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): August 14, 2023

Biora Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39334**	**27-3950390**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4330 La Jolla Village Drive, Suite 300 **San Diego, California** **(Address of Principal Executive Offices)**	**92122** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (833) 727-2841

N/A
(Former Name or Former Address, if Changed Since Last Report)

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

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

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

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

Item 2.02 Results of Operations and Financial Condition.

On August 14, 2023, Biora Therapeutics, Inc. issued a press release announcing its financial results for the second quarter ended June 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 August 14, 2023
99.2	Corporate presentation, dated August 14, 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: August 14, 2023

By: /s/ Aditya P. Mohanty

Aditya P. Mohanty
Chief Executive Officer

Exhibit 99.1

Biora Therapeutics Provides Corporate Update and Reports Second Quarter 2023 Financial Results

NaviCap™ targeted oral delivery platform on track for September IND filing; achieved successful device function study results in humans with phase 1-ready device

BioJet™ systemic oral delivery platform device development achieved function targets while continuing to exceed bioavailability targets

The company strengthened its intellectual property position with additional patents for both platforms

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

SAN DIEGO, August 14, 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 second quarter ended June 30, 2023.

Biora recently announced preliminary results from a device function study in humans with the phase 1-ready device for its NaviCap™ targeted oral delivery platform. The company subsequently completed the study as planned with a total of sixteen healthy volunteers participating in the study. The NaviCap device accurately identified entry into the colon, triggered release of its non-drug payload, and achieved distribution throughout the colon in 15 out of 16 subjects.

“In this fourth human functional study, we once again demonstrated the robustness of our NaviCap platform, which performed as designed across a range of expected differences in GI motility among study participants,” said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. “We remain on track for IND filing in September for our BT-600 program. We believe the NaviCap platform can address the large unmet need for ulcerative colitis patients by solving one of the primary treatment gaps, which is the inability to achieve high enough drug levels in the diseased tissue without systemic toxicity,” continued Mr. Mohanty.

“During the second quarter, we continued development of our BioJet™ platform, which has shown category-leading oral bioavailability of large molecules. We successfully tested the autonomously triggered version of our next-gen device, achieving our device function targets, while continuing to exceed our performance target of 15% average bioavailability,” said Mr. Mohanty.

Also during the second quarter, Biora presented data at the American Diabetes Association assessing the delivery of semaglutide via the BioJet device in an animal model. In two studies,

the company achieved more than double its target average bioavailability. Biora will be presenting additional data from the BioJet platform at the European Association for the Study of Diabetes annual meeting in Hamburg, Germany, October 2-6, 2023.

In addition, Biora recently further strengthened its intellectual property position for both platforms. The company was awarded a group of US and European patents related to additional therapeutic targets for its NaviCap targeted oral delivery platform, which could help the company broaden its NaviCap pipeline in the future. Biora also recently announced additional patents covering key features of the proprietary liquid jet injection technology used in its BioJet platform. The company's recent patents are part of its larger corporate portfolio consisting of 73 patent families, including approximately 167 issued patents and 143 pending applications in major jurisdictions around the world.

Second Quarter 2023 and Other Recent Corporate Highlights

- Biora achieved successful device function study results in humans with its phase 1-ready NaviCap device.
- The company remains on track for a September 2023 IND filing for the BT-600 program.
- Biora presented data from its BioJet systemic oral delivery platform at the American Diabetes Association Scientific Sessions assessing the bioavailability of semaglutide delivered via the BioJet device in an animal model.
- The company continued development of its autonomously triggered next-gen BioJet device, successfully achieving its device function targets, while continuing to achieve bioavailability similar to subcutaneous injection. Confirmatory studies are underway.
- Biora will be presenting additional data from the BioJet platform at the European Association for the Study of Diabetes annual meeting in Hamburg, Germany, October 2-6, 2023.
- The company was awarded a group of US and European patents related to the use of its NaviCap targeted oral delivery platform to deliver well-known IBD therapeutics at the site of disease in the colon.
- Biora also recently announced additional patents covering key features of the proprietary liquid jet injection technology, a core component of its BioJet platform.
- The company raised $8 million in gross proceeds via a registered direct offering during the second quarter, funding the majority of its Q2 operating expenses.

Second Quarter 2023 Financial Results

Comparison of Three Months Ended June 30, 2023 and March 31, 2023

Operating expenses were $14.9 million for the three months ended June 30, 2023, compared to $15.5 million for the three months ended March 31, 2023.

Net loss was $17.8 million and net loss per share was $1.47 for the three months ended June 30, 2023, compared to a net loss of $17.4 million and net loss per share of $1.59 for the for the three months ended March 31, 2023.

