systemic Oral Delivery Platform development

- The company expects data from a recently completed animal study with its newest large pharmaceutical collaborator during Q2.
- An update on data from recent animal studies will be shared at the Next Gen Peptide Formulation & Delivery Summit in June 2024.

- Biora anticipates continued progress toward a partnership agreement for the BioJet platform.

Fourth Quarter and Full-Year 2023 Financial Results

Comparison of Three Months Ended December 31, 2023 and September 30, 2023

Operating expenses were $13.3 million for the three months ended December 31, 2023, compared to $23.3 million for the three months ended September 30, 2023. The decrease was primarily attributable to a one-time stock-based compensation non-cash charge of approximately $9.0 million related to vesting of employees' restricted stock units (RSUs) in Q3 2023.

Net loss was $15.4 million and net loss per share was $0.62 for the three months ended December 31, 2023, compared to a net loss of $73.5 million and net loss per share of $4.89 for the three months ended September 30, 2023. Q4 2023 includes non-cash charges of $6.4 million attributable to the December convertible notes exchange and $3.0 million impairment on equity investments. Q3 2023 includes non-cash charges to stock-based compensation expense of $9.0 million noted above and a non-cash charge of $53.2 million attributable to the convertible notes exchange implemented by the company in September 2023.

Net gain from discontinued operations was $0.2 million and net gain per share was $0.01 for the three months ended December 31, 2023. There was no gain or loss from discontinued operations for the three months ended September 30, 2023.

Comparison of Three Months Ended December 31, 2023 and 2022

Operating expenses were $13.3 million for the three months ended December 31, 2023, compared to $13.8 million for the three months ended December 31, 2022.

Net loss was $15.4 million and net loss per share was $0.62 for the three months ended December 31, 2023, compared to a net loss of $13.7 million and net loss per share of $1.64 for the three months ended December 31, 2022.

Net gain from discontinued operations was $0.2 million and net gain per share was $0.01 for the three months ended December 31, 2023 compared to net loss from discontinued operations of $0.3 million and net loss per share of $0.03 for the three months ended December 31, 2022.

Comparison of Full-Year Ended December 31, 2023 and 2022

Operating expenses were $67.1 million for the year ended December 31, 2023, compared to $62.1 million for the year ended December 31, 2022.

Net loss was $124.1 million and net loss per share was $7.87 for the year ended December 31, 2023, compared to a net loss of $38.2 million and net loss per share of $5.00 for the year ended December 31, 2022. This includes non-cash charges to stock-based compensation expense of $9.0 million related to vesting of employees' restricted stock units (RSUs) in Q3 2023, a non-cash charge of $53.2 million attributable to the convertible notes exchange implemented by the company in September 2023, an extinguishment loss on the convertible notes exchange implemented by the company in December 2023, and an impairment loss on equity investments.

Net gain from discontinued operations was $0.2 million and net gain per share was $0.01 for the year ended December 31, 2023, compared to net gain from discontinued operations of $10.7 million and net gain per share of $1.40 for the year ended December 31, 2022.

Conference Call and Webcast Information

Date:	Tuesday, March 26, 2024
Time:	4:30 PM Eastern time / 1:30 PM Pacific time
Conference Call:	Domestic 1-877-423-9813 International 1-201-689-8573 Conference ID 13744533 Call me for instant telephone access
Webcast:	https://investors.bioratherapeutics.com/events-presentations

About Biora Therapeutics

Biora Therapeutics 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, preclinical, and clinical trial efforts including our phase 1 trial execution and data timelines, 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," "forward," "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 and execute 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 or partners, 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	
	December 31, 2023	September 30, 2023
Revenues	$ —	$ —
Operating expenses:		
Research and development	6,118	10,547
Selling, general and administrative	7,226	12,774
Total operating expenses	13,344	23,321
Loss from operations	(13,344)	(23,321)
Interest expense, net	(1,840)	(2,592)
Gain on warrant liabilities	12,733	4,568
Other expense, net	(13,276)	(52,108)
Loss before income taxes	(15,727)	(73,453)
Income tax (benefit) expense	(95)	1
Loss from continuing operations	(15,632)	(73,454)
Gain from discontinued operations	219	—
Net loss	$ (15,413)	$ (73,454)
Net loss per share from continuing operations, basic and diluted	$ (0.63)	$ (4.89)
Net gain per share from discontinued operations, basic and diluted	$ 0.01	$ —
Net loss per share, basic and diluted	$ (0.62)	$ (4.89)
Weighted average shares outstanding, basic and diluted	24,810,923	15,024,726

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Revenues	$ —	14	$ 4	$ 305
Operating expenses:				
Research and development	6,118	5,767	29,838	24,049
Selling, general and administrative	7,226	8,023	37,309	38,037
Total operating expenses	13,344	13,790	67,147	62,086
Loss from operations	(13,344)	(13,776)	(67,143)	(61,781)
Interest expense, net	(1,840)	(2,685)	(9,815)	(10,990)
Gain on warrant liabilities	12,733	5,458	18,004	20,904
Other (expense) income, net	(13,276)	(2,207)	(65,470)	2,617
Loss before income taxes	(15,727)	(13,210)	(124,424)	(49,250)
Income tax (benefit) expense	(95)	259	(90)	(420)
Loss from continuing operations	(15,632)	(13,469)	(124,334)	(48,830)
Gain (loss) from discontinued operations	219	(253)	219	10,673
Net loss	$ (15,413)	$ (13,722)	$ (124,115)	$ (38,157)
Net loss per share from continuing operations, basic and diluted	$ (0.63)	$ (1.61)	$ (7.88)	$ (6.40)
Net gain (loss) per share from discontinued operations, basic and diluted	$ 0.01	$ (0.03)	$ 0.01	$ 1.40
Net loss per share, basic and diluted	$ (0.62)	$ (1.64)	$ (7.87)	$ (5.00)
Weighted average shares outstanding, basic and diluted	24,810,923	8,349,844	15,773,297	7,635,107

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

	December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash, cash equivalents and restricted cash	$ 15,211	$ 30,486
Income tax receivable	830	828
Prepaid expenses and other current assets	3,030	4,199
Current assets of disposal group held for sale	—	2,603
Total current assets	19,071	38,116
Property and equipment, net	1,156	1,654
Right-of-use assets	1,614	1,482
Other assets	3,302	6,201
Goodwill	6,072	6,072
Total assets	$ 31,215	$ 53,525
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 2,843	$ 3,606
Accrued expenses and other current liabilities	17,319	16,161
Warrant liabilities	40,834	3,538
Related party senior secured convertible notes, current portion	1,976	—
Total current liabilities	62,972	23,305
Convertible notes, net	9,966	127,811
Senior secured convertible notes, net	14,591	—
Related party senior secured convertible notes, net	19,179	—
Derivative liabilities	22,899	—
Other long-term liabilities	3,029	4,696
Total liabilities	$ 132,636	$ 155,812
Stockholders' deficit:		
Common stock	25	8
Additional paid-in capital	868,591	743,626
Accumulated deficit	(950,958)	(826,843)
Treasury stock	(19,079)	(19,078)
Total stockholders' deficit	(101,421)	(102,287)
Total liabilities and stockholders' deficit	$ 31,215	$ 53,525