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 9, 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 January 9, 2023, the Company issued a press release announcing the receipt of feedback from a pre-Investigational New Drug supplemental Type C response from the U.S. Food and Drug Administration and providing further detail with respect to anticipated key milestones that the Company expects to achieve in 2023 regarding its PGN-600 program. 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 January 9, 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: January 12, 2023

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

Exhibit 99.1

Biora Therapeutics Receives Pre-IND Feedback from FDA and Provides Update on Key Programs for 2023

Company is on track to move into the clinic with its lead targeted therapeutics program

SAN DIEGO, January 9, 2023 – Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutic delivery, today announced feedback from the United States Food and Drug Administration (FDA) on its clinical development plans for its PGN-600 program, and provided program updates.

For Biora's Targeted Therapeutics Platform, which is focused on treatment of ulcerative colitis (UC), the company remains on track for an IND filing for its PGN-600 program followed by clinical trial initiation. During Q4 2022, Biora continued its engagement with the FDA with a pre-IND supplemental Type C filing requesting agency feedback on its proposed PGN-600 clinical development plans, including the company's proposed approach to toxicity studies and other aspects of its clinical plan.

"The recent Type C response from the FDA further strengthens our confidence in our plans to enter the clinic during the first half of 2023 with IND filing followed by trial initiation in Q2, and data readouts anticipated in Q3," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "Based on previous studies, we know that achieving the appropriate concentration of tofacitinib in the tissue of the large intestine is correlated with endoscopic improvement, and we believe that reducing systemic exposure to tofacitinib could be a paradigm shift in the ability to help a substantial percentage of patients. Our planned clinical trial should provide insights on these very important tissue and plasma levels, along with the safety of our approach. With this critical data anticipated during the phase 1 trial, we look forward to progressing a program that could have significant impact on patient care for ulcerative colitis."

Biora Therapeutics has previously shown the strong potential of its Targeted Therapeutics platform to help patients with ulcerative colitis (UC) through data demonstrating that:

- Higher tissue levels of tofacitinib in UC patients are correlated with endoscopic improvement.
- Biora's device can accurately deliver liquid payload to the correct location in the colon of healthy volunteers.
- Biora's device can accurately identify colon entry and deliver liquid payload to the site of disease in active ulcerative colitis patients, despite a challenging environment of inflammation, bleeding, and highly variable motility.
- Biora's device can function as intended when administered both with and without food.

For Biora's Systemic Therapeutics program, the company has been transitioning from early concept to a clinical-ready device. With several of the key device upgrades implemented, the company expects to report data from preclinical studies on its next-generation device during Q1 and Q2 of 2023.

"We are making good progress with our systemic therapeutics program and expecting additional bioavailability data in the coming months," said Mr. Mohanty. "These data, if consistent with data from our previous version of the device, which showed average bioavailability of approximately 25% with a variant of adalimumab, should enable us to progress the relationships with our existing pharma collaborators, and potentially establish relationships with additional entities. Achieving meaningful partnerships based on our systemic platform is a fundamental goal for Biora in the coming year, with potential for multiple partnerships over time due to the broad applicability of the platform to different molecules."

Key 2023 Milestones

- Present the first detailed results from the Targeted Therapeutics program device performance study indicating successful device function when administered with food, which could potentially enable non-fasted administration in patients, at the Crohn's & Colitis Congress on January 19, 2023.
- File an IND for Targeted Therapeutics PGN-600 and enter the clinic in the first half of 2023.
- Generate key Targeted Therapeutics PGN-600 data by Q3.
- Complete Systemic Therapeutics preclinical data generation with the next generation device in Q1 and Q2.
- Initiate next-phase pharma partnerships for Systemic Therapeutics program in 2023.

Biora also remains committed to efficient use of resources by maintaining its target monthly cash burn rate while rapidly progressing development.

About Biora Therapeutics' Targeted Therapeutics Platform

Biora Therapeutics' targeted therapeutics platform utilizes a novel approach that could improve IBD 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. Recent data have shown that targeted delivery of therapeutics has the potential to improve patient outcomes in IBD.

Biora's Drug Delivery System (DDS) is an ingestible capsule designed for targeted delivery of therapeutics to improve treatment of IBD. It is approximately the size of a fish oil capsule and delivers a payload of up to 500µl liquid or solid formulation. Once swallowed, the capsule is designed to autonomously identify specific locations in the GI tract and release a therapeutic dose.

Biora is developing the PGN-600 program, which consists of a liquid formulation of tofacitinib delivered to the colon via the DDS capsule, for the treatment of ulcerative colitis. Studies in healthy volunteers have demonstrated accurate localization and delivery in a fasted state and also 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. The company plans to submit an Investigational New Drug (IND) application to begin a Phase 1 study with its PGN-600 drug-device combination to evaluate drug concentration in tissue and plasma.

About Biora Therapeutics' Systemic Therapeutics Platform

Biora Therapeutics' systemic therapeutics platform uses an ingestible smart capsule for needle-free, oral delivery of biotherapeutics, with the potential to deliver a broad range of large molecules including monoclonal antibodies, peptides, and nucleic acids. Biora's Oral Biotherapeutics Delivery System (OBDS) is an ingestible capsule designed to use proprietary liquid jet delivery to increase systemic uptake and bioavailability of large molecules. Once swallowed, the capsule is designed to transit through the digestive system and trigger in the small intestine, where liquid jets deliver drug directly into the intestinal tissue for uptake into systemic circulation. The capsule is approximately the size of a multivitamin and can deliver up to 400µL of liquid formulation, such as proteins, peptides, and nucleic acids.

Biora is developing the PGN-OB2 program, which consists of a GLP-1 receptor agonist delivered via liquid jet into the small intestinal tissue using the OBDS capsule, for the treatment of type 2 diabetes. Oral GLP-1 receptor agonists are preferred by patients, and research indicates that people who start treatment with an injectable GLP-1 receptor agonist have a 71% higher discontinuation rate than those starting oral therapy. The company is currently advancing development of PGN-OB2 with preclinical studies.

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 envisions a world where patients have access to needle-free drug delivery and better therapeutic outcomes.

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, 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 precision medicine, 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, the ongoing COVID-19 pandemic, 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, 2021 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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