Comparison of Three Months Ended June 30, 2023 and 2022

Operating expenses were $14.9 million for the three months ended June 30, 2023, compared to $14.3 million for the three months ended June 30, 2022.

Net loss was $17.8 million and net loss per share was $1.47 for the three months ended June 30, 2023, compared to a net loss of $5.5 million and net loss per share of $0.75 for the three months ended June 30, 2022.

Webcast and Conference Call Information

Biora Therapeutics will host a webcast and conference call to discuss the second quarter financial results and provide a corporate update today, Monday, August 14, 2023 at 4:30 PM Eastern time / 1:30 PM Pacific time.

The live call may be accessed by dialing 1-877-423-9813 (domestic) or 1-201-689-8573 (international) and entering the conference code: 13740025. A live webcast will be available via the Investors section of the company website, with a replay available online for 60 days following the call.

About Biora Therapeutics

Biora Therapeutics is the biotech company that is reimagining therapeutic delivery. By creating innovative smart pills designed for targeted drug delivery to the GI tract, and systemic, needle-free delivery of biotherapeutics, the company is developing therapies to improve patients' lives.

Biora 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, and phase 1 readiness, 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.

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

	Three Months Ended	
	June 30, 2023	**March 31, 2023**
Revenues	$ 2	$ 2
Operating expenses:		
Research and development	5,983	7,190
Selling, general and administrative	8,953	8,356
Total operating expenses	14,936	15,546
Loss from operations	(14,934)	(15,544)
Interest expense, net	(2,703)	(2,680)
(Loss) gain on warrant liabilities	(161)	864
Other expense, net	(5)	(81)
Loss before income taxes	(17,803)	(17,441)
Income tax expense	4	—
Net loss	$ (17,807)	$ (17,441)
Net loss per share, basic and diluted	$ (1.47)	$ (1.59)
Weighted average shares outstanding, basic and diluted	12,143,108	10,970,583

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

	Three Months Ended June 30,	
	2023	**2022**
Revenues	$ 2	$ 104
Operating expenses:		
Research and development	5,983	5,904
Selling, general and administrative	8,953	8,410
Total operating expenses	14,936	14,314
Loss from operations	(14,934)	(14,210)
Interest expense, net	(2,703)	(2,772)
(Loss) gain on warrant liabilities	(161)	4,413
Other (expense) income, net	(5)	5,735
Loss before income taxes	(17,803)	(6,834)
Income tax expense (benefit)	4	(837)
Loss from continuing operations	(17,807)	(5,997)
Gain from discontinued operations	—	484
Net loss	$ (17,807)	$ (5,513)
Net loss per share from continuing operations, basic and diluted	$ (1.47)	$ (0.81)
Net gain per share from discontinued operations, basic and diluted	$ —	$ 0.06
Net loss per share, basic and diluted	$ (1.47)	$ (0.75)
Weighted average shares outstanding, basic and diluted	12,143,108	7,374,865

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

	June 30, 2023	December 31, 2022 (1)
Assets		
Current assets:		
Cash, cash equivalents and restricted cash	$ 26,452	$ 30,486
Income tax receivable	819	828
Prepaid expenses and other current assets	4,105	4,199
Current assets of disposal group held for sale	2,509	2,603
Total current assets	33,885	38,116
Property and equipment, net	1,351	1,654
Right-of-use assets	1,887	1,482
Other assets	6,478	6,201
Goodwill	6,072	6,072
Total assets	$ 49,673	$ 53,525
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 5,042	$ 3,606
Accrued expenses and other current liabilities	21,791	16,161
Warrant liabilities	10,835	3,538
Total current liabilities	37,668	23,305
Convertible notes, net	128,568	127,811
Other long-term liabilities	4,318	4,696
Total liabilities	$ 170,554	$ 155,812
Stockholders' deficit:		
Common stock	11	8
Additional paid-in capital	760,277	743,626
Accumulated deficit	(862,091)	(826,843)
Treasury stock	(19,078)	(19,078)
Total stockholders' deficit	(120,881)	(102,287)
Total liabilities and stockholders' deficit	$ 49,673	$ 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

August 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

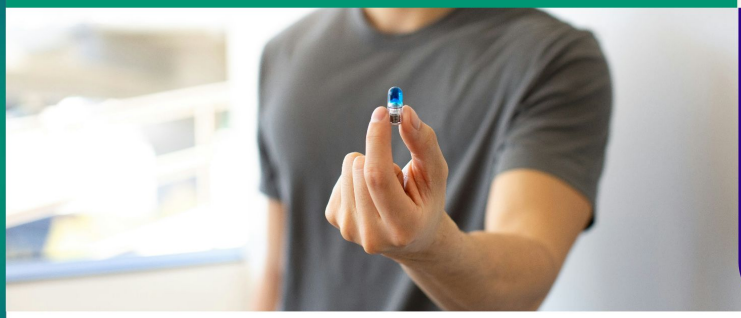
Innovating smart capsule technologies to deliver the right dose to the right place, safely

