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): January 16, 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 7.01 Regulation FD Disclosure.

On January 16, 2024, Biora Therapeutics, Inc. (the "Company") issued a press release announcing its outlook for 2024.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein. The exhibit furnished under this Item 7.01 of this Current Report on Form 8-K 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 it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Item 8.01. Other Events.

On January 16, 2024, the Company announced its 2024 anticipated milestones.

2024 Anticipated Milestones

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

- **Phase 1 SAD/MAD study data for BT-600 in healthy volunteers.** Initial data from the SAD arm expected in 2-3 months, followed by MAD results including tissue data.
- **Potential phase 1B study in UC patients.** Developing study protocol with a goal to generate data for BT-600 in ulcerative colitis patients ahead of future phase 2 study.
- **56-day GLP tox study with BT-600.** Planned to begin in 2H 2024; enabling requirement for larger and longer duration clinical studies.

BioJet™ Systemic Oral Delivery Platform development

- **Progress with pharma collaborations.** Ongoing preclinical data generation through animal studies with multiple collaborators' molecules anticipated throughout 2024. Anticipate expanding research collaborations into development partnerships.

Forward-Looking Statements

This Current Report on Form 8-K 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 Current Report on Form 8-K, including statements concerning our anticipated milestones, the progress and future expectations and goals of our research and development and clinical efforts and research collaboration plans and expectations are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipate," "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "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 Current Report on Form 8-K. 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 Current Report on Form 8-K. 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 clinical trials on expected timelines or at all, our ability to obtain and maintain regulatory approval, clearance, or acceptance of our clinical trials or 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, 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press Release, dated January 16, 2024
104	Cover Page Interactive Data File (embedded within 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: January 16, 2024

By: /s/ Eric d'Esparbes
Eric d'Esparbes
Chief Financial Officer

Biora Therapeutics Provides Outlook for 2024

Multiple catalysts anticipated in 2024, including clinical study results for NaviCap™ Targeted Oral Delivery Platform and progress on pharma partnerships for BioJet™ Systemic Oral Delivery Platform

SAN DIEGO, January 16, 2024 – Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutic delivery, today provided guidance on anticipated milestones during 2024.

“In 2023, we completed the transformation of the company, focusing on strong execution which laid the foundation for significant value inflection in the coming months,” said Adi Mohanty, Chief Executive Officer of Biora Therapeutics.

“We begin 2024 in the clinic with our phase 1 study for BT-600, which will be a major de-risking step in the development of our NaviCap™ platform. We already have data on the device alone in humans, and tofacitinib is already used to treat UC. In this study, we combine the two. Based on our previous work, we know that increased colon tissue concentration correlates with endoscopic healing in UC patients, and we observed the NaviCap platform achieve increased colon tissue concentration in animals. This clinical study should provide critical data to help prove our treatment hypothesis, setting the stage for a possible new treatment paradigm for the treatment of GI-related diseases,” continued Mr. Mohanty.

“The BioJet platform continues to exceed its performance targets and shows outstanding promise to solve the challenges of oral delivery of large molecules—the holy grail of drug delivery. We are seeing increased interest in the platform as we generate additional performance data with multiple molecules from collaborators, including AstraZeneca and other large pharma companies, and we expect to progress these relationships toward broad partnership structures later this year, which could provide non-dilutive funding for further development,” said Mr. Mohanty.

2024 Anticipated Milestones

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

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About the NaviCap™ Targeted Oral Delivery Platform and BT-600

Biora's NaviCap targeted oral therapeutics platform utilizes a novel approach that could improve patient outcomes by enabling delivery of therapeutics directly to the site of disease, increasing therapeutic levels in tissue while reducing systemic uptake. For the 1.8 million patients in the United States who suffer from inflammatory bowel disease (IBD), existing therapeutics offer less than ideal efficacy, likely because of the challenges with safely achieving sufficient drug levels in the affected tissues. Research has shown that targeted delivery of therapeutics has the potential to improve patient outcomes in IBD.

The NaviCap platform uses an ingestible device designed for targeted delivery of therapeutics to improve treatment of IBD. Once swallowed, Biora's proprietary GItrac™ autolocation technology enables the device to autonomously identify targeted locations in the GI tract and release a therapeutic dose of up to 500µl. Studies in healthy volunteers have demonstrated accurate localization and delivery in a fasted state and demonstrated the device's ability to function in both fasted and fed states, making it potentially the first ingestible therapeutic delivery device that does not require fasting or other food restriction for use. A device function study in participants with active ulcerative colitis (UC) also demonstrated successful device performance in active UC patients.

Biora's BT-600 program is a drug/device combination designed to use the NaviCap™ ingestible drug delivery device with a proprietary liquid formulation of tofacitinib, for the potential treatment of moderate to severe ulcerative colitis. The NaviCap device is orally administered and has been designed for targeted therapeutic delivery directly to the colon in this application. The company is currently conducting a phase 1 clinical study with BT-600 in adult healthy volunteers.

About the BioJet™ Systemic Oral Delivery Platform

Biora's BioJet systemic oral therapeutics platform uses an ingestible capsule for needle-free, oral delivery of large molecules designed to achieve systemic bioavailability and replace injection for better management of chronic diseases.

The BioJet platform uses an ingestible device designed to transit through the digestive system and activate in the small intestine, where liquid jets deliver drug directly into the small intestine for uptake into systemic circulation. The BioJet device is approximately the size of a multivitamin and is designed to autonomously deliver a wide range of large molecules, such as proteins, peptides, and nucleic acids, in liquid formulation at multi-milligram doses, without requiring complex reformulation.

Biora holds a comprehensive patent position for the BioJet systemic oral delivery platform, with approximately 12 issued patents and 29 pending applications that cover its delivery platform and methods for using the platform to treat a disease or condition in a patient using liquid jet delivery of a wide range of drugs.

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 clinical-stage 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 preclinical-stage 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 our anticipated milestones, the progress and future expectations and goals of our research and development and clinical efforts and research collaboration plans and expectations are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipate," "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "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 clinical trials on expected timelines or at all, our ability to obtain and maintain regulatory approval, clearance, or acceptance of our clinical trials or 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, 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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