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): July 1, 2024

Biora Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39334**	**27-3950390**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4330 La Jolla Village Drive, Suite 300 **San Diego, California**	**92122**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (833) 727-2841

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	BIOR	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure

On July 1, 2024, Biora Therapeutics, Inc. (the "Company") issued a press release announcing positive topline results from its clinical trial of BT-600. The Company will hold a conference call with members of its Clinical Advisory Board on July 17, 2024 to provide additional details regarding the data results.

Also on July 1, 2024, the Company made available an updated corporate presentation on the Company's website.

Copies of the press release and the corporate presentation are furnished as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K and are incorporated by reference herein. The exhibits furnished under Item 7.01 of this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Item 8.01 Other Events

On July 1, 2024, the Company announced the following positive topline results from its clinical trial of BT-600, an orally-administered drug-device combination in development for the potential treatment of patients with ulcerative colitis that leverages the Company's ingestible NaviCap™ device to deliver a proprietary liquid formulation of tofacitinib directly to the colon:

Summary of Key BT-600 Phase 1 Trial Results

Results from the Phase 1 clinical trial demonstrate a pharmacokinetic profile consistent with drug delivery and absorption in the colon for both single and multiple ascending dose ("SAD/MAD") cohorts.

- First evidence of systemic absorption of tofacitinib was at six hours, consistent with colonic (vs. upper gastrointestinal) delivery. Maximal levels in the trial occurred at eight to ten hours vs. 30 minutes for conventional oral tofacitinib in other trials.
- Maximal systemic drug exposure was three to four times lower than that seen with conventional oral tofacitinib in other trials, demonstrating the NaviCap platform's ability to deliver locally to the colon and limit systemic drug exposure.

The distribution of colon tissue exposure suggests that pan-colonic delivery of tofacitinib was achieved.

- Sites in the distal colon were biopsied, following delivery of tofacitinib in the proximal colon, for evidence of tissue drug exposure.
- Biopsy results provided evidence of drug exposure extending to the distal colon, at common sites of disease.
- Post-retrieval device analysis further confirmed that NaviCap devices accurately delivered drug in the colon, with 100% of devices (SAD) and 98% of devices (MAD) detecting colon entry.

NaviCap devices were well tolerated by participants in both the SAD and MAD cohorts.

Phase 1 Clinical Trial Design

The objectives of this Phase 1 randomized, double-blind, placebo-controlled, SAD/MAD clinical trial were to evaluate the safety and pharmacokinetics of BT-600 when administered orally in healthy adult participants. The trial, which was conducted in the United States, consisted of two parts: The first part was comprised of 24 participants receiving a single ascending dose of BT-600 with tofacitinib at 5 mg or 10 mg doses or placebo. The

second part was comprised of 24 participants receiving multiple ascending-doses of BT-600 with tofacitinib at 5 mg or 10 mg doses or placebo daily for 7 days. The trial is listed at clinicaltrials.gov (NCT06275464). The "other trials" referred to in the summary of the Phase 1 clinical trial results above were conducted at different times, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made and no head-to-head clinical trials have been conducted.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits*.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated July 1, 2024
99.2	Corporate Presentation (July 2024)
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Biora Therapeutics, Inc.

Date: July 1, 2024

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

Biora Therapeutics Announces Positive Clinical Trial Results for BT-600

Drug-device combination leverages Biora's NaviCap™ platform to deliver tofacitinib directly to colonic tissue as a potential treatment for ulcerative colitis

BT-600 was well tolerated and met all trial objectives, demonstrating the NaviCap platform's ability to deliver therapeutics directly to the colon

Drug absorption in colonic tissue extended to distal colon, suggesting pan-colonic delivery

Company to host virtual event with key opinion leaders on July 17

SAN DIEGO, July 1, 2024 – Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company reimagining therapeutic delivery, today shared positive topline results from its clinical trial of BT-600, an orally administered drug-device combination in development for the potential treatment of patients with ulcerative colitis (UC). BT-600 leverages Biora's ingestible NaviCap™ device to deliver a proprietary liquid formulation of tofacitinib directly to the colon. Results from this Phase 1 clinical trial involving 48 healthy volunteers met all trial objectives, with demonstrated drug absorption in colonic tissue that extended to the distal colon, suggesting pan-colonic delivery. Daily dosing with BT-600 was well tolerated by all participants.

"Successful completion of our Phase 1 clinical trial is an important milestone for Biora," said Ariella Kelman, MD, Chief Medical Officer of Biora Therapeutics. "All study objectives were met, and we confirmed that the NaviCap platform can deliver tofacitinib topically to the colon, with lower peak systemic exposure than with conventional oral delivery. These results support our plan to advance BT-600 into our Phase 1b clinical trial in patients with UC."

"We are extremely encouraged by the results from this trial, which demonstrate the NaviCap platform's ability to deliver drug to the location of disease, where it's needed," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "Our anatomically targeted approach has the potential to improve the efficacy of JAK inhibitors and other drug classes. We envision a portfolio of NaviCap-delivered therapeutics unlocking new treatment potential for patients with GI diseases."

"I would like to thank the study participants, clinicians, and our Biora team for conducting such a well-executed trial," continued Mr. Mohanty. "Our team continues to execute at a high level as we meet our NaviCap platform milestones, while the BioJet™ platform is also progressing well and is on track to meet our previously stated goals."