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

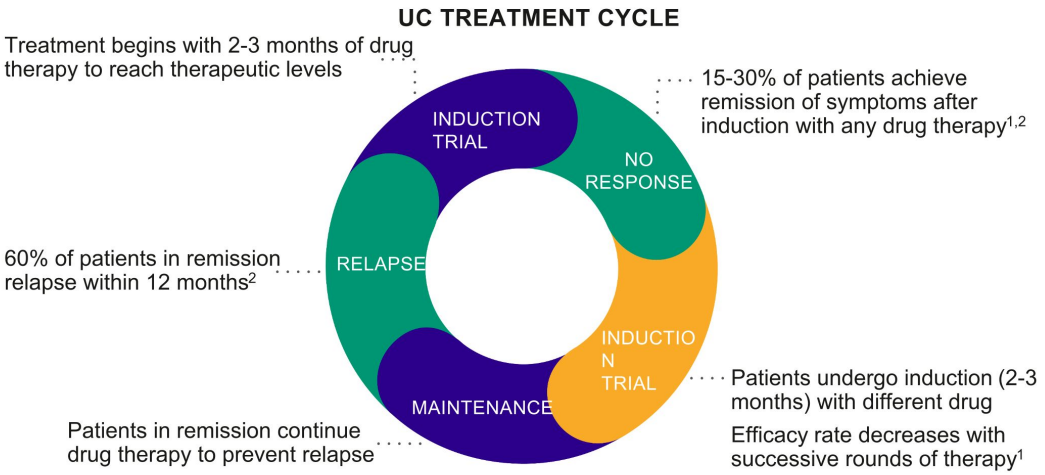
THERAPEUTIC PIPELINE

	PROGRAM	INDICATION	DESIGN/FEASIBILITY	PRECLINICAL	CLINICAL
TARGETED THERAPEUTICS	**NaviCap™** Targeted Oral Delivery Platform	--			
	BT-600 NaviCap + tofacitinib	UC			
	BT-001 NaviCap + adalimumab variant	UC			
SYSTEMIC THERAPEUTICS	**BioJet™** Systemic Oral Delivery Platform	--			
	BT-200 BioJet + GLP-1 receptor agonist	Diabetes			
	BT-002 BioJet + adalimumab variant	Autoimmune			
	Ionis Collaboration BioJet + antisense therapy	Undisclosed			
	Large Pharma 1 Collaboration BioJet + undisclosed drug	Undisclosed			
	Large Pharma 2 Collaboration BioJet + undisclosed drug	Undisclosed			


NAVIcap™
TARGETED ORAL DELIVERY

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

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

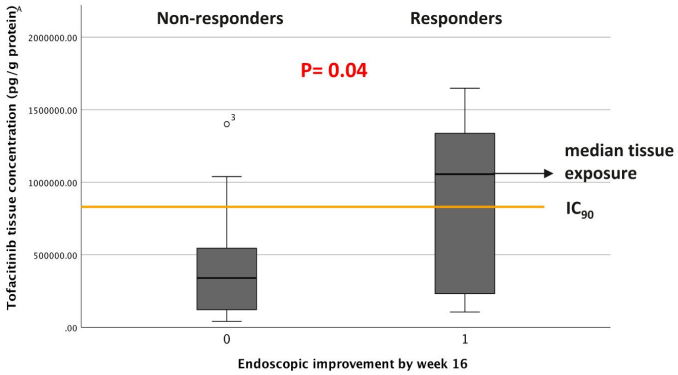
Tissue drug concentration correlates with endoscopic outcomes in UC

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

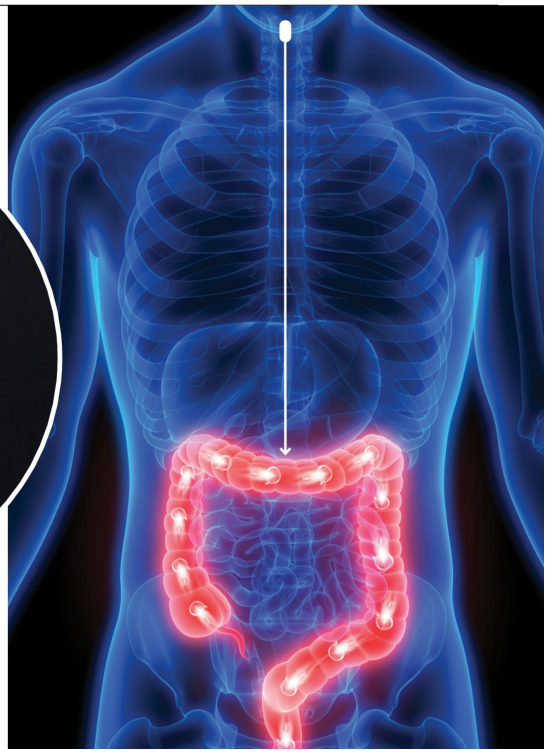
Convenient oral capsule the size of a fish-oil pill

