

Reimagining therapeutic delivery

CORPORATE PRESENTATION

April 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, 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, 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.



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



# NAVIcap

TARGETED ORAL DELIVERY

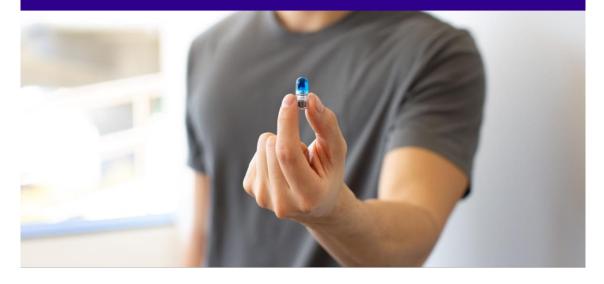
Treatment at the site of disease in the GI tract could improve outcomes for patients with inflammatory bowel disease



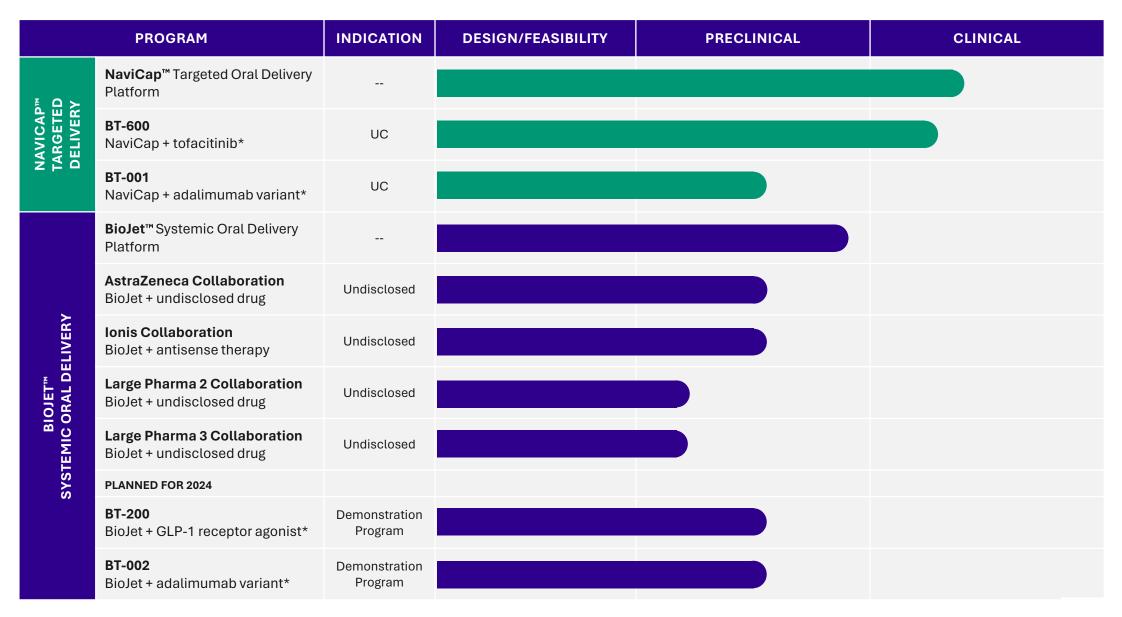
# BlOjet™

SYSTEMIC ORAL DELIVERY

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



### THERAPEUTIC PIPELINE

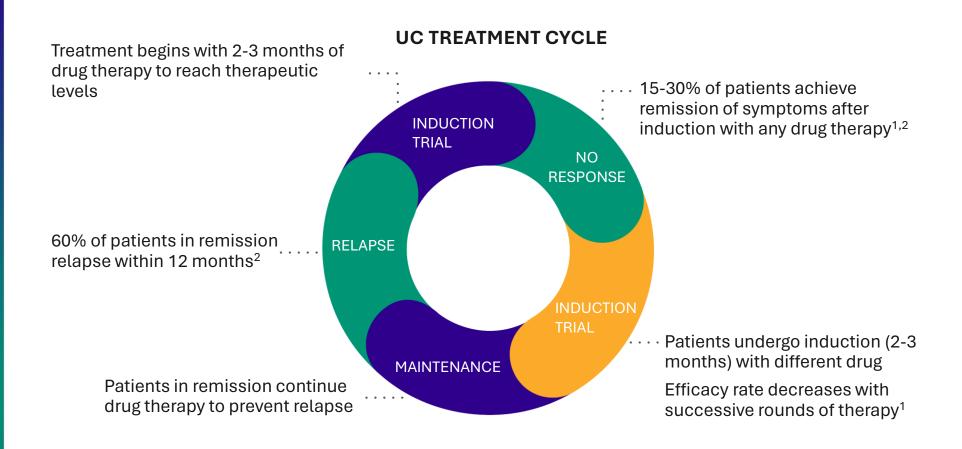


<sup>\*</sup>Biora's own molecules



### 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.
- 3. Shiyashankar 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<sup>3</sup>

#### UNMET NEED IN ULCERATIVE COLITIS

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

#### THERAPEUTIC CHALLENGES

- Difficulty of achieving sufficient drug levels at site of disease
- Systemic toxicity issues may limit daily dosage of UC drugs
