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 30, 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** **(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 8.01. Other Events.

On November 30, 2023, Biora Therapeutics, Inc. issued a press release announcing clearance by the U.S. Food and Drug Administration of its Investigational New Drug application for BT-600, a drug/device combination for the treatment of moderate to severe ulcerative colitis. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press Release, dated November 30, 2023
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: December 1, 2023

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

Biora Therapeutics Announces FDA Clearance of IND Application for Drug/Device Combination BT-600 Targeting Treatment of Ulcerative Colitis

BT-600 will deliver a proprietary liquid formulation of tofacitinib via the NaviCap™ device for topical delivery to the colon

SAN DIEGO, November 30, 2023 – Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutic delivery, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application for BT-600, a drug/device combination for the treatment of moderate to severe ulcerative colitis.

"The FDA has agreed with our plans to proceed with clinical development of BT-600 and has activated our IND application. We appreciate the agency's collaborative relationship as they have worked with us to achieve what is, to our knowledge, the first active IND for an ingestible drug and device combination," said Ariella Kelman, MD, Chief Medical Officer of Biora Therapeutics. "We believe our therapeutic approach could lead to better outcomes for patients suffering from ulcerative colitis. We look forward to completing the activities required by FDA and the trial site prior to enrolling the first subject in our phase 1 clinical trial in the United States in the coming weeks."

BT-600 is a drug/device combination designed to use Biora's NaviCap™ ingestible drug delivery device with a proprietary liquid formulation of tofacitinib, for the treatment of moderate to severe ulcerative colitis. The NaviCap device has been designed for targeted delivery directly to the colon in this application. The phase 1 trial of BT-600 is planned as a randomized, double-blind, placebo-controlled, single and multiple ascending dose study to evaluate safety, pharmacokinetics and pharmacodynamics, including effects on colon tissue, in healthy volunteers receiving BT-600 with tofacitinib at 5 mg and 10 mg doses.

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 GItrac™ autolocation technology enables the device to autonomously identify targeted locations in the GI tract and release a therapeutic dose of up to 500µl.

Biora's BT-600 program consists of a unique, liquid formulation of tofacitinib delivered to the colon via the NaviCap device, for the treatment of ulcerative colitis. 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.

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 and clinical efforts including phase 1 trial readiness, phase 1 trial execution timeline, phase 1 trial commencement, and working through the final FDA and trial site requirements prior to enrolling the first subject, 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," "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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