Summary of Key BT-600 Phase 1 Trial Results

Results from the Phase 1 clinical trial demonstrate a pharmacokinetic (PK) profile consistent with drug delivery and absorption in the colon for both single and multiple ascending dose (SAD/MAD) cohorts.

- First evidence of systemic absorption of tofacitinib was at six hours, consistent with colonic (vs. upper gastrointestinal) delivery. Maximal levels in the trial occurred at eight to ten hours vs. 30 minutes for conventional oral tofacitinib in other trials.

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NaviCap devices were well tolerated by participants in both the SAD and MAD cohorts.

Virtual Event Details

The company will host a KOL event with members of management and its Clinical Advisory Board to provide additional details regarding the Phase 1 trial and plans for the next phase of clinical development.

Date: Wednesday, July 17, 2024
Time: 2:00 PM Eastern / 11:00 AM Pacific time
Live Webcast: https://lifescievents.com/event/biora/

Attendees may register in advance using the webcast link above. A replay will be available online following the event.

Phase 1 Clinical Trial Design

The objectives of this Phase 1 randomized, double-blind, placebo-controlled, single and multiple ascending dose (SAD/MAD) clinical trial were to evaluate the safety and pharmacokinetics of BT-600 when administered orally in healthy adult participants. The trial, which was conducted in the United States, consisted of two parts: The first part was comprised of 24 participants receiving a single ascending dose of BT-600 with tofacitinib at 5 mg or 10 mg doses or placebo. The second part was comprised of 24 participants receiving multiple ascending-doses of BT-600 with tofacitinib at 5 mg or 10 mg doses or placebo daily for 7 days. The trial is listed at clinicaltrials.gov (NCT06275464). The "other trials" referred to in the summary of the Phase 1 clinical trial results above were conducted at different times, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made and no head-to-head clinical trials have been conducted.

About BT-600

BT-600 is a drug/device combination of Biora's NaviCap™ ingestible drug delivery device with a proprietary liquid formulation of tofacitinib, for the potential treatment of moderate to severe ulcerative colitis. The NaviCap device is orally administered and has been designed for anatomically targeted therapeutic delivery directly to the colon in this application.

About the NaviCap™ Targeted Oral Delivery Platform

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 activity 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 activity 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 ulcerative colitis. 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. Studies of the NaviCap device in healthy volunteers and patients with ulcerative colitis demonstrated successful delivery to the colon regardless of variable GI conditions, in both fasted and fed states.

About Ulcerative Colitis

Ulcerative colitis (UC) is a type of IBD that causes chronic inflammation and damage to the colon. Common symptoms include abdominal pain, increased bowel movements, stool urgency, and rectal bleeding. Despite the availability of advanced treatments for UC, including biologics, immunomodulators, and targeted synthetic small molecules, only about 40% of patients achieve clinical remission in induction trials. Surgical intervention is needed in approximately 20% of UC patients, with up to 10% of patients requiring surgical removal of the colon. About 1.5 million people are affected with UC in the United States alone, and ~40,000 new cases are diagnosed each year.

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, 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, 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 X.

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, preclinical and clinical trial activities, including those involving BT-600 and our NaviCap platform, and partnering and collaboration efforts with third parties, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "envision," "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "anticipate," "forward," "believe," "design," "estimate," "predict," "potential," "plan," "goal(s)" "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 FDA filings and initiate and execute 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 or partners, our ability to raise sufficient capital to achieve our business objectives, our ability to maintain our listing on the Nasdaq Global Market, 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, 2023 filed with the Securities and Exchange Commission (SEC) and other subsequent documents, including Quarterly Reports on Form 10-Q, 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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Exhibit 99.2


BIORA™
Therapeutics
Reimagining
therapeutic delivery
CORPORATE
PRESENTATION
July 2024

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, including with respect to BT-600 and our NaviCap platform, 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; risks related to our continued listing on the Nasdaq Global Market; 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, 2023, 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

Innovating smart pill technologies to deliver the right dose to the right place, safely.

BIORA Therapeutics

NAVIcap™

TARGETED ORAL DELIVERY

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

BIOjet™

SYSTEMIC ORAL DELIVERY

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

THERAPEUTIC PIPELINE

NAVICAP™ PROGRAMS	DRUG	DESIGN/FEASIBILITY	PRECLINICAL	CLINICAL
NaviCap™ Targeted Oral Delivery Platform	--			
BT-600 in ulcerative colitis	tofacitinib*			
BT-001 in ulcerative colitis	adalimumab variant*			

BIOJET™ PROGRAMS	DRUG	DESIGN/FEASIBILITY	PRECLINICAL	CLINICAL
BioJet™ Systemic Oral Delivery Platform	--			
AstraZeneca collaboration	undisclosed			
Ionis collaboration	antisense oligonucleotide			
Multiple pharma collaborations	undisclosed			