AUTONOMOUS LOCATION

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

TARGETED DRUG DELIVERY

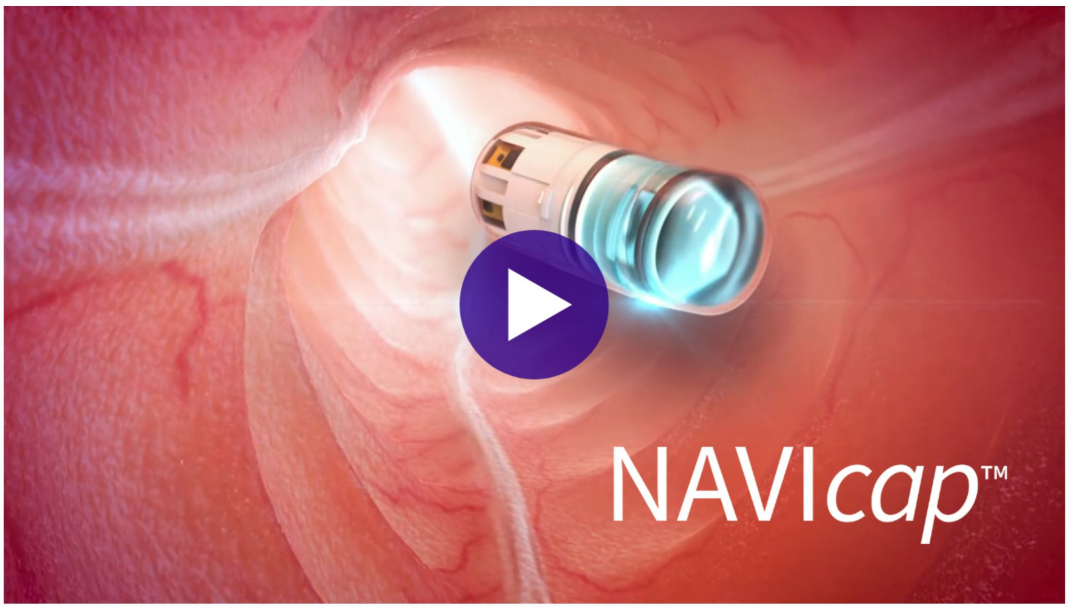
Method designed to coat the length of the colon with liquid formulation, minimizing systemic uptake



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

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] • Achieved distribution of payload across the entire colon[1] • 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] • 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

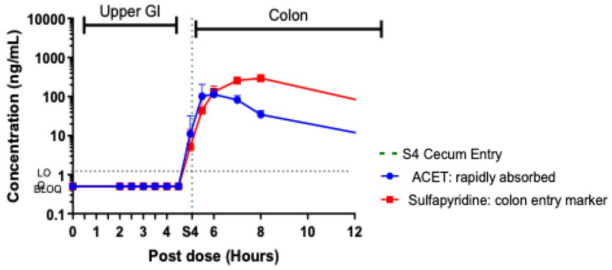
BIORA Therapeutics

Demonstrated accurate localization and delivery to colon

NAVIcap™

ACCURATE DELIVERY TO COLON IN CANINES

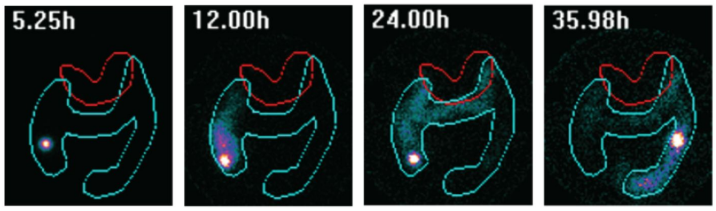
Pharmacokinetic data from two marker drugs administered in canine model



