# 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 13, 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**<br>**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 2.02 Results of Operations and Financial Condition.**

On November 13, 2023, Biora Therapeutics, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2023 and an updated corporate presentation. The press release and corporate presentation are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, 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 and Exhibit 99.2 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 Exhibits 99.1 and 99.2 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 13, 2023 |
| 99.2 | Corporate presentation dated November 13, 2023 |
| 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 13, 2023

By: /s/ Aditya P. Mohanty

Aditya P. Mohanty
Chief Executive Officer

**Biora Therapeutics Provides Corporate Update and Reports Third Quarter 2023 Financial Results**

*NaviCap™ Targeted Oral Delivery platform advancing toward initiation of phase 1 clinical trial by year end*

*Pharma collaborations accelerate for the BioJet™ Systemic Oral Delivery platform, which shows potential for liver-targeted delivery of large molecules*

*Management will host conference call and webcast today at 4:30 PM Eastern / 1:30 PM Pacific*

SAN DIEGO, November 13, 2023 – Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutic delivery, today provided a corporate update and reported financial results for the third quarter ended September 30, 2023.

"We took a big step in advancing our NaviCap platform toward the clinic, with the filing of our IND and a planned phase 1 trial for BT-600 on track for initiation in December," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "We're excited about the NaviCap platform's potential to improve outcomes for ulcerative colitis patients who still have significant unmet needs. With our proprietary technology, we have unique potential to achieve higher drug levels in the diseased tissue without systemic toxicity," continued Mr. Mohanty.

"The third quarter was also marked by accelerating development of our BioJet™ platform. We progressed our three existing pharma collaborations during the quarter and are actively negotiating with a potential fourth pharma collaborator. The BioJet platform has demonstrated not only category-leading bioavailability, but the potential to enable liver-targeted, oral delivery of large molecules," stated Mr. Mohanty.

**Third Quarter 2023 and Other Recent Highlights**

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

- **BT-600 IND Filing.** Biora filed an IND application with the FDA for BT-600 in September 2023. The company responded to agency questions and filed an updated IND in late October to provide additional time for regulatory review.
- **NaviCap Patent for Targeted Delivery of JAK Inhibitors to the GI Tract.** The USPTO recently allowed a new patent regarding the novel treatment paradigm of the BT-600 program, which provides targeted delivery of a JAK inhibitor to the GI tract.

*BioJet™ Systemic Oral Delivery Platform preclinical development*

- **EASD Presentation of BioJet 2 Data.** New data was presented at the European Association for the Study of Diabetes, demonstrating that the BioJet 2 device met its performance targets. Across three studies in a porcine model, 96% of animals showed semaglutide in systemic circulation at clinically relevant levels, and oral bioavailability averaged 20.5%.
- **Liver-Targeted Delivery of Large Molecules.** Early collaborator data indicates the BioJet platform could provide a unique advantage for liver-targeted, oral delivery of

large molecules through its proprietary liquid jet injection into the small intestine, where the hepatic portal system provides optimal delivery to the liver.

- **BioJet Research Collaborations.** Biora received data analysis from animal studies with one pharma collaborator; completed studies with a second collaborator and awaits sample analysis; and is initiating new studies with a third collaborator. Active negotiations are underway with a fourth potential pharma collaborator.

*Capital Markets*

- **Optimization of Capital Structure.** Biora materially reduced its convertible notes balance by $50 million through a notes exchange agreement during the third quarter and raised more than $5.5 million through various sources including monetization of legacy business assets and direct capital investments.

**Anticipated Milestones**

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

- FDA response to IND application for BT-600 is anticipated, with Phase 1 trial initiation expected before the end of 2023, followed by execution in Q1 2024, and final data assessment in Q2 2024

*BioJet™ Systemic Oral Delivery Platform development*

- Potential  new collaboration and progress with existing collaborators
- Ongoing preclinical data generation through animal studies with multiple collaborators' molecules anticipated during Q4 2024

**Third Quarter 2023 Financial Results**

***Comparison of Three Months Ended September 30, 2023 and June 30, 2023***

Operating expenses were $23.3 million for the three months ended September 30, 2023, compared to $14.9 million for the three months ended June 30, 2023. The increase was primarily attributable to a one-time stock-based compensation non-cash charge of approximately $9.0 million related to vesting of employees' restricted stock units (RSUs).

Net loss was $73.5 million and net loss per share was $4.89 for the three months ended September 30, 2023, compared to a net loss of $17.8 million and net loss per share of $1.47 for the three months ended June 30, 2023. This includes non-cash charges to stock-based compensation expense of $9.0 million noted above and a non-cash charge of $53.2 million attributable to the convertible notes exchange implemented by the company in September 2023.

***Comparison of Three Months Ended September 30, 2023 and 2022***

Operating expenses were $23.3 million for the three months ended September 30, 2023, compared to $14.0 million for the three months ended September 30, 2022. The increase was primarily attributable to a $9.0 million one-time stock-based compensation non-cash charge related to vesting of employees' RSUs.

Net loss was $73.5 million and net loss per share was $4.89 for the three months ended September 30, 2023, compared to a net loss of $5.1 million and net loss per share of $0.68 for the three months ended September 30, 2022. This includes non-cash charges to stock-based compensation expense of $9.0 million noted above and a non-cash charge of $53.2 million attributable to the convertible note exchange implemented by the company in September 2023.

**Conference Call and Webcast Information**

| | |
|---|---|
| **Date:** | Monday, November 13, 2023 |
| **Time:** | 4:30 PM Eastern time / 1:30 PM Pacific time |
| **Conference Call:** | Domestic 1-877-423-9813<br>International 1-201-689-8573<br>Conference ID 13741259<br>Call me for instant telephone access |
| **Webcast:** | https://investors.bioratherapeutics.com/events-presentations |

**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 and execution timeline, FDA acceptance, and trial commencement, 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 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, 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.

**Investor Contact**
Chuck Padala
Managing Director, LifeSci Advisors
IR@bioratherapeutics.com
(646) 627-8390

**Media Contact**
media@bioratherapeutics.com

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

| | Three Months Ended | |
|---|---|---|
| | **September 30, 2023** | **June 30, 2023** |
| Revenues | $ — | $ 2 |
| Operating expenses: | | |
| Research and development | 10,547 | 5,983 |
| Selling, general and administrative | 12,774 | 8,953 |
| Total operating expenses | 23,321 | 14,936 |
| Loss from operations | (23,321) | (14,934) |
| Interest expense, net | (2,592) | (2,703) |
| Gain (loss) on warrant liabilities | 4,568 | (161) |
| Other expense, net | (52,108) | (5) |
| Loss before income taxes | (73,453) | (17,803) |
| Income tax expense | 1 | 4 |
| Net loss | $ (73,454) | $ (17,807) |
| Net loss per share, basic and diluted | $ (4.89) | $ (1.47) |
| Weighted average shares outstanding, basic and diluted | 15,024,726 | 12,143,108 |