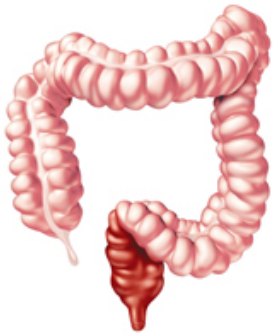
*Biora's own molecules

BIORA Therapeutics


NAVIcap™
TARGETED ORAL DELIVERY

Clinical presentation of ulcerative colitis

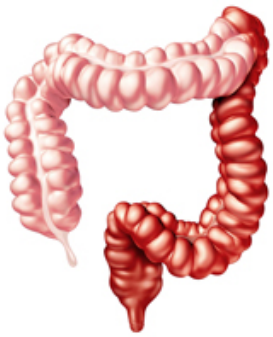
E1: PROCTITIS



SYMPTOMS
Rectal bleeding, tenesmus, urgency

30-60% of patients

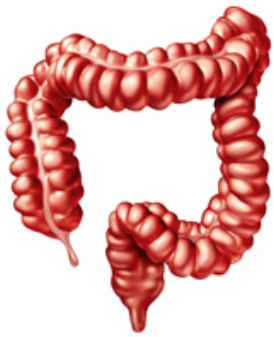
E2: DISTAL COLITIS



SYMPTOMS
E1 plus diarrhea, abdominal cramping

16-45% of patients

E1: PANCOLITIS



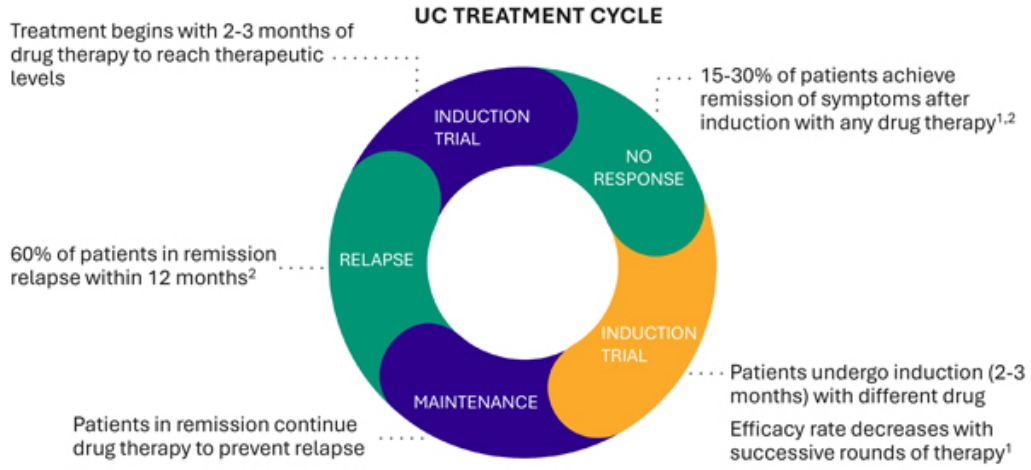
SYMPTOMS
E2 plus constitutional symptoms (fatigue, fever)

15-35% of patients

BIORA Therapeutics

ULCERATIVE COLITIS: THE TREATMENT GAP

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



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

Anatomically targeted delivery could enable rapid induction and improve patient response

THERAPEUTIC CHALLENGES	POTENTIAL SOLUTION
1 Difficulty of achieving sufficient drug activity at site of disease	Localized delivery could increase drug activity 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.

NAVICAP™ TARGETED ORAL DELIVERY PLATFORM

Needle-free, oral drug delivery to the colon

NAVIcap™

ORAL ADMINISTRATION

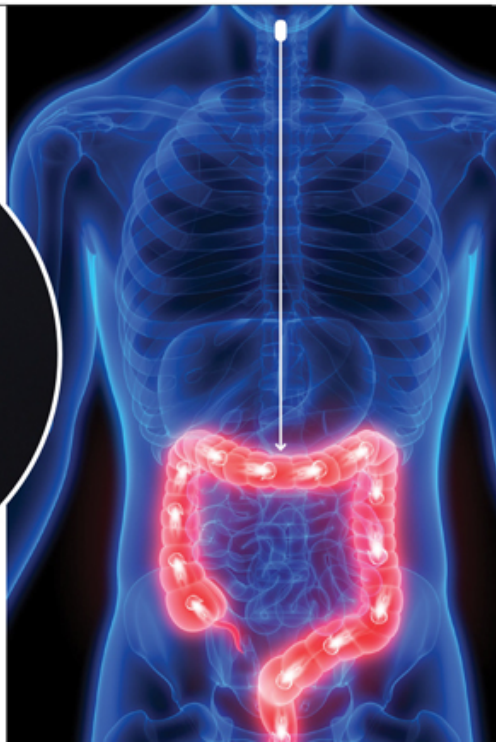
Convenient oral capsule the size of a fish-oil pill