- Combination therapy is limited by toxicity

Development in partnership with:

#### POTENTIAL SOLUTION

- Targeted delivery could increase drug levels at the site of disease, which is correlated with improved outcomes<sup>1</sup>
- Reduced systemic uptake is designed to reduce toxicity and adverse events
- Reduced toxicity could enable combination therapy<sup>2</sup>



- and Colitis Organisation (ECCO), February 18, 2022, virtua
- 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  $IC_{90}$

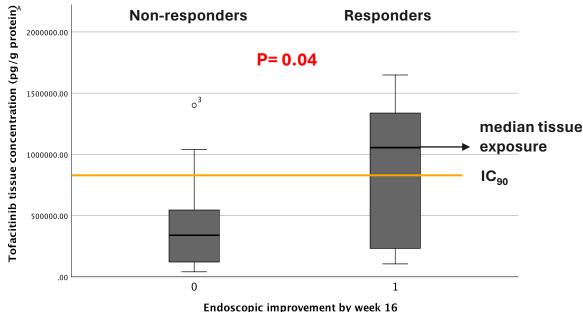
Research presented at ECCO 2022 and DDW 2022 in collaboration with:







### TOFACITINIB TISSUE EXPOSURE EXCEEDED IC<sub>90</sub> IN RESPONDERS



Endoscopic improvement by week 16



#### NAVICAP™ TARGETED ORAL DELIVERY PLATFORM

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



#### **ORAL ADMINISTRATION**

Convenient oral capsule the size of a fish-oil pill

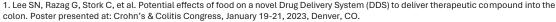
#### **AUTONOMOUS LOCATION**

GITrac™ autolocation technology enables targeted delivery to the colon, regardless of fasted or fed state<sup>1</sup>