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

| | Three Months Ended September 30, | |
|---|---|---|
| | **2023** | **2022** |
| Revenues | $ — | $ 80 |
| Operating expenses: | | |
| Research and development | 10,547 | 5,820 |
| Selling, general and administrative | 12,774 | 8,147 |
| Total operating expenses | 23,321 | 13,967 |
| Loss from operations | (23,321) | (13,887) |
| Interest expense, net | (2,592) | (2,773) |
| Gain on warrant liabilities | 4,568 | 2,044 |
| Other expense, net | (52,108) | (100) |
| Loss before income taxes | (73,453) | (14,716) |
| Income tax expense | 1 | 158 |
| Loss from continuing operations | (73,454) | (14,874) |
| Gain from discontinued operations | — | 9,760 |
| Net loss | $ (73,454) | $ (5,114) |
| Net loss per share from continuing operations, basic and diluted | $ (4.89) | $ (1.99) |
| Net gain per share from discontinued operations, basic and diluted | $ — | $ 1.30 |
| Net loss per share, basic and diluted | $ (4.89) | $ (0.68) |
| Weighted average shares outstanding, basic and diluted | 15,024,726 | 7,478,150 |

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

| | September 30, 2023 | December 31, 2022 (1) |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash, cash equivalents and restricted cash | $ 12,569 | $ 30,486 |
| Income tax receivable | 818 | 828 |
| Prepaid expenses and other current assets | 3,351 | 4,199 |
| Current assets of disposal group held for sale | 2,509 | 2,603 |
| Total current assets | 19,247 | 38,116 |
| Property and equipment, net | 1,236 | 1,654 |
| Right-of-use assets | 1,834 | 1,482 |
| Other assets | 6,314 | 6,201 |
| Goodwill | 6,072 | 6,072 |
| Total assets | $ 34,703 | $ 53,525 |
| **Liabilities and Stockholders' Deficit** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,905 | $ 3,606 |
| Accrued expenses and other current liabilities | 24,314 | 16,161 |
| Warrant liabilities | 41,325 | 3,538 |
| Total current liabilities | 69,544 | 23,305 |
| Convertible notes, net | 80,378 | 127,811 |
| Other long-term liabilities | 3,567 | 4,696 |
| Total liabilities | $ 153,489 | $ 155,812 |
| Stockholders' deficit: | | |
| Common stock | 21 | 8 |
| Additional paid-in capital | 835,817 | 743,626 |
| Accumulated deficit | (935,545) | (826,843) |
| Treasury stock | (19,079) | (19,078) |
| Total stockholders' deficit | (118,786) | (102,287) |
| Total liabilities and stockholders' deficit | $ 34,703 | $ 53,525 |

(1) The condensed consolidated balance sheet data as of December 31, 2022 has been derived from the audited consolidated financial statements

Exhibit 99.2


BIORA™
Therapeutics
CORPORATE
PRESENTATION
November 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.

# *Our mission is to reimagine therapeutic delivery*

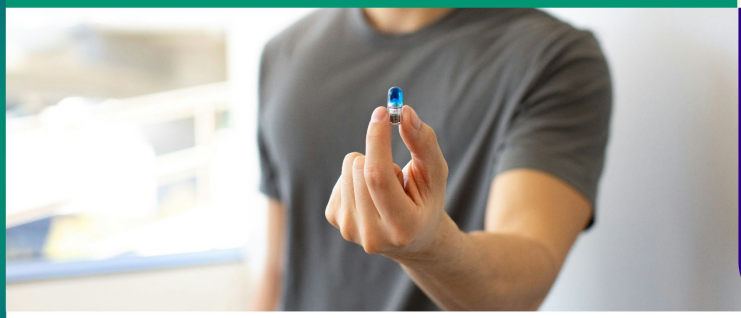
Innovating smart capsule technologies to deliver the right dose to the right place, safely

BIORA™ Therapeutics

## 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

# THERAPEUTIC PIPELINE

| | PROGRAM | INDICATION | DESIGN/FEASIBILITY | PRECLINICAL | CLINICAL |
|---|---|---|---|---|---|
| NAVICAP™ TARGETED DELIVERY | **NaviCap™** Targeted Oral Delivery Platform | -- | | | |
| | **BT-600** NaviCap + tofacitinib* | UC | | | |
| | **BT-001** NaviCap + adalimumab variant* | UC | | | |
| BIOJET™ SYSTEMIC ORAL DELIVERY | **BioJet™** Systemic Oral Delivery Platform | -- | | | |
| | **Ionis Collaboration** BioJet + antisense therapy | Undisclosed | | | |
| | **Large Pharma 1 Collaboration** BioJet + undisclosed drug | Undisclosed | | | |
| | **Large Pharma 2 Collaboration** BioJet + undisclosed drug | Undisclosed | | | |
| | **PLANNED FOR 2024** | | | | |
| | **BT-200** BioJet + GLP-1 receptor agonist* | Demonstration Program | | | |
| | **BT-002** BioJet + adalimumab variant* | Demonstration Program | | | |

*Biora's own molecules

IND FILED

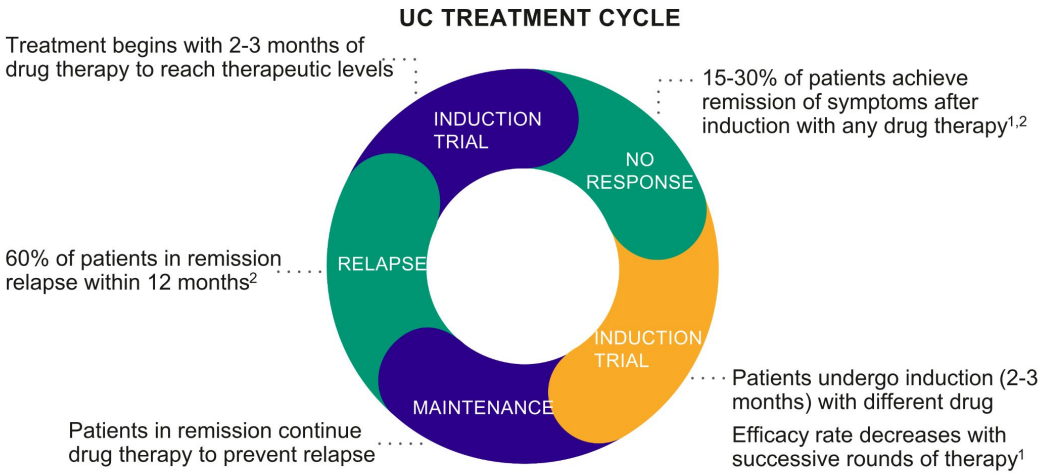
BIORA Therapeutics


NAVIcap™
TARGETED ORAL DELIVERY

# ULCERATIVE COLITIS: THE TREATMENT GAP

## *Despite therapeutics targeting different pathways, few patients achieve long-term remission*

**UC TREATMENT CYCLE**





1. Alsoud D, Verstockt B, Fiocchi C, Vermeire S. Breaking the therapeutic ceiling in drug development in ulcerative colitis. Lancet Gastroenterol Hepatol. 2021;6(7):589-595.
2. Hirten RP, Sands BE. New Therapeutics for Ulcerative Colitis. Annu Rev Med. 2021;72:199-213.
3. Shivashankar R, Tremaine WJ, Harmsen WS, Loftus EV Jr. Incidence and Prevalence of Crohn's Disease and Ulcerative Colitis in Olmsted County, Minnesota From 1970 Through 2010. Clin Gastroenterol Hepatol. 2017;15(6):857-863.