AUTONOMOUS LOCATION

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

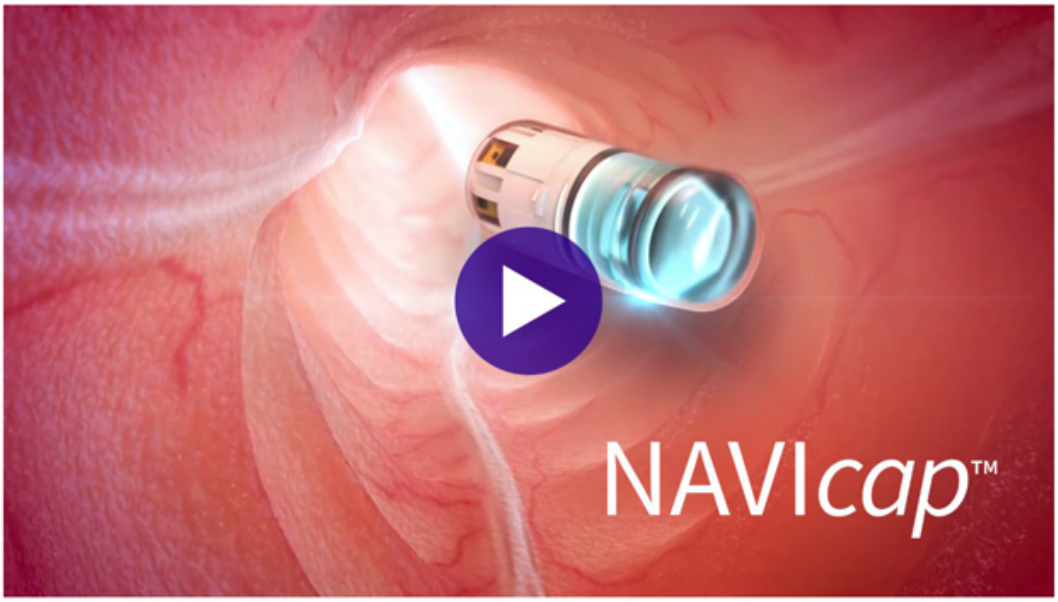
TARGETED DRUG DELIVERY

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.

Autonomous location and delivery to the colon



SCAN ME

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

DEVICE FUNCTION STUDIES (WITHOUT DRUG)

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

NAVIcap™

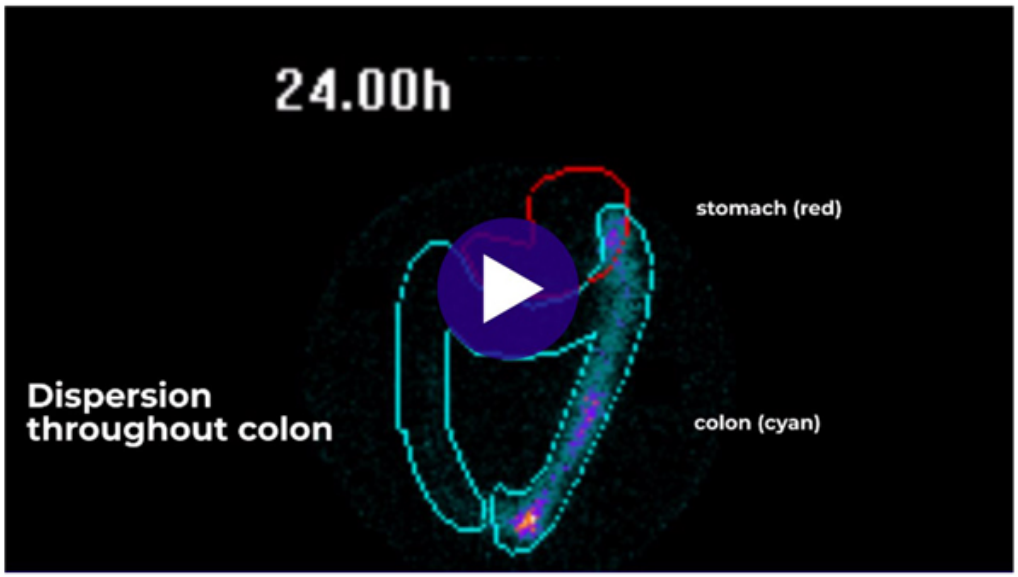
Q4 2022	Q4 2022	Q1 2023	Q2 2023
PM-601 Device Function Study in Healthy Participants – Fasted State	**PM-602 Device Function Study in Patients with Active UC – Fasted State**	**PM-611 Device Function Study in Healthy Participants – Fasted & Fed**	**BT-603 Device Function Study in Healthy Participants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

1. Lee SN, Razag G, Kelly C, et al. Results of human device function studies for the NaviCap™ Targeted Oral Delivery Platform in healthy volunteers and patients with UC. Poster presented at: *Digestive Disease Week*, May 18 – 21, 2024, Washington DC.

BIORA Therapeutics

DEVICE FUNCTION STUDIES (WITHOUT DRUG)

Scintigraphic imaging of NaviCap delivery in healthy participant



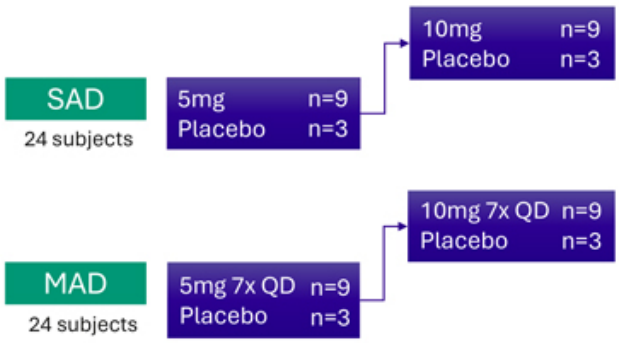
Despite variability in the GI environment among participants, the NaviCap device has been observed to perform as designed across a range of expected differences in motility.