- 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



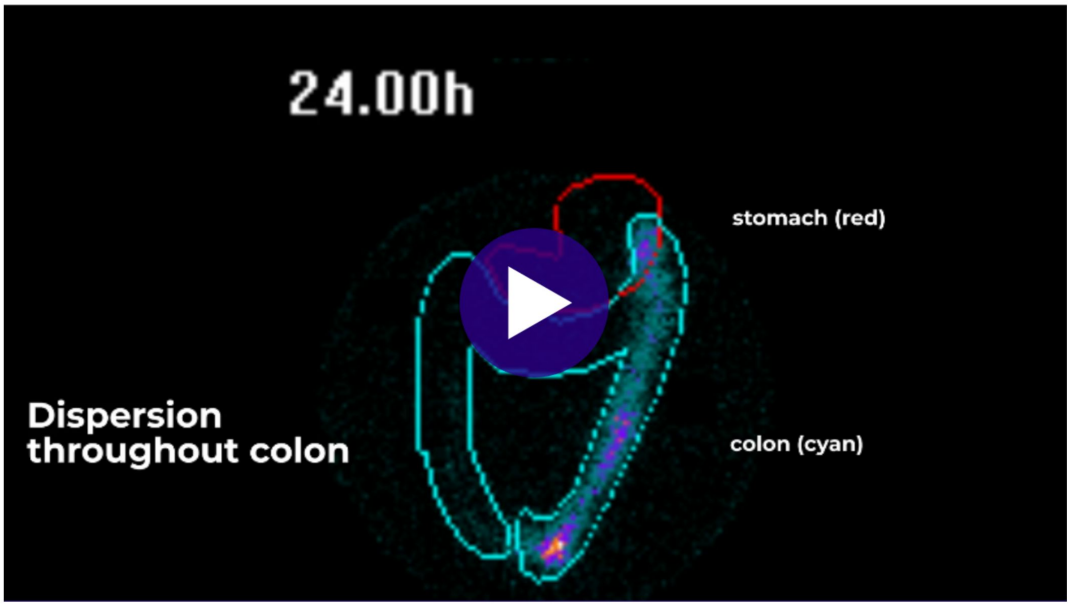
- Achieved distribution across the entire colon

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

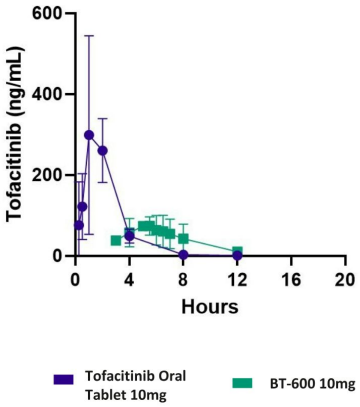
NAVIcap™

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)