#### TARGETED DRUG DELIVERY

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





### NAVI*cap*™

### Autonomous location and delivery to the colon

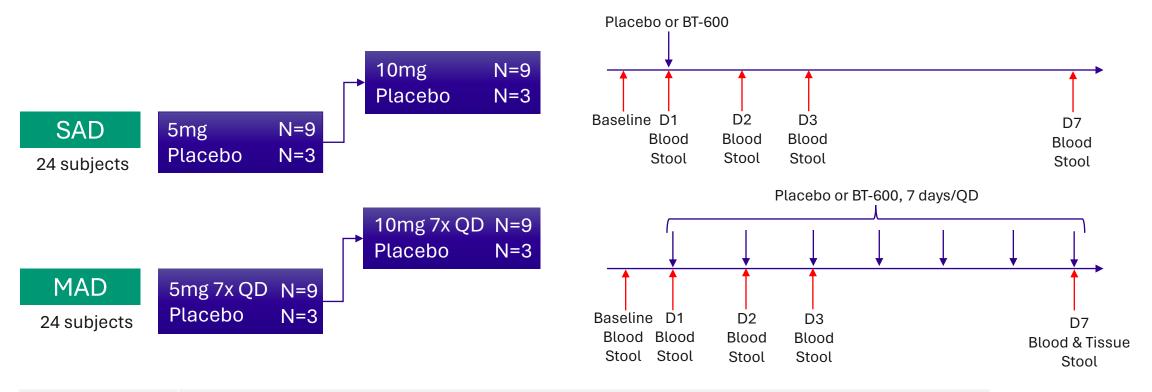




#### PHASE 1 CLINICAL TRIAL



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



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



PHASE 1 CLINICAL TRIAL: INTERIM ANALYSIS (PART 1, SAD)



### Successful device performance; all pharmacokinetic endpoints achieved

#### SAFETY AND TOLERABILITY

### No safety signals were observed

 NaviCap devices were well tolerated by healthy participants in the SAD cohort

#### **DEVICE FUNCTION**

### Devices performed as intended

- All participants receiving BT-600 showed systemic drug absorption, indicating that all NaviCap devices released and delivered drug as intended
- Tofacitinib was present in fecal samples of all subjects, further confirming drug delivery in the colon

#### PLASMA PHARMACOKINETICS

### Achieved PK profile suggesting drug delivery in the colon

- The desired pharmacokinetic profile was achieved, indicating drug delivery and absorption in the colon instead of the upper GI tract
- Dose-proportional pharmacokinetics were observed, with consistently lower plasma drug concentrations with the 5 mg dose than with the 10 mg dose



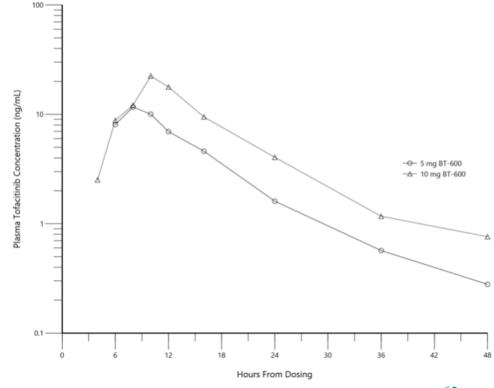
### PHASE 1 INTERIM ANALYSIS: SINGLE ASCENDING DOSE IN HEALTHY PARTICIPANTS



### 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<sub>max</sub> 8-10 hours (vs. 0.5 hours for conventional oral tofacitinib<sup>1</sup>)
- 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<sup>1</sup>)
- 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





### **DEVICE FUNCTION STUDIES (WITHOUT DRUG)**



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

O4 2022

**PM-601 Device Function** Study in Healthy **Participants – Fasted State** 

- 83% of devices accurately identified entry into the colon (10/12)<sup>1</sup>
- Achieved distribution of payload across the entire colon<sup>1</sup>
- No early deployment before colon detection<sup>1</sup>

**HEALTHY PARTICIPANTS** 



O4 2022

**PM-602 Device Function Study in Patients with Active UC** 

 100% of devices accurately identified entry into the colon, triggered release of a liquid payload, and achieved distribution across the entire colon  $(7/7)^3$ 

**ACTIVE UC PATIENTS** 



O1 2023

**PM-611 Device Function** Study in Healthy **Participants – Fasted & Fed** 

- 100% of analyzed devices successfully identified entry to the colon and activated gas cells for delivery in all fasted/fed schedules (39/39)<sup>2</sup>
- 97.4% of analyzed devices activated the payload release function (38/39)<sup>2</sup>

**FUNCTION** WITH/WITHOUT FOOD



Q2 2023

**BT-603 Device Function** Study in Healthy **Participants – Fasted State** 

94% of devices accurately identified entry into the colon, triggered release of a liquid payload, and achieved distribution across the entire colon  $(15/16)^4$ 