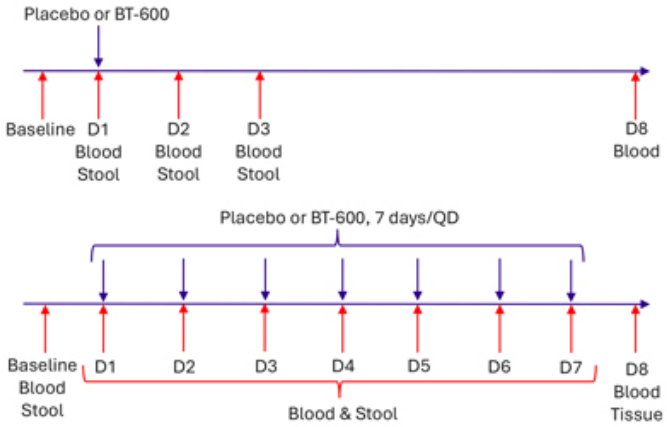
SCAN ME

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

PHASE 1 CLINICAL TRIAL DESIGN

Evaluate safety, tolerability, and pharmacokinetics of BT-600 in healthy participants





PATIENT POPULATION	Total of 48 healthy participants (24 SAD and 24 MAD participants)
TRIAL DESIGN	Randomized, double-blind, placebo-controlled clinical trial to evaluate the safety, tolerability, and PK of SAD and MAD doses of BT-600 in healthy participants

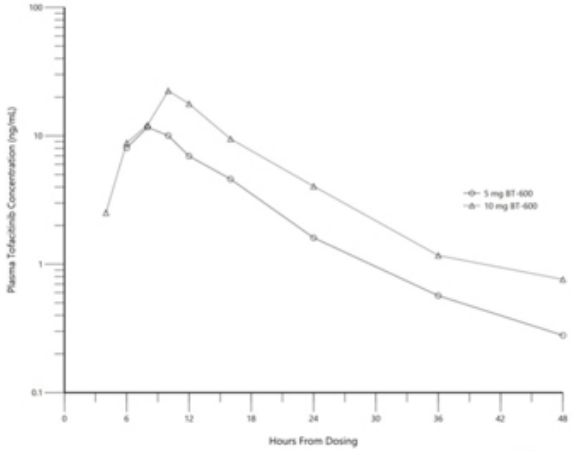
PHASE 1 INTERIM ANALYSIS: SINGLE ASCENDING DOSE IN HEALTHY PARTICIPANTS

NAVIcap™

Pharmacokinetic profile consistent with anatomically targeted delivery in the colon

- First evidence of systemic absorption at ~6 hours, consistent with colonic (vs. upper GI) delivery
  - T_{max} 8-10 hours (vs. 0.5 hours for conventional oral tofacitinib[1])
- Colonic delivery associated with 3-4x lower systemic absorption
  - C_{max} mean 26 ng/mL for BT-600 10 mg dose (vs. 88 ng/mL for conventional oral tofacitinib[1])
- Consistently lower drug concentrations observed with 5 mg vs. 10 mg dose

MEAN PLASMA TOFACITINIB CONCENTRATION FOLLOWING ADMINISTRATION OF A SINGLE ORAL DOSE OF 5 mg AND 10 mg BT-600



1. Krishnaswami S, Boy M, Chow V, Chan G. Safety, tolerability, and pharmacokinetics of single oral doses of tofacitinib, a Janus kinase inhibitor, in healthy volunteers. *Clin Pharmacol Drug Dev*. 2015;4(2):83-88. doi:10.1002/cpdd.171

BIORA Therapeutics

PHASE 1 SAD/MAD: TOPLINE RESULTS

NAVIcap™

All trial objectives met; Demonstrated drug delivery to the colon

PLASMA PHARMACOKINETICS (PK)	**Achieved PK profile consistent with drug delivery in the colon**	• Tofacitinib first detected in blood at ~6 hours, consistent with colonic delivery • Maximal blood levels were 3–4 times lower than seen with Xeljanz[1] • Demonstrated ability to deliver tofacitinib to the colon with lower systemic levels than seen with conventional oral delivery in both SAD/MAD cohorts[1]
COLON TISSUE EXPOSURE	**Demonstrated pan-colonic drug delivery**	• After delivery to the proximal colon, tofacitinib was detected across multiple biopsy sites in the distal colon • Distribution of tissue exposure consistent with delivery to the entire colon
DEVICE FUNCTION	**Accurately delivered to the colon**	• 100% of devices (SAD) and 98% of devices (MAD) successfully detected colon entry
SAFETY & TOLERABILITY	**Showed safety of daily administration**	• BT-600 was well tolerated by participants in SAD and MAD cohorts

Further details to be presented at virtual KOL event on July 17, 2024

Data on file, Biora Therapeutics, Inc.

1. These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

BIORA Therapeutics

BT-600 in ULCERATIVE COLITIS

Clinical development plan

NAVIcap™

RANDOMIZED, PLACEBO CONTROLLED, BLINDED CLINICAL TRIALS

PHASE 1	PHASE 1b	PHASE 2
Purpose Provide evidence of NaviCap colonic delivery of a therapeutic	**Purpose** Confirm PK profile in UC patients; inform Ph2 dose selection	**Purpose** Proof of concept: efficacy of tofacitinib delivered via NaviCap
Population 48 healthy participants	**Population** ~15 UC patients	**Population** ~150 UC patients
Design Single-center SAD/MAD trial	**Design** Single-center trial	**Design** Global multicenter induction efficacy trial
Endpoints • Safety & tolerability • PK/PD • Device function	**Endpoints** • Safety & tolerability • PK/PD • Device function	**Endpoints** • Clinical and endoscopic response • Mucosal healing • PROs • Biomarkers
COMPLETE	**PLANNED START: Q4 2024** **DURATION: 6 MO**	**PLANNED START: Q4 2025** **DURATION: TBD**