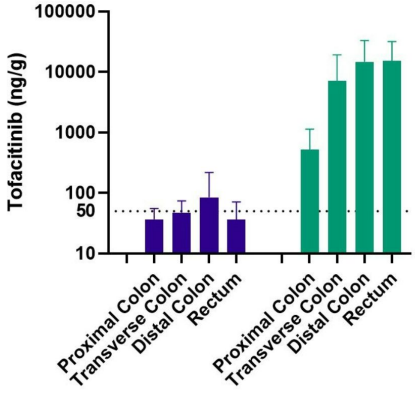
RESULTS

- 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

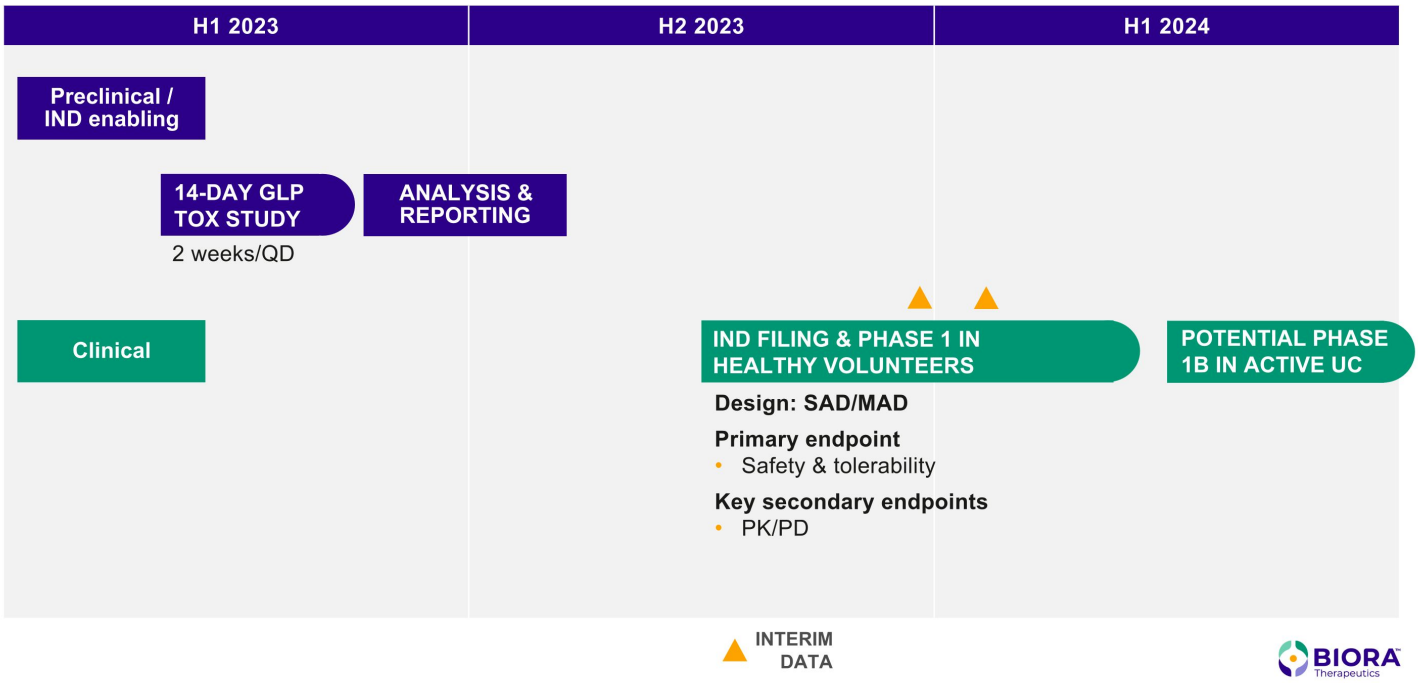


Biora Therapeutics internal data

BIORA Therapeutics

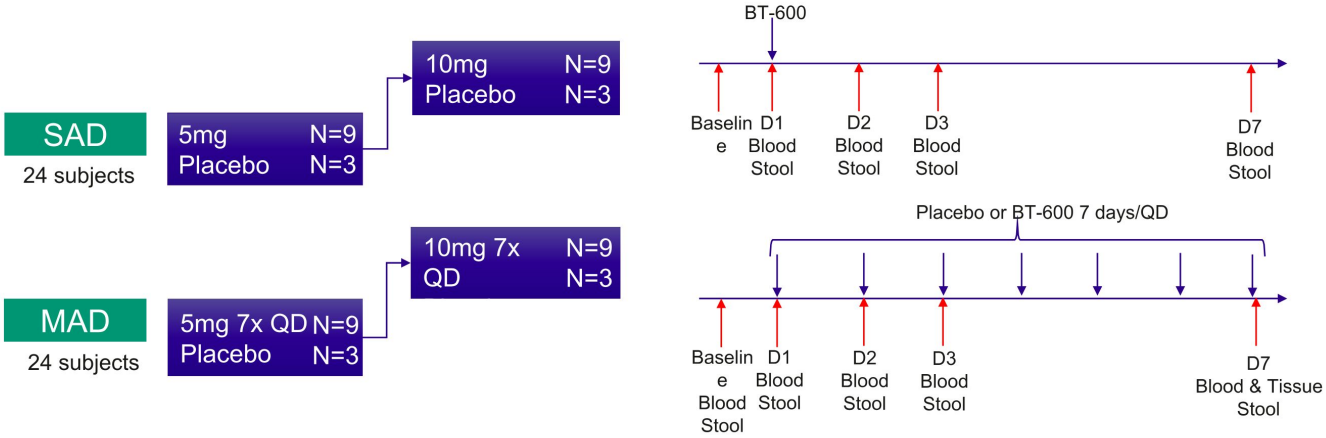
BT-600 (NAVICAP™ + TOFACITINIB)

Clinical Development Plan



PHASE 1: SINGLE AND MULTIPLE ASCENDING DOSE STUDIES

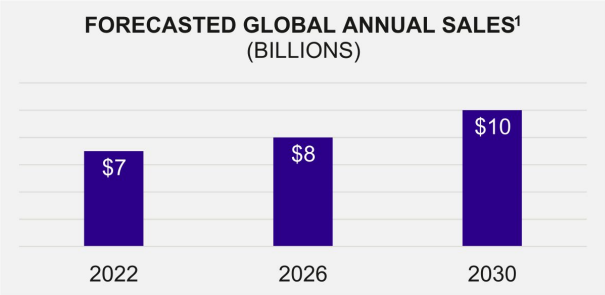
Evaluate safety, tolerability, pharmacokinetics and pharmacodynamics of BT-600 in healthy volunteers