**PHASE 1-READY DEVICE** 



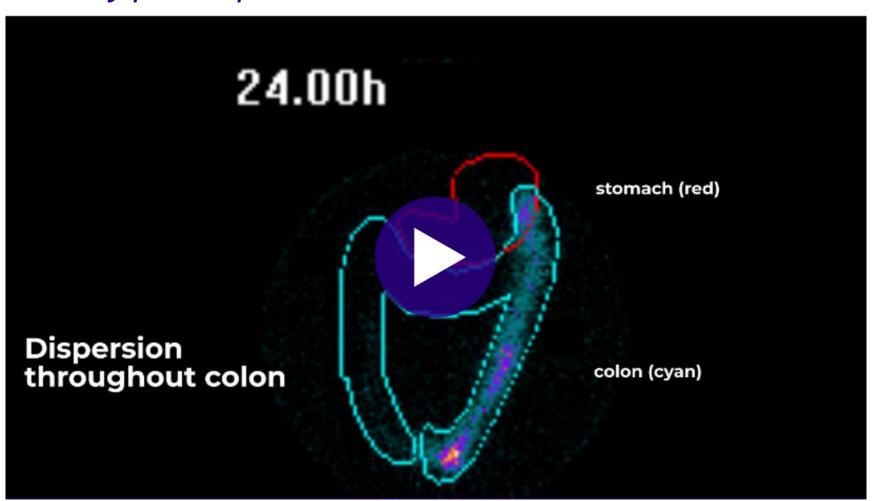
- 1. Lee SN, Sandefer E, Doll W, et al. A Scintigraphic Study to Evaluate the Safety, Tolerability, and Functionality of a Drug Delivery System (DDS) Device in Healthy Volunteers in Fasted State. Poster presented at: American College of Gastroenterology Annual Scientific Meeting, October 21-26, 2022, 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



### **DEVICE FUNCTION STUDIES (WITHOUT DRUG)**

### Scintigraphic imaging of NaviCap delivery in healthy participant





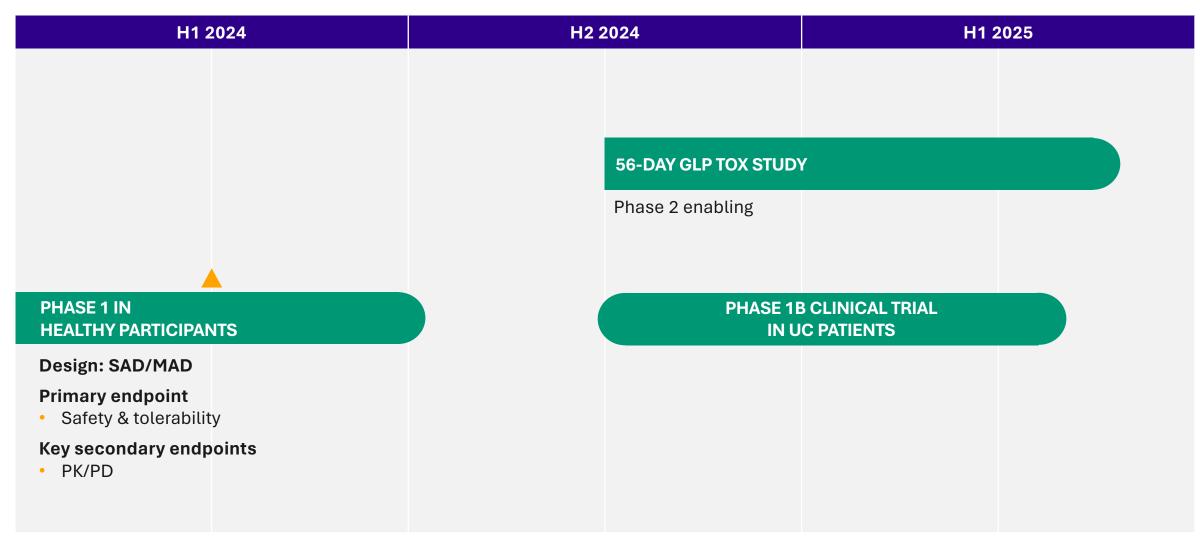
Despite variability in the GI environment among participants, the NaviCap device has been shown to perform as designed across a range of expected differences in motility.