BIORA Therapeutics

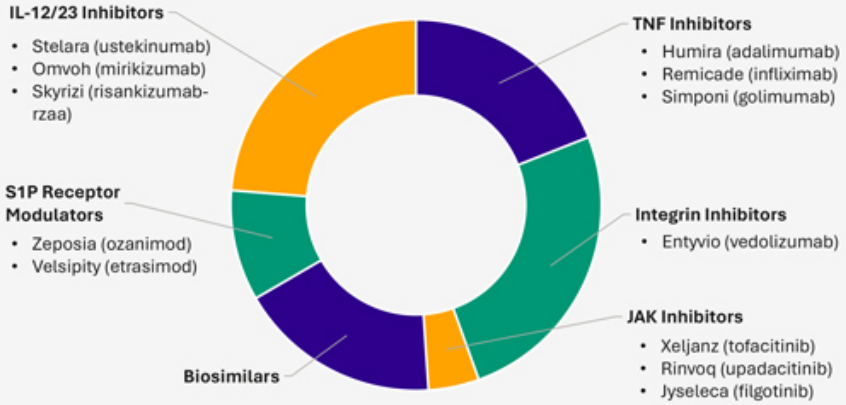
NAVIcap™

NaviCap could optimize delivery of IBD therapies, enabling drugs to act at site of disease and improve outcomes

- Across established UC therapies, drug activity at the site of disease is known to correlate with better outcomes:
  - JAK inhibitors[1]
  - TNF inhibitors[2]
  - Integrin inhibitors[3]
- NaviCap could optimize therapeutic classes by enabling drugs to reach and act in the colon for better outcomes in UC and beyond

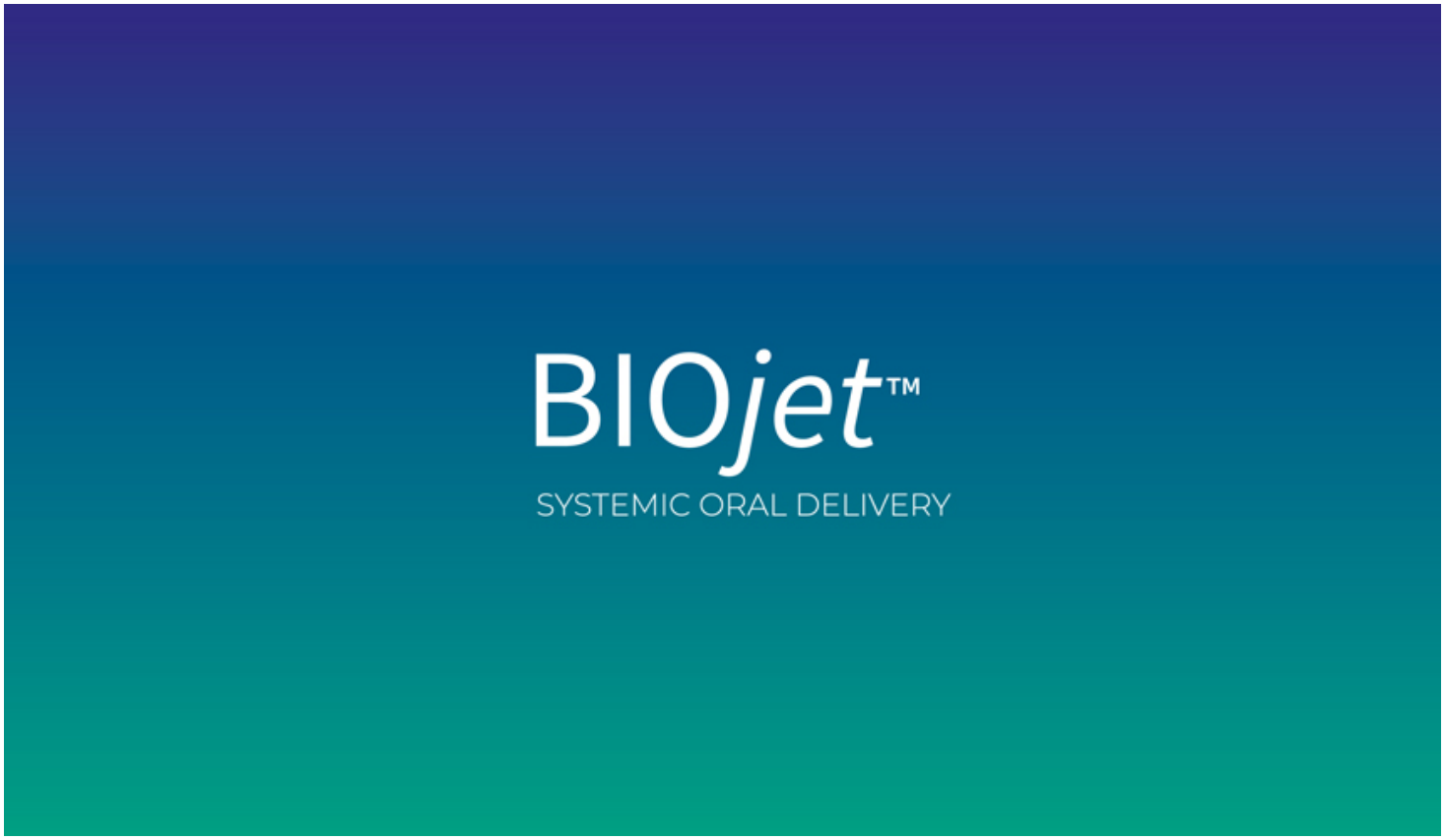
UC THERAPEUTICS GLOBAL SALES[4]