**ABOUT ULCERATIVE COLITIS**

- Inflammatory bowel disease (IBD) includes Crohn's disease and ulcerative colitis (UC)
- UC causes inflammation and damage to the large intestine
- About 1 million people in the U.S. are affected with UC, and ~40,000 cases are diagnosed each year[3]

UNMET NEED IN ULCERATIVE COLITIS

# *Targeted delivery could enable rapid induction and improve patient response*

| THERAPEUTIC CHALLENGES | POTENTIAL SOLUTION |
|---|---|
| 1 Difficulty of achieving sufficient drug levels at site of disease | Targeted delivery is designed to increase drug levels at the site of disease, which is correlated with improved outcomes[1] |
| 2 Systemic toxicity issues may limit daily dosage of UC drugs | Reduced systemic uptake is designed to reduce toxicity and adverse events |
| 3 Combination therapy is limited by toxicity | Reduced toxicity could enable combination therapy[2] |

Development in partnership with: CROHN'S & COLITIS FOUNDATION

1. Verstockt B, Alsoud D, van Oostrom J, et al. Tofacitinib tissue exposure correlates with endoscopic outcome. Poster presented at: *17th Congress of the European Crohn's and Colitis Organisation* (ECCO). February 18, 2022. virtual.
2. van Oostrom J, Verstockt B, Hanzel J, et al. Pharmacokinetic stratification of cytokine profiles during anti-TNF induction treatment in moderate-to-severe ulcerative colitis. Poster presented at: *17th Congress of the European Crohn's and Colitis Organisation* (ECCO). February 18, 2022. virtual.

# RESEARCH DATA SUPPORTS TARGETED APPROACH

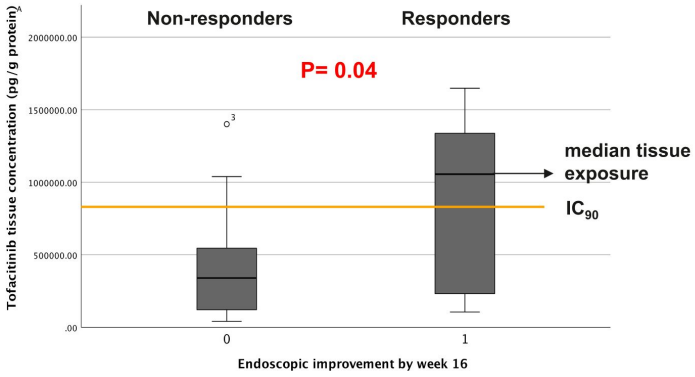
## *Tissue drug concentration correlates with endoscopic outcomes in UC*

30 consecutive UC patients with active endoscopic disease initiated treatment with tofacitinib and prospectively monitored

### RESULTS

- Tofacitinib tissue exposure at the end of induction was associated with endoscopic improvement by week 16 (p=0.04)
- In responders (n=14), median tofacitinib tissue exposure exceeded $IC_{90}$

### TOFACITINIB TISSUE EXPOSURE EXCEEDED $IC_{90}$ IN RESPONDERS




Research presented at ECCO 2022 and DDW 2022 in collaboration with:

KU LEUVEN · IBD Leuven · Amsterdam UMC University Medical Centers

Verstockt B, Alsoud D, van Oostrom J, et al. Tofacitinib tissue exposure correlates with endoscopic outcome. Poster presented at: *17th Congress of the European Crohn's and Colitis Organisation* (ECCO), February 18, 2022, virtual.

BIORA Therapeutics

# NAVICAP™ TARGETED DRUG DELIVERY PLATFORM

## *Needle-free, oral drug delivery to the colon*

### ORAL ADMINISTRATION

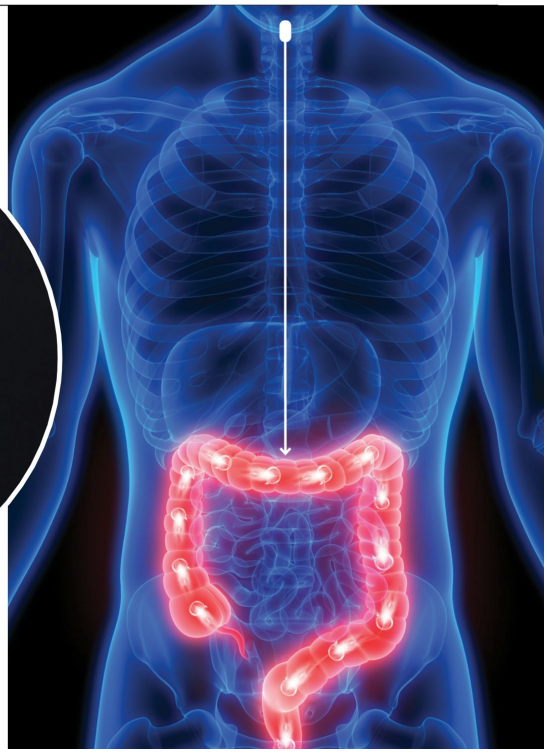
Convenient oral capsule the size of a fish-oil pill

### AUTONOMOUS LOCATION

GITrac™ autolocation technology enables targeted delivery to the colon, regardless of fasted or fed state[1]

### TARGETED DRUG DELIVERY

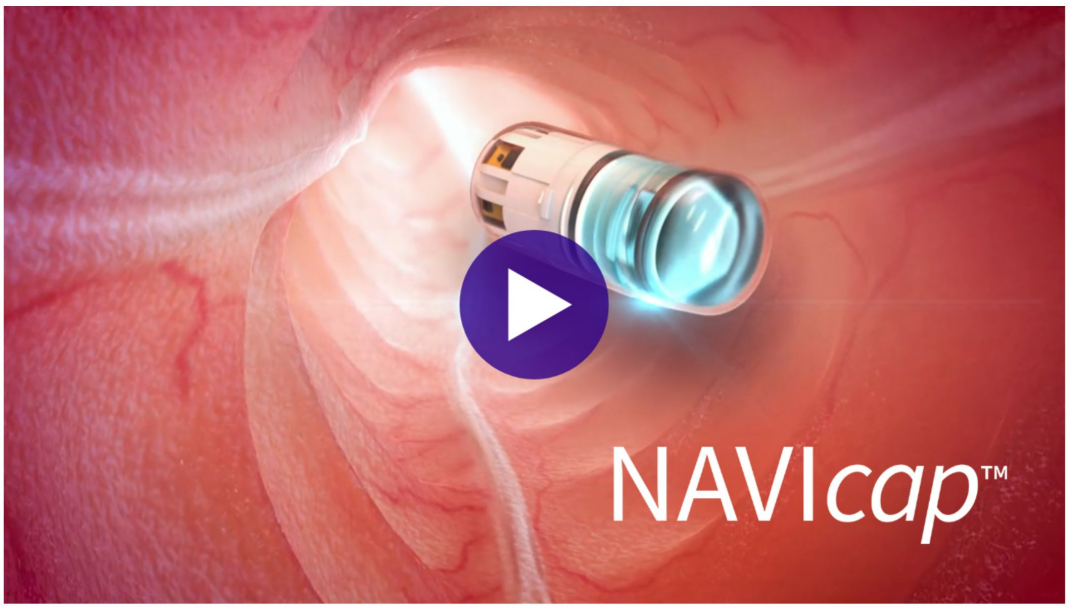
Method designed to coat the length of the colon with liquid formulation, minimizing systemic uptake



1. Lee SN, Razag G, Stork C, et al. Potential effects of food on a novel Drug Delivery System (DDS) to deliver therapeutic compound into the colon. Poster presented at: Crohn's & Colitis Congress, January 19-21, 2023, Denver, CO.

