BIORA™ Therapeutics

INVESTOR Q&A

March 2023

FORWARD-LOOKING STATEMENTS

This presentation contains “forward-looking statements” within the meaning of the federal securities laws, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical fact included in this presentation, including statements concerning our plans, objectives, goals, strategies, future events, plans or intentions relating to product candidates, estimates of market size, the anticipated timing, design and conduct of our planned pre-clinical and clinical trials, the anticipated timing for pre-clinical and clinical data, the development of our product candidates, the potential clinical benefits of our product candidates, including efficacy and safety benefits, the potential benefits of strategic partnerships and licensing arrangements and our intent to enter into any strategic partnerships or licensing arrangements, the timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated product development 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” or the negative of these terms, and similar expressions intended to identify forward-looking statements. 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 presentation, including competition from third parties with respect to our product candidates; risks related to the supply and manufacturing of and complexity of components in our devices; whether we will be able to develop our precision medicine products, and, if developed, that such product candidates will be authorized for marketing by regulatory authorities, or will be commercially successful; and those 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 fiscal year ended December 31, 2022, and elsewhere in such filing and in other subsequent disclosure documents, including our Quarterly Reports on Form 10-Q, filed with the U.S. Securities and Exchange Commission.

We cannot assure you that we will realize the results, benefits or developments that we expect or anticipate or, even if substantially realized, that they will result in the consequences or affect us or our business in the way expected. Forward-looking statements are not historical facts and reflect our current views with respect to future events. Given the significant uncertainties, you should evaluate all forward-looking statements made in this presentation in the context of these risks and uncertainties and not place undue reliance on these forward-looking statements as predictions of future events. All forward-looking statements in this presentation apply only as of the date made and are expressly qualified in their entirety by the cautionary statements included in this presentation. We disclaim any intent to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances, except as required by law.

Industry and Market Data: We obtained the industry, market, and competitive position data used throughout this presentation from our own internal estimates and research, as well as from industry and general publications, and research, surveys, and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of the industry and market, which we believe to be reasonable. In addition, while we believe the industry, market, and competitive position data included in this prospectus is reliable and based on reasonable assumptions, we have not independently verified any third-party information, and all such data involve risks and uncertainties and are subject to change based on various factors. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

BIORA™ Therapeutics

Our mission is to reimagine therapeutic delivery

Innovating smart capsule technologies to deliver the right dose to the right place, safely

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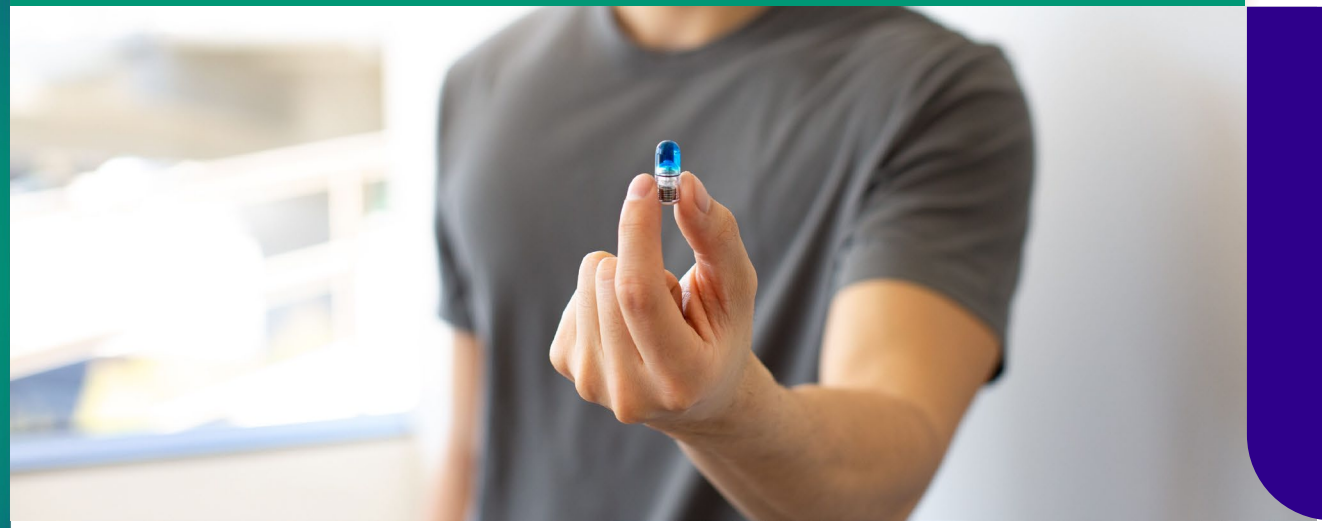
NAVI*cap*™