UC ADVANCED THERAPEUTICS FORECASTED GLOBAL MARKET SHARE BY DRUG CLASS[5]



1. Verstockt B, Alsoud D, van Oostrom J, et al. Poster presented at: *17th Congress of the European Crohn's and Colitis Organisation* (ECCO), February 18, 2022, virtual.
2. Yarur AJ, Jain A, Sussman DA, et al. The association of tissue anti-TNF drug levels with serological and endoscopic disease activity in inflammatory bowel disease: the ATLAS study. *Gut*. 2016;65(2):249-255. doi:10.1136/gutjnl-2014-308099
3. Pauwels RWM, Proietti E, van der Woude CJ, et al. Vedolizumab Tissue Concentration Correlates to Mucosal Inflammation and Objective Treatment Response in Inflammatory Bowel Disease. *Inflamm Bowel Dis*. 2021;27(11):1813-1820. doi:10.1093/ibd/izab053
4. GlobalData, Ulcerative Colitis: Global Drug Forecast and Market Analysis to 2029 (2020), based on 6.0% CAGR
5. GlobalData, Ulcerative Colitis: Global Drug Forecast and Market Analysis to 2029 (2020), based on forecasted 2029 global sales

BIORA Therapeutics


BIOjet™
SYSTEMIC ORAL DELIVERY

CASE STUDY

Unmet need in peptide delivery for treatment of diabetes

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 ORAL DELIVERY PLATFORM

Needle-free, oral delivery to small intestine

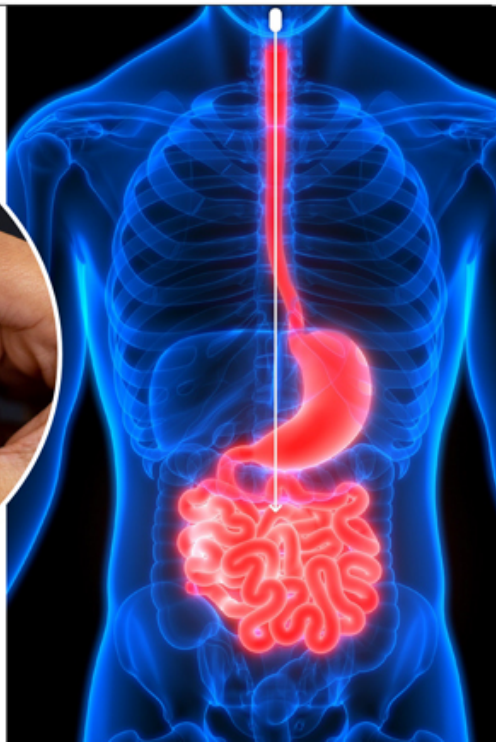
BIOjet™

PRECISE DELIVERY

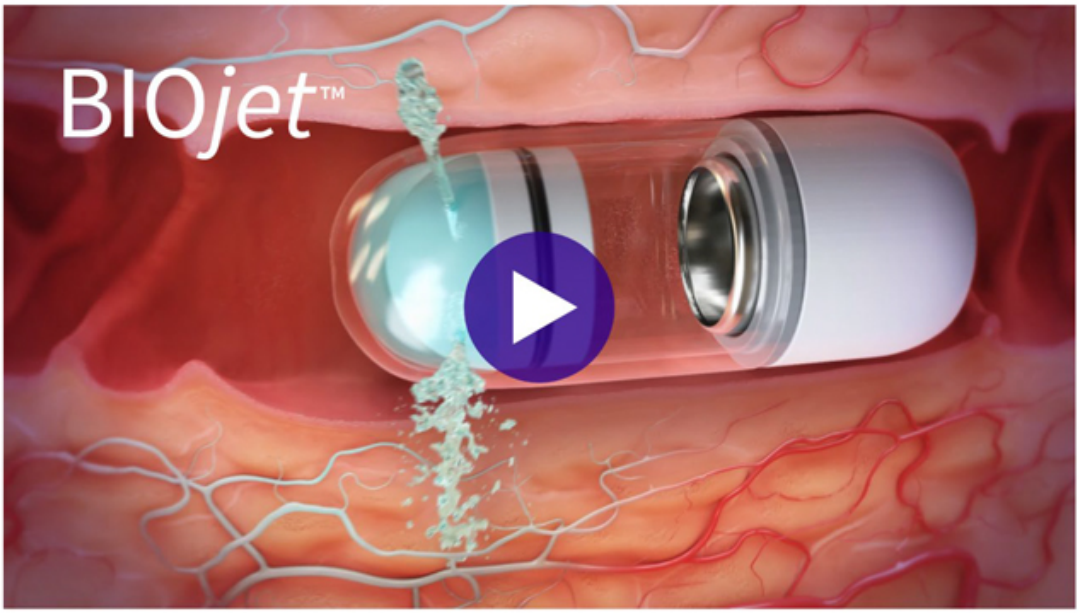
- Enteric trigger for precise timing of drug delivery to the small intestine
- Potential to enable liver-targeted delivery

UNIQUE SOLUTION

- Uses existing liquid formulations, without complex reformulation
- Deliver large payloads in the multi-milligram range