# NAVICAP™ TARGETED DRUG DELIVERY PLATFORM

## *Autonomous location and delivery to the colon*




SCAN ME

https://biora.wistia.com/medias/r65935rbqs

DEVICE FUNCTION STUDIES

# *Four successful studies in humans showing the NaviCap™ device was well tolerated and performed as intended*

NAVIcap™

| Q4 2022 | Q4 2022 | Q1 2023 | Q2 2023 |
|---|---|---|---|
| **PM-601 Device Function Study in Healthy Volunteers – Fasted State** | **PM-602 Device Function Study in Patients with Active UC** | **PM-611 Device Function Study in Healthy Volunteers – Fasted & Fed** | **BT-603 Device Function Study in Healthy Volunteers – Fasted State** |
| • 83% of devices accurately identified entry into the colon (10/12)[1]<br>• Achieved distribution of payload across the entire colon[1]<br>• No early deployment before colon detection[1] | • 100% of devices accurately identified entry into the colon, triggered release of a liquid payload, and achieved distribution across the entire colon (7/7)[3] | • 100% of analyzed devices successfully identified entry to the colon and activated gas cells for delivery in all fasted/fed schedules (39/39)[2]<br>• 97.4% of analyzed devices activated the payload release function (38/39)[2] | • 94% of devices accurately identified entry into the colon, triggered release of a liquid payload, and achieved distribution across the entire colon (15/16)[4] |
| **HEALTHY VOLUNTEERS** ✓ | **ACTIVE UC PATIENTS** ✓ | **FUNCTION WITH/WITHOUT FOOD** ✓ | **PHASE 1-READY DEVICE** ✓ |

1. Lee SN, Sandefer E, Doll W, et al. A Scintigraphic Study to Evaluate the Safety, Tolerability, and Functionality of a Drug Delivery System (DDS) Device in Healthy Volunteers in Fasted State. Poster presented at: *American College of Gastroenterology Annual Scientific Meeting*, October 21-26, 2022, Charlotte, NC.
2. Lee SN, Razag G, Stork C, et al. Potential effects of food on a novel Drug Delivery System (DDS) to deliver therapeutic compound into the colon. Poster presented at: Crohn's & Colitis Congress, January 19-21, 2023, Denver, CO.
3. Martin K, Lee SN, Stork C, et al. A Scintigraphic Study to Evaluate the Localization and Delivery Function of a Drug Delivery System (DDS) Device in Patients with Active Ulcerative Colitis (UC) in Fasted State. Poster presented at: *American College of Gastroenterology Annual Scientific Meeting*, October 21-26, 2022, Charlotte, NC.
4. Biora Therapeutics internal data

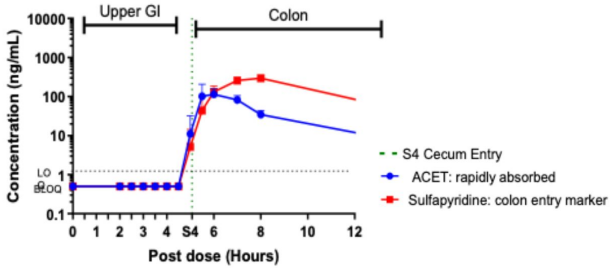
BIORA Therapeutics

# *Demonstrated accurate localization and delivery to colon*

NAVIcap™

## ACCURATE DELIVERY TO COLON IN CANINES

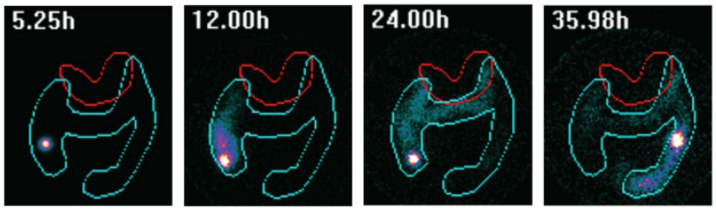
Pharmacokinetic data from two marker drugs administered in canine model




- Successful delivery to colon via device
- No early release of drug
- No drug absorption in upper GI tract

## ACCURATE LOCALIZATION AND DELIVERY TO HUMAN COLON

Clinical device validation for localization and delivery function using scintigraphic imaging in patients with active ulcerative colitis



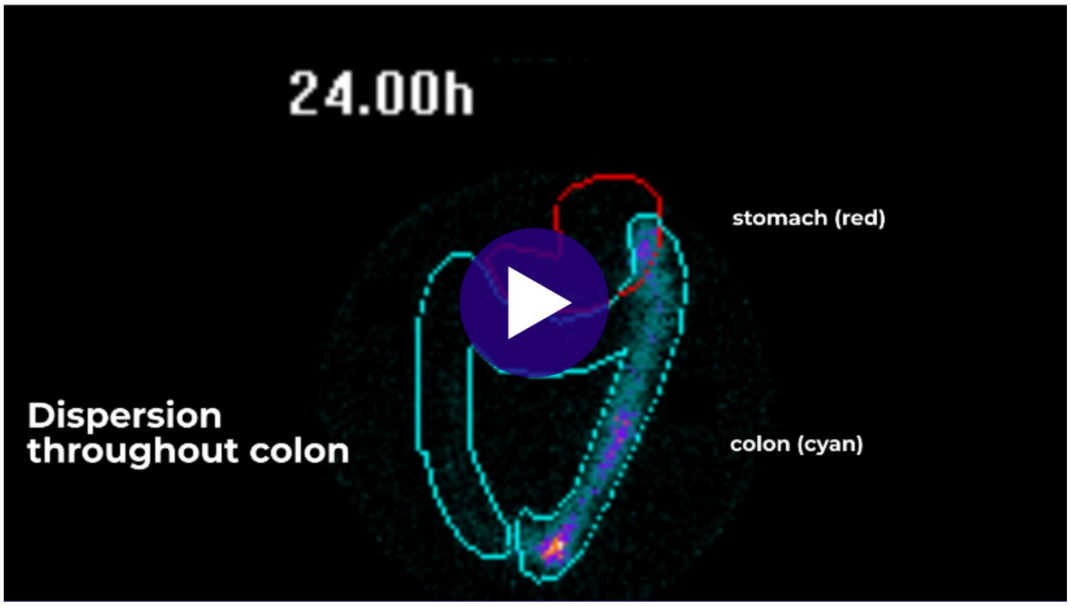

- Achieved distribution across the entire colon

Biora Therapeutics internal data

BIORA Therapeutics

DEVICE FUNCTION STUDIES

# *Scintigraphic imaging of NaviCap delivery in healthy subject*




**Despite variability in the GI environment among subjects, the NaviCap device has been shown to perform as designed across a range of expected differences in motility.**