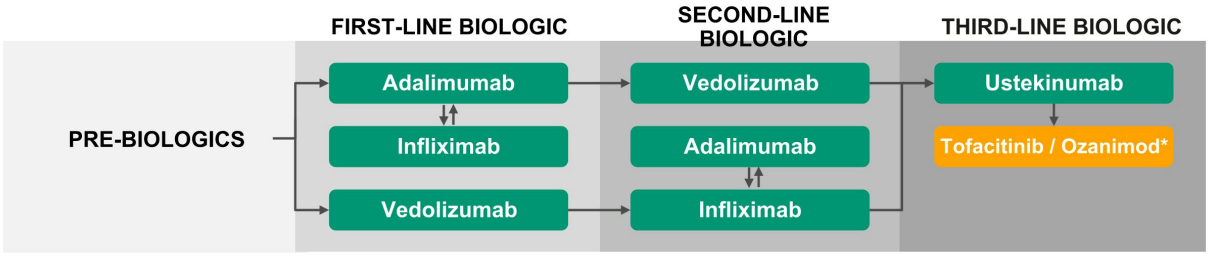


PATIENT POPULATION	Normal healthy volunteers Total of 48 subjects (24 SAD and 24 MAD subjects)
STUDY DESIGN	Randomized, double-blind (participant and site), placebo-controlled study to evaluate the safety, tolerability, and PK/PD of SAD and MAD doses of BT-600 in healthy subjects
OBJECTIVES	Demonstrate 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

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 diabetics miss 4+ injections per week[1]

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. Frost & Sullivan research commissioned by Rani Therapeutics Holdings, Inc. https://ir.ranitherapeutics.com/static-files/b1f080bf-a860-4136-87cb-d6f7c49c1502
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

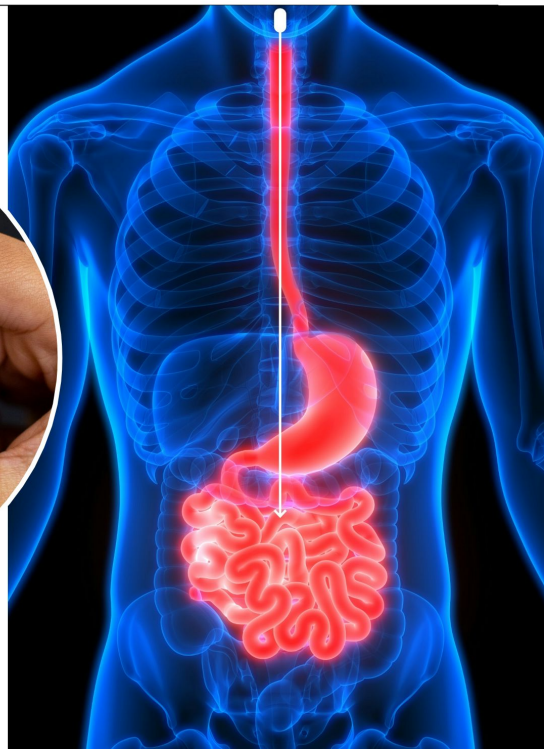
- Enteric trigger for precise timing of drug delivery to the small intestine

