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): November 14, 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** **(Address of Principal Executive Offices)**	**92122** **(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 November 14, 2024, Biora Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2024. 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 November 14, 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: November 14, 2024

By: /s/ Aditya P. Mohanty

Aditya P. Mohanty
Chief Executive Officer

Exhibit 99.1

Biora Therapeutics Provides Corporate Update and Reports Third Quarter 2024 Financial Results

Testing in advanced animal model planned in Q4 for smaller, 00-size BioJet device with largest capacity of any ingestible injectable

Company granted extension until December 9 to regain compliance with Nasdaq listing requirements for market value of securities

SAN DIEGO, November 14, 2024 – Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company reimagining therapeutic delivery, today provided a corporate update and reported financial results for the third quarter ended September 30, 2024. The company will not host a conference call.

“We’ve made much faster progress than anticipated developing a smaller BioJet device that is highly desired by pharma companies,” said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. “We recently presented initial animal data on our 00-size, clinical BioJet device. We were able to increase device capacity while decreasing overall size, giving BioJet the largest payload capacity of anything in the ingestible injectables category, and further increasing the number of drugs that can be delivered.”

“The rapid development allowed us to reassess our partnering strategy, making the decision to shift from a co-development model to a focus on licensing the 00-size clinical BioJet device. We expect to pursue licensing agreements within multiple verticals in the near term, which we believe is preferable to a single co-development partner for a period of time. There has been tremendous interest from our pharma collaborators, both existing and new parties, and our capacity for testing various molecules during Q1 is starting to fill up. We continue to believe, based on our extensive engagement with many pharma companies, that BioJet is the category-leading technology for oral delivery of macromolecules. We look forward to testing in a more advanced animal model during Q4 and enabling progress into IND-enabling studies,” stated Mr. Mohanty.

“Regarding our NaviCap platform, following a successful Phase 1 trial of BT-600, our team has concluded that the results may support proceeding to a larger clinical trial in ulcerative colitis patients, instead of the smaller Phase 1B trial we had been planning. We are working to facilitate the proper regulatory interactions to determine the next steps for this program,” continued Mr. Mohanty.

“We are working with our noteholders and investors to potentially increase the company's capitalization with the goal of maintaining our Nasdaq listing status after December 9. We appreciate the support of many of these investors as they have continued to provide funds to progress our programs, although their commitment cannot be guaranteed going forward. We are actively engaged with many parties regarding strategic alternatives and plan to provide a more detailed update soon,” stated Mr. Mohanty.

Third Quarter 2024 and Recent Highlights

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

- **Presented Phase 1 Clinical Trial Data at ACG 2024.** Biora presented a summary of the Phase 1 clinical trial results for BT-600 at the American College of Gastroenterology Annual Meeting, receiving a Presidential Poster Award from ACG for high quality, novel research. The poster can be viewed on the company's website.

BioJet™ Systemic Oral Delivery Platform Preclinical Development

- **Smaller, 00-Size BioJet Clinical Device.** Biora recently announced a smaller version of the BioJet device based on market research indicating strong patient preference for a smaller, 00-size capsule. The smaller device uses the same core technology of internal, liquid jet injection that has been proven in over 30 animal studies to date.
    - Payload capacity was increased while decreasing the overall size of the device from a 000-size capsule to a 00-size. The BioJet device now has a payload capacity of over 300 microliters, enabling delivery of upwards of 50 milligram doses, even for molecules that are difficult to concentrate, such as antibodies.
    - The 00-size BioJet device is designed to be more easily tested in non-human primates. It has also been designed for compatibility with human clinical trial requirements and ease of automated manufacturing, including sterile fill and finish. Biora's clinical and regulatory experience with the NaviCap platform informed this work and helped to streamline BioJet development.
    - Biora has tested the trigger function of the 00-size device on the bench as well as in animals, achieving almost 100% device performance. The company is now conducting further animal studies to confirm complete device function with a test molecule.