SCAN ME

https://www.bioratherapeutics.com/pipeline/targeted-therapeutics#scintigraphy

BT-600 PRECLINICAL STUDY RESULTS

# *Reduced systemic uptake, better distribution and tissue coverage*

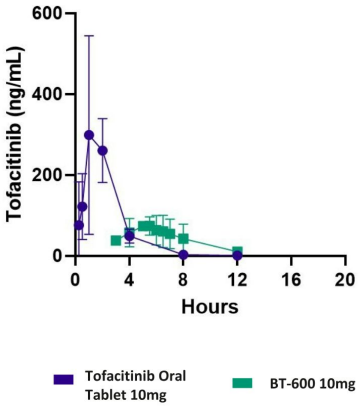
NAVIcap™

Non-GLP study; 7 days/QD in canine model compared BT-600 (tofacitinib 10mg liquid formulation delivered via device) vs. standard oral tablet (tofacitinib 10mg)

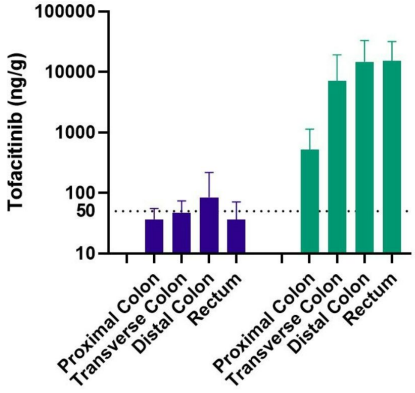
## RESULTS

- Reduced drug levels in blood vs. standard oral tablet
- Tissue drug levels at average ~100X higher along the length of the colon vs. standard oral tablet
- Data suggest that a dose lower than the standard 10mg tofacitinib may provide increased tissue levels while reducing systemic exposure

### PLASMA LEVEL CMAX ~5X LOWER




### COLON TISSUE COVERAGE ~100X HIGHER

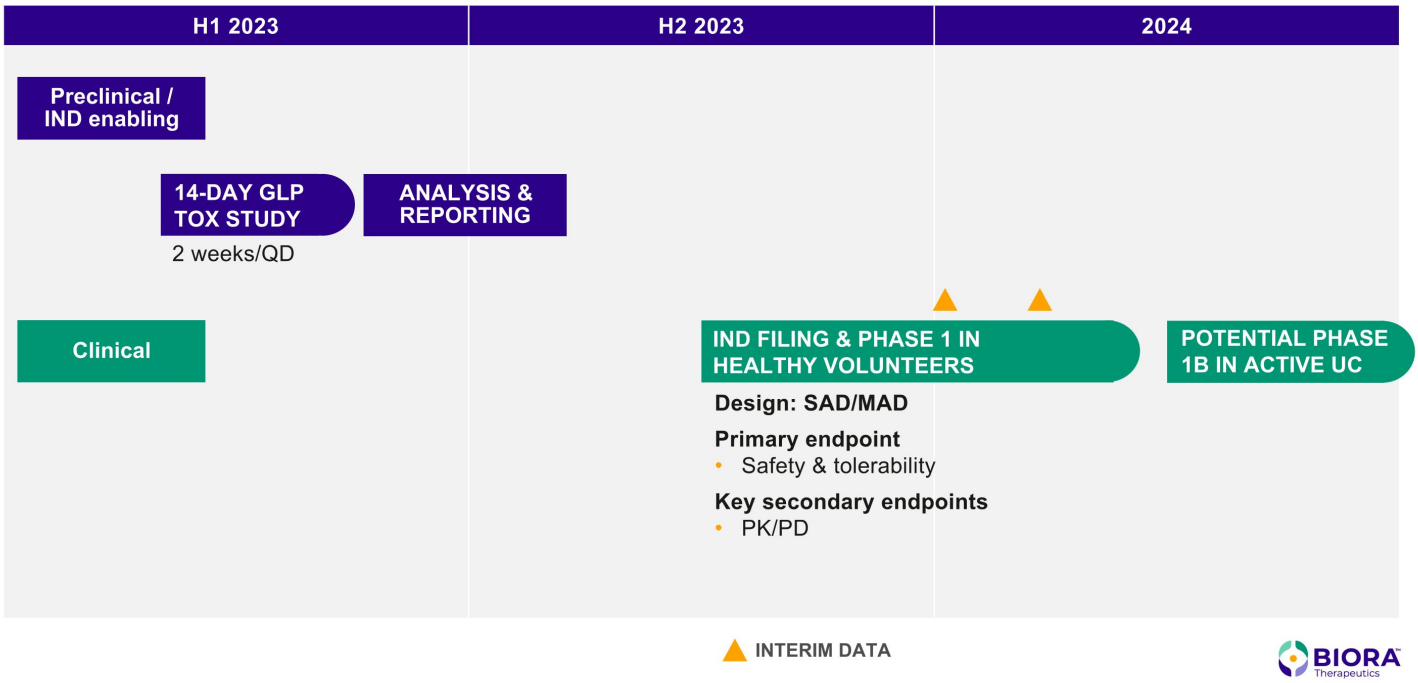



Biora Therapeutics internal data

BIORA Therapeutics

BT-600 (NAVICAP™ + TOFACITINIB)