TARGETED ORAL DELIVERY

Treatment at the site of disease in the GI tract could improve outcomes for patients with inflammatory bowel disease



BIO*jet*™

SYSTEMIC ORAL DELIVERY

Needle-free, oral delivery of large molecules designed to replace injection for better management of chronic diseases

Guide to therapeutics programs

PLATFORM Current Name	PLATFORM Previous Name	PROGRAM Current Name	PROGRAM Previous Name
NAVI*cap*™ Targeted Oral Delivery Platform	*formerly* *Drug Delivery System (DDS)*	**BT-600** NaviCap™ + tofacitinib	*PGN-600*
		BT-001 NaviCap™ + adalimumab variant	*PGN-001*
BIO*jet*™ Systemic Oral Delivery Platform	*formerly* *Oral Biotherapeutic Delivery System (OBDS)*	**BT-200** BioJet™ + GLP-1 receptor agonist	*PGN-OB2*
		BT-002 BioJet™ + adalimumab variant	*PGN-OB1*

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NAVI*cap*™

TARGETED ORAL DELIVERY PLATFORM

What is the NaviCap Targeted Oral Delivery Platform?

- Biora's **NaviCap Targeted Oral Delivery platform (formerly the Drug Delivery System or DDS)** utilizes a novel approach that could improve IBD patient outcomes by enabling delivery of therapeutics directly to the site of disease. The objective is to increase 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 **NaviCap device (formerly the DDS device)** 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 formulation. Once swallowed, the capsule is designed to autonomously identify specific locations in the GI tract and release a therapeutic dose.
- Learn more here: https://www.bioratherapeutics.com/pipeline/targeted-therapeutics

What is BT-600?

- **BT-600 (formerly PGN-600)** is a liquid formulation of tofacitinib delivered to the colon via the NaviCap device, for the treatment of ulcerative colitis.
- Biora conducted a 7-day preclinical study early in the BT-600 program (formerly PGN-600) to evaluate the safety, tolerability, and pharmacokinetic and pharmacodynamic effects of BT-600 (a proprietary liquid formulation of tofacitinib delivered by the NaviCap device, formerly the DDS device). The objectives of this study were to establish the use of the animal model, evaluate safety and tolerability and to provide comparative data between administration of BT-600 and a standard oral tablet dose of tofacitinib to help guide dosing in future studies.
- The study demonstrated the ability to utilize the animal model for preclinical studies of BT-600. The study also gave Biora confidence to move forward with the program by demonstrating that BT-600 was well tolerated and can achieve pan-colonic distribution with significantly higher tissue concentrations of tofacitinib than the equivalent dose in standard oral tablet form. These results suggest that a dose lower than the standard dose for tofacitinib can provide increased drug levels in tissue while reducing systemic exposure.
- Topline results of the study were released here and are included in Biora's latest corporate presentation.

What is the PM-601 study?

- **PM-601** was Biora's first device function study in healthy volunteers to test the tolerability and performance of the NaviCap platform (formerly the Drug Delivery System or DDS). This study evaluated the capsule's safety and tolerability and collected the first clinical data on the ability of the NaviCap device to accurately auto-locate and deliver a payload to the proximal colon, a key delivery site for the treatment of ulcerative colitis and Crohn's disease.
- The single administration study used the well-established method of scintigraphic characterization to validate the device localization and drug delivery mechanism by using a saline solution payload that included radioisotopes. Initial analysis of the study results suggests the device was well tolerated and the majority of devices functioned as intended and could accurately identify entry into the colon, trigger release of a liquid payload, and achieve pan-colonic distribution. No drug was administered during the study.
- Study results were presented at the 2022 American College of Gastroenterology Annual Scientific Meeting.
- An overview of device function study results is included in Biora's latest corporate presentation.

What is the PM-611 study?