NEEDLE-FREE ADMINISTRATION

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

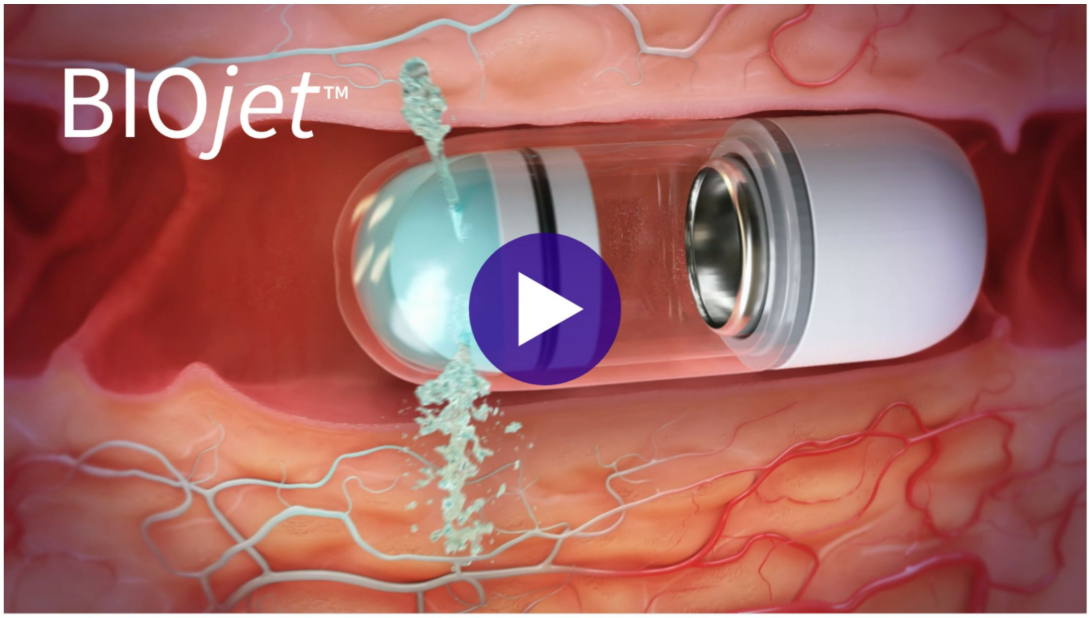
RESEARCH COLLABORATIONS

- 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

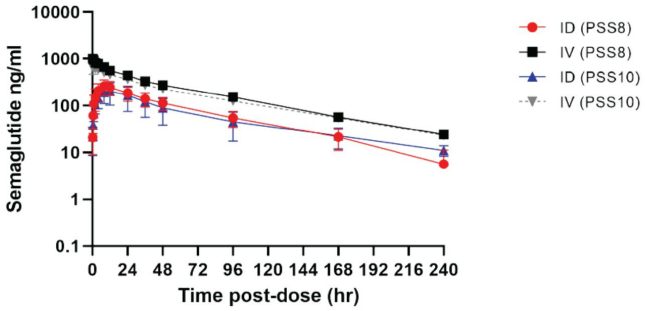
Excellent systemic uptake for orally delivered large molecules demonstrated in animals

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 (ID) 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

Achieved more than double our target bioavailability levels using next-generation device

Observed variability (CV) similar to subcutaneous injection for each drug

51.3% variant of adalimumab (monoclonal antibody) bioavailability average[1]

COMPARISON

- *15% target bioavailability[2]*
- *64% bioavailability via subcutaneous injection in humans for adalimumab[3]*

37% semaglutide (GLP-1 receptor agonist) bioavailability average[4]

COMPARISON

- *15% target bioavailability[2]*
- *1% bioavailability in humans for commercially available oral semaglutide[5]*

1. Biora Therapeutics preclinical studies in porcine model with endoscopically placed and activated next-generation device to evaluate device function. Internal data, pending presentation of results at upcoming conference(s).
2. Bioavailability target of 15% set by Biora Therapeutics and pharma collaborators for progression of systemic therapeutics platform.
3. Abbvie, Inc. Humira (adalimumab) [package insert]. U.S. Food and Drug Administration website. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125057s417lbl.pdf. Revised February 2021. Accessed March 3, 2023.
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.
5. Novo Nordisk A/S. Rybelsus (oral semaglutide) [package insert]. U.S. Food and Drug Administration website. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213051s006lbl.pdf. Revised January 2023. Accessed March 3, 2023.

DEVELOPMENT TIMELINE

Systemic Therapeutics Platform Milestones

BIOjet™

H1 2022	H2 2022	H1 2023	H2 2023	MILESTONES/CATALYSTS
Research-Grade Device Function ✓				Successfully confirmed viability of platform with research-grade device
	Next-Gen Device Development			Incorporating updated medical-grade components
		Preclinical Data Generation		Intent to replicate data from research-grade device with next-generation device
			Expand Collaborations & Partnerships	Progress existing collaborations and develop additional agreements

BIORA Therapeutics

Our mission is to reimagine therapeutic delivery

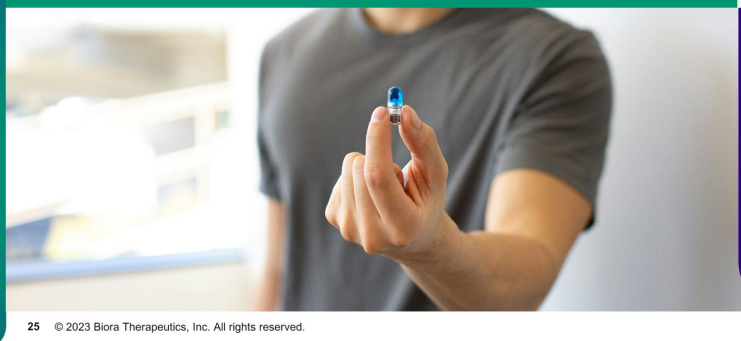
Innovating smart capsule technologies to deliver the right dose to the right place, safely

BIORA™ Therapeutics

NAVI*cap*™

TARGETED ORAL DELIVERY

- Preparing for IND filing with the FDA
- Subsequently entering the clinic with phase 1 trial



BIO*jet*™

SYSTEMIC ORAL DELIVERY

- Completing development of next-generation device
- Progressing pharma collaborations

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.

INTELLECTUAL PROPERTY PORTFOLIO

Diverse patent portfolio with 73 distinct patent families[1]

NaviCap™ Platform
31 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
5 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
37 patent families covering:

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

1. Approximately **167 granted patents** and **143 pending applications** in major countries and regions around the world


BIORA™
Therapeutics