Other Matters

- **Recent Financings.** Biora partially drew down the facility put in place in August with its lead investors and complemented this funding source with approximately $4M in equity raises through registered direct and ATM program routes.
- **Nasdaq Compliance.** Biora received an extension to December 9 from Nasdaq to comply with the market value of securities requirement. No further extensions are available beyond that date. The company is in active negotiations with its lead investors to increase the company’s capitalization.
- **Operating Expenses.** Biora recently realigned its resources to focus on its BioJet program to ensure it can deliver in the short term the results needed by large pharma collaborators to progress licensing and partnering discussions. The company was able to reduce operating expenses and effective operating cash burn by about 40%, to less than $2.5 million per month on a going forward basis.

Anticipated Milestones

- Biora anticipates sharing data from additional canine studies with the double-zero size BioJet device during Q4 2024.

- Biora plans to perform studies of the double-zero Biora device with its own molecules in non-human primates during Q4 2024.
- The company anticipates announcing an additional expanded collaboration agreement to test the double-zero BioJet device in primates during Q4 2024.
- Testing of collaborators' molecules in primates is anticipated to begin in early 2025, with that round of testing completed during Q1 2025.

Third Quarter 2024 Financial Results

Comparison of Three Months Ended September 30, 2024 and June 30, 2024

Operating expenses were $16.3 million for the three months ended September 30, 2024, including $1.3 million in non-cash stock-based compensation expenses, compared to $16.1 million for the three months ended June 30, 2024, including $1.6 million in non-cash stock-based compensation expenses.

Net loss was $18.4 million, including non-cash items of $4.0 million attributable to an extinguishment loss and the change in fair value of warrant and derivative liabilities, and a gain from discontinued operations of $3.8 million, while net loss per share was $5.04 for the three months ended September 30, 2024, compared to net income of $6.5 million, including non-cash items of $22.8 million attributable to the change in fair value of warrant and derivative liabilities, while diluted net loss per share was $0.35 for the three months ended June 30, 2024.

Comparison of Three Months Ended September 30, 2024 and 2023

Operating expenses were $16.3 million for the three months ended September 30, 2024, including $1.3 million in non-cash stock-based compensation expenses, compared to $23.3 million for the three months ended September 30, 2023, including $10.5 million in non-cash stock-based compensation expenses, primarily attributable to a one-time charge of approximately $9.0 million related to vesting of employees' restricted stock units (RSUs) in 2023.

Net loss was $18.4 million, net of non-cash items of $4.0 million attributable to the change in fair value of warrant and derivative liabilities, and a gain from discontinued operations of $3.8 million, while net loss per share was $5.04 for the three months ended September 30, 2024, compared to a net loss of $73.5 million, including non-cash items of $62.2 million attributable to an inducement loss of $53.2 million and a one-time stock-based compensation charge noted above, while net loss per share was $48.89 for the three months ended September 30, 2023.

About Biora Therapeutics

Biora Therapeutics is a clinical-stage biotech company developing two smart pill-based therapeutics platforms: the NaviCap™ platform for colon-targeted treatment of IBD, designed to improve patient outcomes through treatment at the site of disease in the gastrointestinal tract, and the BioJet™ platform for oral delivery of large molecules, designed to replace injection with needle-free, oral delivery.

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 activities, and partnering and collaboration efforts with third parties, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “envision,” “may,” “might,” “will,” “objective,” “intend,” “should,” “could,” “can,” “would,” “expect,” “anticipate,” “forward,” “believe,” “design,” “estimate,” “predict,” “projects,” “projecting,” “potential,” “plan,” “goal(s),” “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 FDA 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 need of and ability to raise sufficient capital to achieve our business objectives or continue our operations, our ability to maintain our listing on the Nasdaq Global Market or other Nasdaq market by regaining compliance by the December 9 deadline, the fact that delisting from the Nasdaq Global Market is a “fundamental change” under the indentures for our convertible notes triggering an obligation to offer to repurchase the convertible notes, the fact that we do not have cash sufficient to repurchase the notes if the noteholders accept such an offer, 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, 2023 filed with the Securities and Exchange Commission (SEC) and other subsequent documents, including Quarterly Reports on Form 10-Q, 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
(646) 627-8390