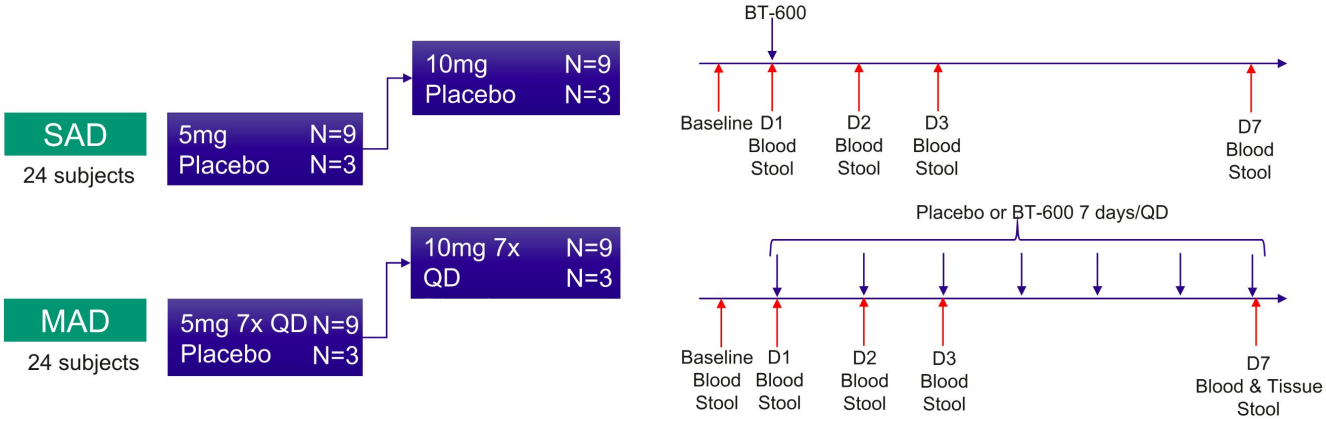
# *Clinical Development Plan*



PHASE 1: SINGLE AND MULTIPLE ASCENDING DOSE STUDIES

NAVIcap™

# *Evaluate safety, tolerability, pharmacokinetics and pharmacodynamics of BT-600 in healthy volunteers*

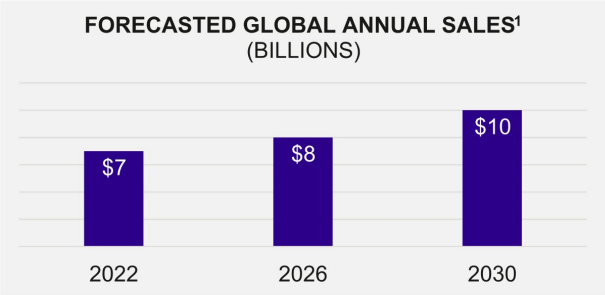


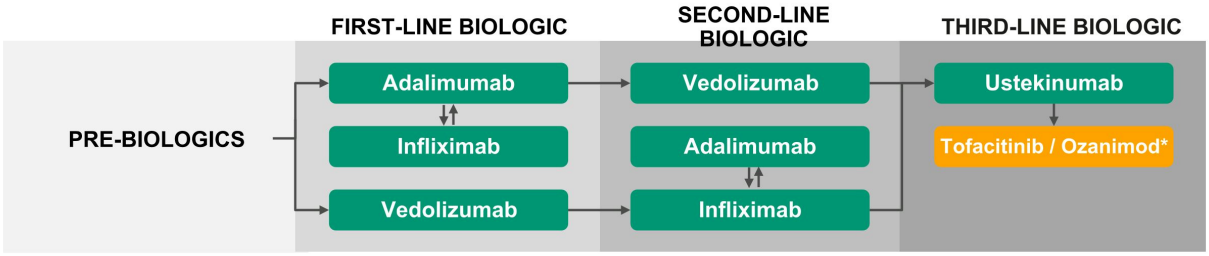

| | |
|---|---|
| **PATIENT POPULATION** | Normal healthy volunteers<br>Total of 48 subjects (24 SAD and 24 MAD subjects) |
| **STUDY DESIGN** | Randomized, double-blind (participant and site), placebo-controlled study to evaluate the safety, tolerability, and PK/PD of SAD and MAD doses of BT-600 in healthy subjects |
| **OBJECTIVES** | Demonstrate safety and tolerability of BT-600, assess PK and PD effects of tofacitinib released from BT-600 over 8 days in NHV in blood and in tissue |

BIORA Therapeutics

# *Potential for market-leading efficacy in tofacitinib creates sizeable opportunity*

- Global annual sales forecast for ulcerative colitis therapeutics:
  - $7 billion in 2022[1]
- >10 FDA-approved drugs for UC




1. Source: Evaluate Pharma; GlobalData

*Non-biologic drug therapies

# BIOjet™

SYSTEMIC ORAL DELIVERY

UNMET NEED

# *Needles are associated with poor disease management*

**38%** of people with diabetes discontinue injectable medications due to injection concerns[1,2]

**42%** of patients fail to maintain diabetes treatment due to injection concerns when using an injectable GLP-1 agonist[2]

**71%** higher discontinuation rate for diabetes patients initiating treatment with an injectable GLP-1 agonist vs. those starting oral therapy[2]


1. Palanca A, Ampudia-Blasco FJ, Calderón JM, et al. Real-World Evaluation of GLP-1 Receptor Agonist Therapy Persistence, Adherence and Therapeutic Inertia Among Obese Adults with Type 2 Diabetes. *Diabetes Ther*. 2023;14(4):723-736. doi:10.1007/s13300-023-01382-9
2. Spain CV, Wright JJ, Hahn RM, Wivel A, Martin AA. Self-reported Barriers to Adherence and Persistence to Treatment With Injectable Medications for Type 2 Diabetes. *Clin Ther*. 2016;38(7):1653-1664.e1. doi:10.1016/j.clinthera.2016.05.009

BIOJET™ SYSTEMIC DRUG DELIVERY PLATFORM

# *Needle-free, oral delivery to small intestine*

## ORAL CAPSULE

- Convenient oral capsule the size of a multivitamin for ease of swallowing

## PRECISE DELIVERY

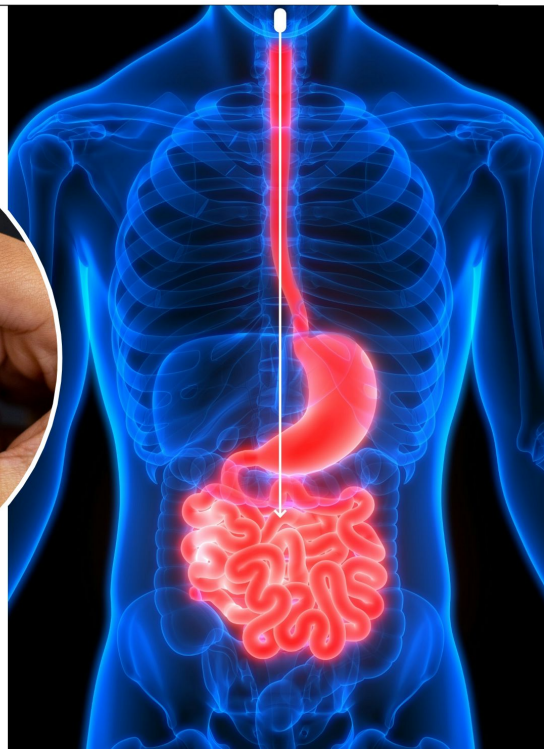
- Enteric trigger for precise timing of drug delivery to the small intestine