- **PM-611** was Biora's second completed device function study for the NaviCap platform (formerly the Drug Delivery System or DDS). The study assessed whether the autonomous location functionality of the device was impacted by a fed state as compared to a fasted state in healthy volunteers. This study demonstrated that the device functioned as designed when administered with food, potentially enabling non-fasted administration.
- The study demonstrated that all capsules were safely ingested and exited the body naturally, with no serious adverse events reported. All analyzed devices (39/39) successfully identified entry to the colon and activated H2 gas cells for delivery in all fasted/fed schedules. 97.4% of analyzed devices (38/39) activated the payload release function. No serious adverse events were reported.
- The PM-611 study included multiple dosage events. Participants were required to ingest a total of four capsules each, with administration occurring following excretion of the previous capsule, as per study protocol. A total of 46 capsules were ingested by 12 participants, with one participant ingesting only two capsules. Forty-three capsules were recovered for analysis and performance was measured by retrieving data from the recovered devices. Data was successfully retrieved from 39 capsules. (Damage to some capsules during data recovery accounted for the difference in the number of analyzed capsules. Some capsule damage was expected as these devices are not designed to be recovered, opened, and analyzed as part of routine clinical use.)
- No drug was administered during the study.
- Study results were presented at the Crohn's & Colitis Congress, January 19-21, 2023.
- An overview of device function study results is included in Biora's latest corporate presentation.

What is the PM-602 study?

- **PM-602** was Biora's third completed device function study for the NaviCap platform (formerly the Drug Delivery System or DDS), and the first to be performed in active ulcerative colitis (UC) patients. It was a follow-on device function study designed to mirror that of the first device function study (PM-601), evaluating the delivery of an imaging agent to the colon using the NaviCap device in patients with active ulcerative colitis.
- The study demonstrated that the device was well tolerated, and that the device performed as intended in active UC patients. In all seven patients, the device accurately identified entry into the colon, triggered release of a liquid payload, and achieved distribution across the entire colon.
- During the PM-602 study, the device was ingested orally by seven patients with active ulcerative colitis in a single dosage event. After identification of colon entry, the device released a saline solution payload that included radioisotopes. Serial gamma-scintigraphy images were used to independently determine device localization and payload delivery to the lower gastrointestinal tract. No drug was administered during the study.
- Study results were presented at the 2022 American College of Gastroenterology Annual Scientific Meeting.
- An overview of device function study results is included in Biora's latest corporate presentation.

What other studies support Biora's targeted therapeutic approach to IBD?

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- Data supporting the need for high tissue concentrations to achieve remission in ulcerative colitis was presented at Digestive Disease Week in May. Key opinion leader Dr. Séverine Vermiere gave a presentation titled "Tofacitinib tissue exposure correlates with endoscopic outcome," which Dr. Vermiere co-authored with lead author Dr. Bram Verstockt and others. In the presentation, Dr. Vermiere presented patient data confirming a significant relationship between drug levels in colon tissue and endoscopic improvement in patients with moderate to severe ulcerative colitis who were treated with tofacitinib.
- This study supports the hypothesis that a tissue concentration of tofacitinib at or exceeding IC_{90} is directly correlated to significant improvement in patient outcomes and endoscopic improvement in patients with moderate to severe ulcerative colitis who were treated with tofacitinib. Preclinical data indicates that these tissue concentrations can be achieved with BT-600 even with lower doses than commercially available oral doses of tofacitinib.
- In addition, key opinion leader Dr. Geert D'Haens presented at the 17th Congress of the European Crohn's and Colitis Organisation (ECCO) in February 2022 a poster titled "Pharmacokinetic stratification of cytokine profiles during anti-TNF induction treatment in moderate-to-severe UC," which suggests a need for combination therapy to target multiple inflammatory pathways in some UC patients who today are unable to achieve remission of symptoms. However, combination therapies must overcome the systemic toxicity limits of current approaches. Biora's NaviCap platform is designed to achieve higher doses in tissue while reducing systemic uptake. This approach could enable combination therapy to simultaneously target multiple inflammatory pathways and improve therapeutic outcomes.

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What are the clinical development plans for BT-600?