Liquid jet delivery to the small intestine



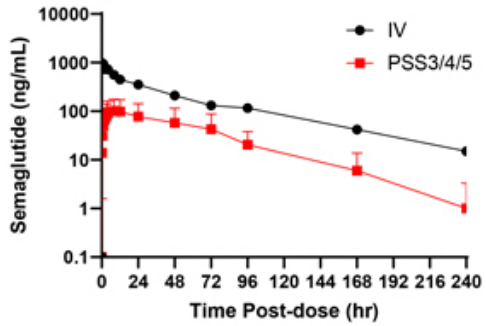
SCAN ME

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

Pharmacokinetics of semaglutide delivered via the BioJet™ device in a porcine model

BIOjet™

SYSTEMIC EXPOSURE TO SEMAGLUTIDE FOLLOWING AUTONOMOUS TRIGGERING OF BIOJET DEVICE ACROSS MULTIPLE STUDIES



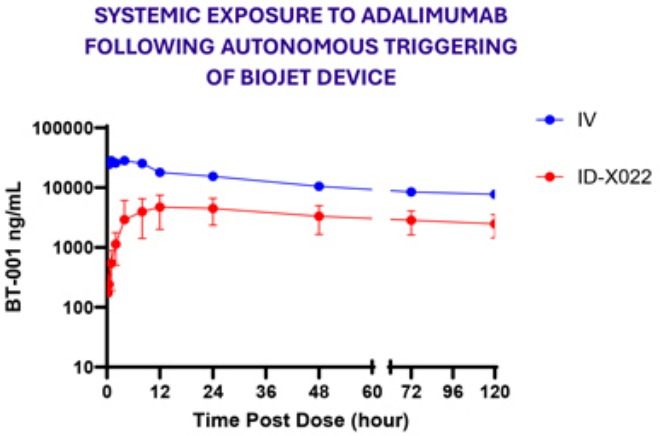
- Multiple studies performed in swine across different animal colonies
- Average oral bioavailability vs. IV administration of 36% ± 10% (*n*=55; SD ~25%)[1]
- Detectable drug levels up to ten days post-dosing
- No significant clinical signs observed in any of the animals for up to 10 days

1. Biora Therapeutics, Inc. Data on file. Average bioavailability calculation is based on animals with drug in blood across studies using multiple device configurations.

BIORA Therapeutics

Pharmacokinetics of BT-001 (adalimumab variant) delivered via the BioJet™ device in a porcine model

BIOjet™



- Mean bioavailability >30% shown with newer device configurations across multiple studies
- Detectable drug levels up to ten days post-dosing
- No significant clinical signs observed in any of the animals for up to 10 days

1. Biora Therapeutics, Inc. Data on file. Average bioavailability calculation is based on animals with drug in blood across studies using multiple device configurations.

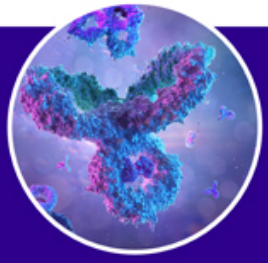
BIORA Therapeutics

Needle-free, liquid jet delivery of biomolecules

BIOjet™
SYSTEMIC ORAL DELIVERY

CATEGORY-LEADING BIOAVAILABILITY

- Liquid jet delivery to the small intestine designed to **maximize systemic uptake**
- Enables **liver-targeted delivery** of large molecules



BROAD APPLICABILITY

- **Platform technology** proven to deliver multiple molecule classes
- Delivers large payload at **multi-milligram doses**
- Leverages **liquid formulation** without complex reformulation

NOVEL DRUG DELIVERY TECHNOLOGY

- Possesses **comprehensive patent protection**
- Provides opportunity to **extend drug exclusivity**

BIORA Therapeutics

PRECLINICAL RESULTS

Demonstrated bioavailability across multiple molecules

BIOjet™

Preclinical studies in swine model with endoscopically placed and autonomously triggered BioJet device

MOLECULE TYPE	DRUG	ORAL BIOAVAILABILITY
ANTIBODY	adalimumab (monoclonal antibody)	**over 40%** mean oral bioavailability vs. IV control demonstrated across all three biomolecule types[1]
PEPTIDE	semaglutide (GLP-1 receptor agonist)	
OLIGONUCLEOTIDE	undisclosed antisense oligonucleotides	

RESEARCH COLLABORATIONS

AstraZeneca

IONIS

multiple undisclosed pharma collaborators

1. Biora Therapeutics data on file

BIORA Therapeutics

Innovating smart pill technologies to deliver the right dose to the right place, safely.

BIORA Therapeutics

NAVIcap™

TARGETED ORAL DELIVERY

- Clinical trial completed
- Anticipating final SAD/MAD data in Q2

BIOjet™

SYSTEMIC ORAL DELIVERY

- Tested in animals with multiple molecule classes, including peptides, ASOs, antibodies
- Progressing toward partnerships

APPENDIX

INTELLECTUAL PROPERTY

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

PUBLICATIONS

NaviCap™ targeted oral delivery platform

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.
13. **Results of human device function studies for the NaviCap™ Targeted Oral Delivery Platform in healthy volunteers and patients with UC.** Poster presented at Digestive Disease Week 2024.

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BioJet™ systemic oral delivery platform

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: an update.** Poster presented at the *59th Annual Meeting of the European Association for the Study of Diabetes*, October 2-6, 2023.
6. **Empowering Peptide Self Administration with Needle-Free Smart Capsules.** Oral presentation at the *Next-Gen Peptide Formulation & Delivery Summit*, June 19, 2024.

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