### BT-600 (NAVICAP™ + TOFACITINIB)

### Clinical Development Plan



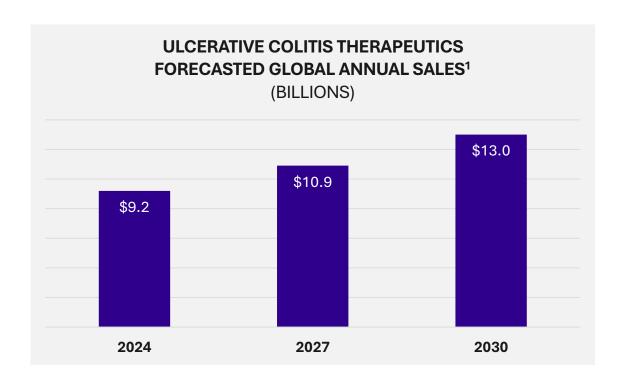








### In a large and expanding market, NaviCap's potential to optimize JAK inhibitor therapy creates tremendous opportunity



- In patients with UC, JAK inhibitors are more efficacious at higher doses, but use of higher doses has been limited by dosedependent safety concerns<sup>2,3</sup>
- Dose-dependent efficacy is likely driven by ability to achieve higher colon tissue concentrations<sup>4,5</sup>
- NaviCap can potentially improve JAK inhibitor efficacy in UC by enabling higher colon tissue concentrations without subjecting patients to high systemic levels



<sup>1.</sup> GlobalData, Ulcerative Colitis: Global Drug Forecast and Market Analysis to 2029 (2020), based on 6.0% CAGR

<sup>2.</sup> Sandborn WJ, Ghosh S, Panes J, et al. Tofacitinib, an oral Janus kinase inhibitor, in active ulcerative colitis. N Engl J Med. 2012;367(7):616-624. doi:10.1056/NEJMoa1112168

<sup>3.</sup> Pfizer, Inc. Xelianz (tofacitinib) tablets, for oral use [package insert], U.S. Food and Drug Administration website, https://www.accessdata.fda.gov/drugsatfda\_docs/label/202 December 2021. Accessed April 1, 2024.

<sup>4.</sup> 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

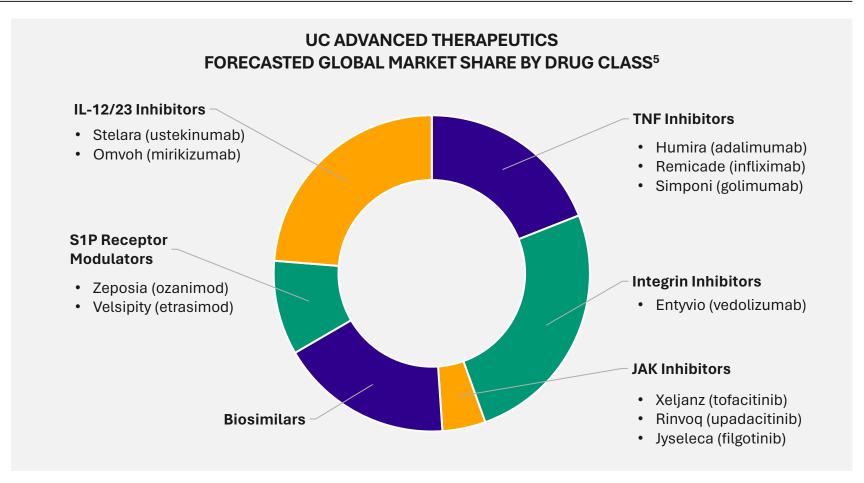
<sup>5.</sup> Yarur AJ, Jain A, Sussman DA, et al. The association of tissue anti-TNF drug levels with serological and endoscopic disease activity in inflammatory bowel disease: the ATLAS study. Gut. 2016;65(2):249-255. doi:10.1136/gutjnl-2014-308099