## NEEDLE-FREE ADMINISTRATION

- Liquid jet injection to the small intestine to maximize systemic uptake

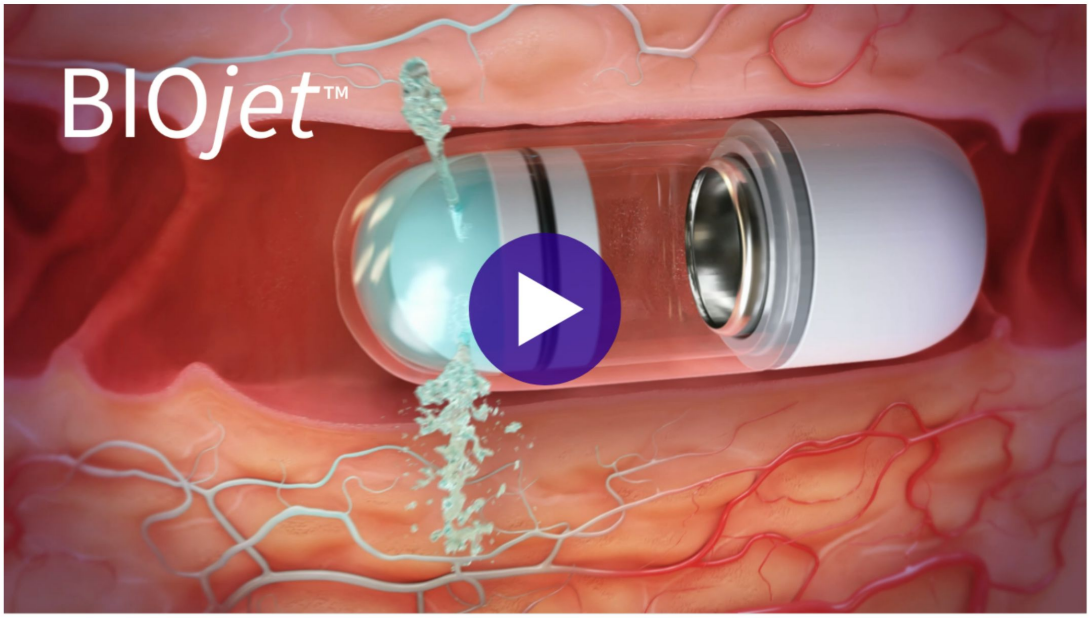
## RESEARCH COLLABORATIONS

- IONIS
- Large Pharma 1
- Large Pharma 2



# BIOJET™ SYSTEMIC DRUG DELIVERY PLATFORM

## *Liquid jet delivery to the small intestine*




SCAN ME

https://biora.wistia.com/medias/embr15eh3a

PRECLINICAL RESULTS

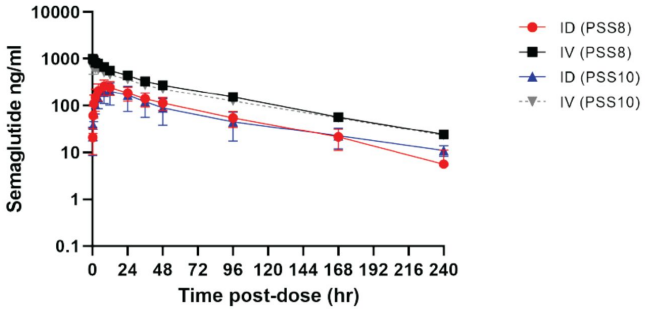
# *Excellent systemic uptake for orally delivered large molecules demonstrated in animals*

Preclinical studies in swine model with endoscopically placed and triggered next-gen device compared to IV administration of GLP-1 agonist (semaglutide)

## RESULTS

- Average oral bioavailability of 37% ± 15% (N=7; CV:40%), ranging up to 60%[1]
- A repeat study (PSS10) showed similar results with average oral bioavailability of 37% (N=5; CV:57%)[1]
- All dosed animals showed detectable drug levels up to ten days post-dosing[1]
- No significant clinical signs were observed in any of the animals for up to 10 days[1]

### SYSTEMIC EXPOSURE TO SEMAGLUTIDE FOLLOWING INTRADUODENAL ADMINISTRATION OF THE BIOJET DEVICE vs. IV CONTROLS




1. Lee SN, Stork C, Valenzuela R, et al. Evaluation of the pharmacokinetics of glucagon-like-peptide-1 (GLP-1) receptor agonist delivered through the BioJet™ oral biotherapeutic delivery platform in a porcine model. Poster presented at: *American Diabetes Association 83rd Scientific Sessions*, June 23-26, 2023, San Diego, California.

PRECLINICAL RESULTS

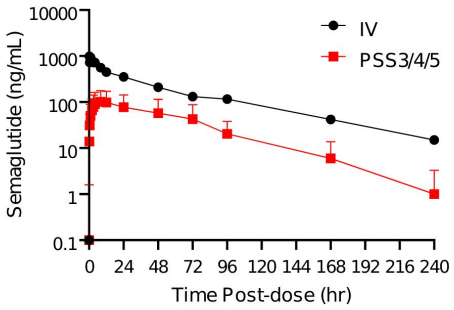
# *UPDATE: Recent experiments with next-generation autonomous device confirm consistent performance*

Preclinical studies in swine model with endoscopically placed and autonomously triggered next-gen device compared to IV administration of GLP-1 agonist (semaglutide)

## RESULTS

- 96% of animals (22/23) showed semaglutide in systemic circulation at clinically relevant levels[1]
- Oral bioavailability for animals with functional devices averaged 20.5% ± 15.3% (N=22; CV: 74.6%), ranging up to 59%[1]
- No significant clinical signs were observed in any of the animals before or after dosing for up to 10 days[1]

**SYSTEMIC EXPOSURE TO SEMAGLUTIDE FOLLOWING AUTONOMOUS TRIGGERING OF THE BIOJET DEVICE vs. IV CONTROLS**




1. Lee SN, Stork C, Valenzuela R, et al. Evaluation of the pharmacokinetics of glucagon-like-peptide-1 (GLP-1) receptor agonist delivered through the BioJet™ oral biotherapeutic delivery platform in a porcine model. Poster presented at: 59th Annual Meeting of the European Association for the Study of Diabetes. October 2-6, 2023. Hamburg, Germany.

PRECLINICAL RESULTS

# *Development pathway for the BioJet™ platform*

BIOjet™

## Q3/Q4 2022

**Preclinical Models to Assess Performance of BioJet 1**

- ≥83% autonomous deployment accuracy of BioJet 1 device in canine model[1]
- 25% bioavailability average in swine with drug detected in blood (variant of adalimumab)[2]

**DEVELOPED ANIMAL MODELS** ✓

## Q1 2023

**Delivery of Adalimumab & Semaglutide with Remotely Triggered BioJet 2**

- Average bioavailability in swine:
  - 51% for adalimumab[3]
  - 37% for semaglutide[4]
- Performance achieved in repeat animal studies

**>2X BIOAVAILABILITY TARGET** ✓

## Q2/Q3 2023

**Improvement of Autonomous Device Function for BioJet 2**

- Achieved target average bioavailability of ≥15% with semaglutide[3]
- Achieved device function targets[3]
- Confirmed with repeat animal studies[3]

**PERFORMANCE TARGETS ACHIEVED** ✓

## Q3/Q4 2023

**Preclinical Testing of Pharma Collaborators' Molecules with BioJet 2**

- Completed preliminary study with Ionis antisense oligonucleotides
- Testing undisclosed molecule with Large Pharma 1 collaborator
- Anticipate additional collaborator developments

**ONGOING STUDIES**

1. Lee SN, Stork C, Smith J, et al. Development of ex-vivo and in-vivo models to assess the performance of an oral biotherapeutic delivery system (OBDS) device. Poster presented at: *American College of Gastroenterology Annual Scientific Meeting*, October 21-26, 2022, Charlotte, North Carolina.
2. Lee SN, Stork C, Smith J, et al. Evaluation of the pharmacokinetics of PGN-OB1 following oral administration of an oral biotherapeutics delivery system (OBDS) in Yucatan swine. Poster presented at: *American College of Gastroenterology Annual Scientific Meeting*, October 21-26, 2022, Charlotte, North Carolina.
3. Lee SN, Stork C, Valenzuela R, et al. Evaluation of the pharmacokinetics of glucagon-like-peptide-1 (GLP-1) receptor agonist delivered through the BioJet™ oral biotherapeutic delivery platform in a porcine model. Poster presented at: 59th Annual Meeting of the European Association for the Study of Diabetes, October 2-6, 2023, Hamburg, Germany.
4. Lee SN, Stork C, Valenzuela R, et al. Evaluation of the pharmacokinetics of glucagon-like-peptide-1 (GLP-1) receptor agonist delivered through the BioJet™ oral biotherapeutic delivery platform in a porcine model. Poster presented at: *American Diabetes Association 83rd Scientific Sessions*, June 23-26, 2023, San Diego, California.