- In May 2022, Biora Therapeutics submitted a Type C meeting request to the FDA asking for feedback on its proposed clinical development plan. In a constructive response, the FDA generally agreed with the proposed clinical trial design and provided helpful feedback on protocols. The FDA also reviewed the proposed supporting data package and confirmed the anticipated need for additional toxicology data.
- During Q4 2022, Biora continued its engagement with the FDA with a pre-IND supplemental Type C filing requesting agency feedback on its proposed BT-600 clinical development plans, including the company's proposed approach to toxicology studies and other aspects of its clinical plan. Based on the response from the FDA, the company finalized plans for its 14-day toxicology study and completed execution of the study. Biora is now completing its analysis of the study data and associated device data.
- The company believes it will be in a position to file an IND during the second half of 2023 to support the initiation of its Phase 1 clinical study.
- Clinical development plans for the targeted therapeutics program are outlined in Biora's latest corporate presentation.

BIO*jet*™

SYSTEMIC ORAL DELIVERY PLATFORM

What is the BioJet Systemic Oral Delivery Platform?

- Biora's **BioJet Systemic Oral Delivery Platform** (formerly the Oral Biotherapeutic Delivery System, or OBDS) is designed for needle-free, oral delivery of large molecules, including monoclonal antibodies, peptides, and nucleic acids. These substances cannot survive stomach acids and are too large to be absorbed in the intestine, and are therefore currently delivered by injection.
- The **BioJet device (formerly the OBDS device)** is an ingestible capsule designed to enable delivery of liquid drug, without the need for reformulation. Once swallowed, the BioJet device is designed to transit the intestinal tract and trigger in the small intestine, where it will use liquid jet release to inject drug directly into the small intestine for optimal bioavailability.
- The device is approximately the size of a multivitamin and can deliver up to 400µL of liquid formulation, making the technology broadly applicable for large molecule candidates.
- With more frequent administration, oral delivery has the potential to improve drug efficacy and safety as compared to current injection regimens.
- Learn more here: https://www.bioratherapeutics.com/pipeline/systemic-therapeutics

What is BT-002?

- **BT-002 (formerly PGN-OB1)** is a proprietary liquid formulation of an adalimumab variant, delivered via the BioJet device. Preclinical studies were conducted in 2021 to demonstrate the bioavailability of BT-002 (formerly PGN-OB1) when administered in swine. The results demonstrated an average bioavailability of 22% in animals where drug was detected in blood, and bioavailability levels of up to 67%.
- The company believes that achieving an average bioavailability of 10-15% will enable daily oral dosing of BT-002 and the oral delivery of numerous commercial and in-development large molecules.
- The company is proceeding with preclinical development of BT-002.
- Learn more here: https://www.bioratherapeutics.com/pipeline/systemic-therapeutics

What is BT-200?

- **BT-200 (formerly PGN-OB2)** is a proprietary liquid formulation of the GLP-1 receptor agonist liraglutide, delivered by the BioJet device for the treatment of type 2 diabetes.
- GLP-1 receptor agonists are a class of drug approved for type 2 diabetes and weight loss, but they are also being evaluated by other parties in other diseases including fatty liver disease and atrial fibrillation. According to leading analytics firm GlobalData, the GLP-1 receptor agonist market is forecasted to be well over $20 billion by 2025.
- The only oral GLP-1 receptor agonist commercially available today is approximately 1% bioavailable. Biora believes it is possible to improve oral bioavailability for GLP-1 receptor agonists.
- Biora holds a strong intellectual property position for devices and methods related to oral delivery of GLP-1 receptor agonists.
- The company is proceeding with preclinical development of BT-200.
- Learn more here: https://www.bioratherapeutics.com/pipeline/systemic-therapeutics

What studies are being conducted for the BioJet platform?

- Biora is currently conducting multiple preclinical studies. The company is testing both BT-200 and BT-002.
- In February 2023, the company announced topline results from preclinical testing of BT-002 (formerly PGN-OB1) , reporting average bioavailability of 51.3% with its variant of adalimumab.
- In February 2023, the company also announced topline results from preclinical testing of the GLP-1 receptor agonist semaglutide, reporting average bioavailability of 37%.
- Data on preclinical model development for the systemic platform was presented at the Controlled Release Substances conference in July 2022 and at the American College of Gastroenterology Annual Scientific Meeting in October 2022.
- Preclinical data on BT-002 (formerly PGN-OB1) was presented at the Controlled Release Substances conference in July 2022 and at the American College of Gastroenterology Annual Scientific Meeting in October 2022.
- Combined data on preclinical model development and BT-002 (formerly PGN-OB1) was presented at the Parenteral Drug Association Universe of Pre-Filled Syringes and Injection Devices Conference in October 2022.
- Development plans for the BioJet platform are outlined in Biora's latest corporate presentation.


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