Media Contact
Liz Robinson
CG life
lrobinson@cglife.com

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

	Three Months Ended	
	September 30, 2024	**June 30 2024**
Revenues	$ 32	$ 318
Operating expenses:		
Research and development	5,610	7,704
Selling, general and administrative	10,649	8,400
Total operating expenses	16,259	16,104
Loss from operations	(16,227)	(15,786)
Interest expense, net	(2,016)	(711)
Gain on warrant liabilities	8,260	13,003
Other (expense) income, net	(12,279)	9,892
(Loss) income before income taxes	(22,262)	6,398
Income tax benefit	(44)	(67)
(Loss) income from continuing operations	(22,218)	6,465
Gain from discontinued operations	3,816	—
Net (loss) income	$ (18,402)	$ 6,465
Net (loss) gain per share from continuing operations:		
Basic	$ (6.08)	$ 1.81
Diluted	$ (6.08)	$ (0.35)
Net gain per share from discontinued operations:		
Basic	$ 1.04	$ —
Diluted	$ 1.04	$ —
Net (loss) gain per share:		
Basic	$ (5.04)	$ 1.81
Diluted	$ (5.04)	$ (0.35)
Weighted average shares outstanding:		
Basic	3,652,862	3,572,017
Diluted	3,652,862	7,421,597

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

	Three Months Ended September 30,	
	2024	**2023**
Revenues	$ 32	$ —
Operating expenses:		
Research and development	5,610	10,547
Selling, general and administrative	10,649	12,774
Total operating expenses	16,259	23,321
Loss from operations	(16,227)	(23,321)
Interest expense, net	(2,016)	(2,592)
Gain on warrant liabilities	8,260	4,568
Other expense, net	(12,279)	(52,108)
Loss before income taxes	(22,262)	(73,453)
Income tax (benefit) expense	(44)	1
Loss from continuing operations	(22,218)	(73,454)
Gain from discontinued operations	3,816	—
Net loss	$ (18,402)	$ (73,454)
Net loss per share from continuing operations, basic and diluted	$ (6.08)	$ (48.89)
Net gain per share from discontinued operations, basic and diluted	$ 1.04	$ —
Net loss per share, basic and diluted	$ (5.04)	$ (48.89)
Weighted average shares outstanding, basic and diluted	3,652,862	1,502,473

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

	September 30, 2024	December 31, 2023 (1)
Assets		
Current assets:		
Cash, cash equivalents and restricted cash	$ 3,196	$ 15,211
Income tax receivable	868	830
Prepaid expenses and other current assets	1,990	3,030
Total current assets	6,054	19,071
Property and equipment, net	1,175	1,156
Right-of-use assets	1,011	1,614
Other assets	193	3,302
Goodwill	6,072	6,072
Total assets	$ 14,505	$ 31,215
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 6,916	$ 2,843
Accrued expenses and other current liabilities	21,404	17,319
Warrant liabilities	18,688	40,834
Convertible notes, net	4,527	—
Senior secured convertible notes, net	14,344	—
Related party senior secured convertible notes, net - current portion	19,721	1,976
Derivative liabilities	35,018	—
Total current liabilities	120,618	62,972
Convertible notes, net	—	9,966
Senior secured convertible notes, net	—	14,591
Related party senior secured convertible notes, net	—	19,179
Derivative liabilities	—	22,899
Other long-term liabilities	516	3,029
Total liabilities	$ 121,134	$ 132,636
Stockholders' deficit:		
Common stock	3	2
Additional paid-in capital	879,530	868,613
Accumulated deficit	(967,084)	(950,958)
Treasury stock	(19,078)	(19,078)
Total stockholders' deficit	(106,629)	(101,421)
Total liabilities and stockholders' deficit	$ 14,505	$ 31,215

(1) The condensed consolidated balance sheet data as of December 31, 2023 has been derived from the audited consolidated financial statements