BIORA Therapeutics

# *Our mission is to reimagine therapeutic delivery*

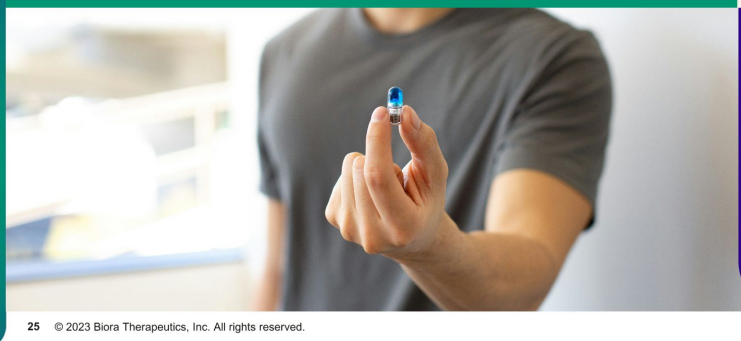
Innovating smart capsule technologies to deliver the right dose to the right place, safely

BIORA™ Therapeutics

## NAVIcap™

TARGETED ORAL DELIVERY

- IND application submitted to FDA
- Planning to initiate phase 1 trial late 2023



## BIOjet™

SYSTEMIC ORAL DELIVERY

- Achieved performance targets with BioJet 2 device
- Performing animal studies with collaborators' molecules

# APPENDIX

# TARGETED THERAPEUTICS PUBLICATIONS

*bioratherapeutics.com/publications*

NAVIcap™

1. **Development of targeted therapeutic antibodies for the treatment of inflammatory bowel disease: A proof of concept**. Poster presented at DDW 2019.
2. **A comparison of systemic versus targeted anti-TNFα antibody in treatment of colitis induced by adoptive transfer of CD44-/CD62L+ T-cells into RAG2-/- mice recipients**. Presented at DDW 2019.
3. **Targeted delivery of soluble tofacitinib citrate to the site of inflammation to improve efficacy and safety**. Poster presented at DDW 2021.
4. **Development of a novel drug delivery system for treatment of Ulcerative Colitis**. Poster resented at DDW 2021.
5. **Development of a Novel Drug Delivery System to Deliver Drugs Directly to the Colonic Mucosa, Resulting in Improved Efficacy and Reduced Systemic Exposure for the Treatment of Ulcerative Colitis**. *Crohn's & Colitis 360.* 2021, 3, 1–5.
6. **Tofacitinib tissue exposure correlates with endoscopic outcome**. Oral presentation at DDW 2022 and BWG. Poster presented at ECCO 2022.
7. **Pharmacokinetic stratification of cytokine profiles during anti-TNF induction treatment in moderate-to-severe UC**. Poster presented at ECCO 2022 and DDW 2022.
8. **Pilot study to assess pharmacokinetic and pharmacodynamic markers following enema-dosing with adalimumab in patients with active ulcerative colitis.** Poster presented at ACG 2022.
9. **A scintigraphic study to evaluate the safety, tolerability, and functionality of a Drug Delivery System (DDS) device in healthy volunteers in fasted state.** Poster presented at ACG 2022.
10. **A scintigraphic study to evaluate the localization and delivery function of a Drug Delivery System (DDS) device in patients with active ulcerative colitis (UC) in fasted state.** Poster presented at ACG 2022.
11. **Development of a novel Drug Delivery System (DDS) to deliver drugs directly to the colonic mucosa to improve efficacy and reduce systemic exposure for the treatment of ulcerative colitis (UC)**. Poster presented at Crohn's & Colitis Congress 2023.
12. **Potential effects of food on a novel Drug Delivery System (DDS) to deliver therapeutic compound into the colon.** Poster presented at Crohn's & Colitis Congress 2023.

BIORA Therapeutics

1. **Development of *ex-vivo* and *in-vivo* models to assess the performance of an oral biotherapeutic delivery system (OBDS) capsule**. Poster presented at the *Controlled Release Society Annual Meeting*, July 13-14, 2022 and at the *American College of Gastroenterology Annual Scientific Meeting*, October 21-26, 2022.
2. **Assessing the performance of an oral biotherapeutic delivery system (OBDS) using intra-duodenal endoscopy delivery in *Yucatan* minipigs**. Poster presented at the *Controlled Release Society Annual Meeting*, July 13-14, 2022 and at the *American College of Gastroenterology Annual Scientific Meeting*, October 21-26, 2022.
3. **Development of preclinical models to assess the performance of the oral biotherapeutic delivery system (OBDS) capsule.** Poster presented at the *Parenteral Drug Association Universe of Pre-Filled Syringes and Injection Devices Conference*, October 18-19, 2022.
4. **Evaluation of the pharmacokinetics of glucagon-like-peptide-1 (GLP-1) receptor agonist delivered through the BioJet™ oral biotherapeutic delivery platform in a porcine model.** Poster presented at the *American Diabetes Association 83rd Scientific Sessions*, June 23-26, 2023.
5. **Evaluation of the pharmacokinetics of glucagon-like-peptide-1 (GLP-1) receptor agonist delivered through the BioJet™ oral biotherapeutic delivery platform in a porcine model.** Poster presented at the *59th Annual Meeting of the European Association for the Study of Diabetes*, October 2-6, 2023.

INTELLECTUAL PROPERTY PORTFOLIO

# *Diverse patent portfolio with 73 distinct patent families*

Approximately 190 granted patents and 136 pending applications in major countries and regions around the world

## NaviCap™ Platform

***30 patent families covering:***

- Device designs, materials, components, and manufacturing
- Localization in the GI tract
- Dosing and PK/PD profiles
- Liquid drug formulations
- IBD-specific drug combinations

## BioJet™ Platform

***7 patent families covering:***

- Device designs, materials, components, and manufacturing
- GI-specific trigger compositions
- Dosing and PK/PD profiles
- Jet parameters
- GI delivery by drug class and drug size

## Other Device & Diagnostic IP

***36 patent families covering:***

- Ingestible devices for GI sampling and diagnostics
- GI sample preservation
- GI analyte detection & quantification
- Diagnostic biomarkers & assays


BIORA™
Therapeutics