### BROAD POTENTIAL FOR OPTIMIZED DELIVERY



### NaviCap could optimize delivery of IBD therapies, enabling higher tissue concentrations and improved outcomes

- Across established classes of UC therapies, higher tissue concentrations are known to correlate with better outcomes:
  - JAK inhibitors<sup>1</sup>
  - TNF inhibitors<sup>2</sup>
  - Integrin inhibitors<sup>3</sup>
- NaviCap has the potential to optimize these therapeutic classes to achieve higher tissue concentrations and better outcomes in UC and beyond



<sup>1.</sup> 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



<sup>2.</sup> 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

<sup>3.</sup> Pauwels RWM, Projetti 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/jbd/izab053

<sup>4.</sup> GlobalData, Ulcerative Colitis: Global Drug Forecast and Market Analysis to 2029 (2020), based on forecasted 2029 global sales

# Blojet<sup>TM</sup> SYSTEMIC ORAL DELIVERY

#### **UNMET NEED**

# Needles are associated with poor disease management



of people with diabetes discontinue injectable medications due to injection concerns<sup>1,2</sup>



of patients fail to maintain diabetes treatment due to injection concerns when using an injectable GLP-1 agonist<sup>2</sup>



higher discontinuation rate for diabetes patients initiating treatment with an injectable GLP-1 agonist vs. those starting oral therapy<sup>2</sup>

<sup>2.</sup> 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



<sup>1.</sup> 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

### 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



### Liquid jet delivery to the small intestine







### PRECLINICAL RESULTS

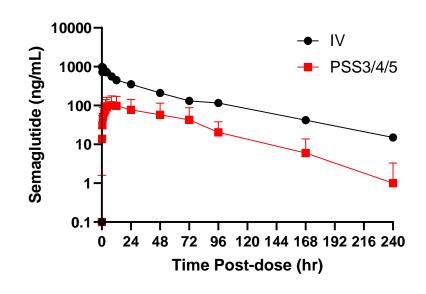


### Demonstrated bioavailability across multiple molecules

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

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

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



#### **RESEARCH COLLABORATIONS**





Large Pharma 2

Large Pharma 3



### Needle-free, liquid jet delivery of biomolecules





### **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



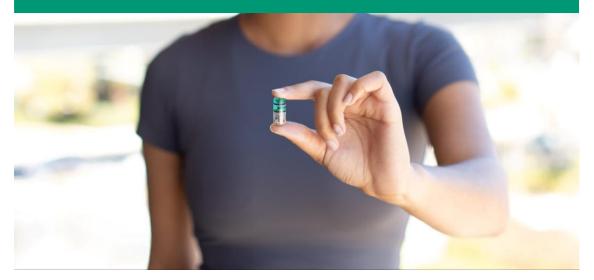
# Innovating smart pill technologies to deliver the right dose to the right place, safely.



# NAVI*cap*™

TARGETED ORAL DELIVERY

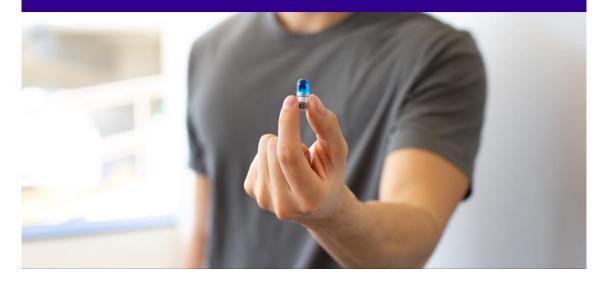
- Clinical trial currently underway in US
- Anticipating final SAD/MAD data in Q2



# BlOjet™

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

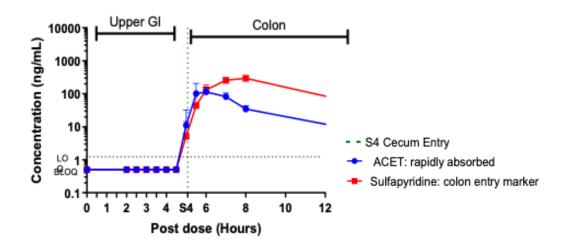




### Demonstrated accurate localization and delivery to colon

#### **ACCURATE DELIVERY TO COLON IN CANINES**

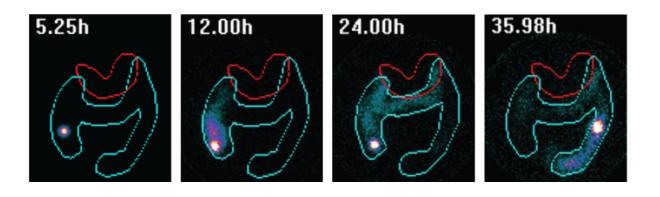
Pharmacokinetic data from two marker drugs administered in canine model



- 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



### BT-600 PRECLINICAL STUDY RESULTS

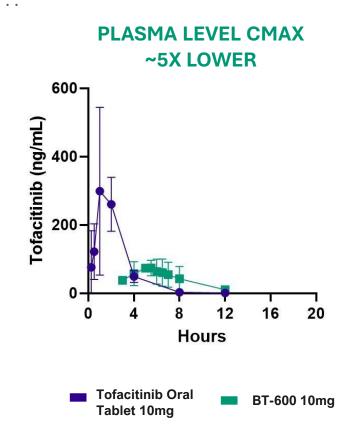
### NAVIcap™

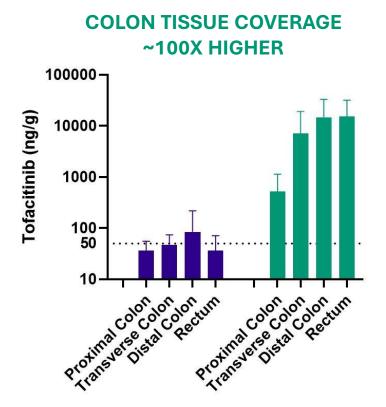
# Reduced systemic uptake, better distribution and tissue coverage

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







#### **PUBLICATIONS**

### NaviCap™ targeted oral delivery platform



- Development of targeted therapeutic antibodies for the treatment of inflammatory bowel disease: A proof of concept. Poster presented at DDW 2019.
- A comparison of systemic versus targeted anti-TNFa antibody in treatment of colitis induced by adoptive transfer of CD44-/CD62L+ Tcells into RAG2-/- mice recipients. Presented at DDW 2019.
- Targeted delivery of soluble tofacitinib citrate to the site of inflammation to improve efficacy and safety. Poster presented at DDW 2021.
- Development of a novel drug delivery system for treatment of Ulcerative Colitis. Poster resented at DDW 2021.
- 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.
- Tofacitinib tissue exposure correlates with endoscopic outcome. Oral presentation at DDW 2022 and BWG. Poster presented at ECCO 2022.
- Pharmacokinetic stratification of cytokine profiles during anti-TNF induction treatment in moderate-to-severe UC. Poster presented at ECCO 2022 and DDW 2022.
- Pilot study to assess pharmacokinetic and pharmacodynamic markers following enema-dosing with adalimumab in patients with active ulcerative colitis. Poster presented at ACG 2022.
- 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.
- 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.



#### **PUBLICATIONS**

### BlOjet™

### 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. Poster presented at the 59th Annual Meeting of the European Association for the Study of Diabetes, October 2-6, 2023.



