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): March 30, 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 March 30, 2023, Biora Therapeutics, Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2022 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 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 Exhibit 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 March 30, 2023
99.2	Corporate presentation, dated March 30, 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: March 30, 2023

By: /s/ Aditya P. Mohanty

Aditya P. Mohanty
Chief Executive Officer

Exhibit 99.1

Biora Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full-Year 2022 Financial Results

Biora initiating preclinical testing with pharma collaborator's molecule following recent data exceeding the company's target bioavailability levels for systemic therapeutics platform

No adverse events indicated in 14-day tox study for targeted therapeutics program

Announcing new brand names for Biora's therapeutics platforms:; the NaviCap™ targeted oral delivery platform and the BioJet™ systemic oral delivery platform

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

SAN DIEGO, March 30, 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 fourth quarter and full year ended December 31, 2022.

Today, the company launched new brand names for its two therapeutics platforms. Its targeted therapeutics platform, previously called the Drug Delivery System (DDS), will now be known as the NaviCap™ targeted oral delivery platform. The NaviCap capsule uses autolocation technology to navigate through the GI tract and deliver drug to a targeted location.

Biora's systemic therapeutics platform, previously called the Oral Biotherapeutic Delivery System (OBDS), is now the BioJet™ systemic oral delivery platform. The BioJet device uses liquid jet injection to deliver biotherapeutics into the small intestine for uptake into systemic circulation. Biora is also taking this opportunity to update its program numbers, replacing PGN with BT, for Biora Therapeutics. A guide to the new platform names and program numbers is available in the Investor Q&A on Biora's website.

Biora recently completed execution of its 14-day toxicology study for its BT-600 program (formerly PGN-600). All planned doses were administered, and the company observed no adverse events or safety signals. The company is completing data analysis and reporting for the study, including analysis of device performance data for the over 600 devices administered during the study.

Biora also recently shared topline results from preclinical studies with two drugs using its BioJet systemic oral delivery platform, in which it achieved more than double its target bioavailability of 15% using an endoscopically placed and activated next-gen device. The company observed an average bioavailability of 37% with semaglutide, a GLP-1 receptor agonist, and an average bioavailability of 51% with adalimumab, a monoclonal antibody. These results significantly exceeded the 15% bioavailability target set by Biora and its pharma collaborators for progression of further development and testing using the platform.

"We are extremely pleased with our recent progress in development of our next-generation BioJet systemic delivery device. The excellent bioavailability results that we observed have enabled us to move forward with preclinical studies with one of our collaborator's molecules, and we are on track for our goal to progress our other collaborations and potential partnerships this year," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "For the NaviCap targeted delivery platform, we achieved an important milestone with the administration of over 600 devices during our 14-day toxicology study for BT-600, which is far more devices than we would expect to administer as part of a phase 1 study. We have some additional work to do to analyze the device performance as part of this animal study, and we look forward to sharing that data with the FDA as we move toward filing our IND for BT-600 later this year," continued Adi Mohanty.

Fourth Quarter and Full Year 2022 and Other Recent Corporate Highlights

- Launched new brands to support the company's two therapeutics platforms: the NaviCap targeted oral delivery platform and the BioJet systemic oral delivery platform.
- Announced topline preclinical results with two drugs using the BioJet systemic oral delivery platform, achieving 37% average bioavailability for a GLP-1 receptor agonist and 51% average bioavailability for a variant of adalimumab.
- Preparing to initiate preclinical studies with pharma collaborator's molecule based on the compelling bioavailability data generated recently.
- Presented detailed results from a device function study of the NaviCap platform at the Crohn's & Colitis Congress, demonstrating minimal effect of food upon device performance in healthy patients.
- Completed execution of a 14-day toxicology study for the BT-600 program with initial results indicating no adverse events or safety signals; device performance analysis is ongoing.
- Completed out-license of the Preecludia™ rule-out test for preeclampsia for commercial development.
- Raised $12.9 million in gross proceeds during the first quarter through the company's ATM program.

Fourth Quarter and Full-Year 2022 Financial Results

Comparison of Three Months Ended December 31, 2022 and September 30, 2022

Operating expenses were $13.8 million for the three months ended December 31, 2022, compared to $14.0 million for the three months ended September 30, 2022.

Net loss was $13.7 million and net loss per share was $1.64 for the three months ended December 31, 2022, compared to net loss of $5.1 million and net loss per share of $0.68 for the three months ended September 30, 2022.

Net loss from discontinued operations was $0.3 million and net loss per share was $0.03 for the three months ended December 31, 2022, compared to net gain from discontinued operations of $9.8 million and net gain per share of $1.31 for the three months ended September 30, 2022.

Comparison of Three Months Ended December 31, 2022 and 2021

Operating expenses were $13.8 million for the three months ended December 31, 2022, compared to $20.6 million for the three months ended December 31, 2021.

Net loss was $13.7 million and net loss per share was $1.64 for the three months ended December 31, 2022, compared to net loss of $92.9 million and net loss per share of $13.98 for the three months ended December 31, 2021.

Net loss from discontinued operations was $0.3 million and net loss per share was $0.03 for the three months ended December 31, 2022, compared to net loss from discontinued operations of $10.1 million and net loss per share of $1.52 for the three months ended December 31, 2021.

Comparison of Full Year Ended December 31, 2022 and 2021

The company generated $12.2 million in revenues for the year ended December 31, 2022, out of which $11.8 million came from discontinued operations, primarily due to a partial reversal of prior period accruals. The company generated $60.6 million in revenues for the year ended December 31, 2021, out of which $59.4 million came from discontinued operations. Operating expenses were $62.1 million for the year ended December 31, 2022, compared to $119.1 million for the year ended December 31, 2021.

Net loss was $38.2 million and net loss per share was $5.00 for the year ended December 31, 2022, compared to net loss of $247.4 million and net loss per share of $64.33 for the year ended December 31, 2021.

Net gain from discontinued operations was $10.7 million and net gain per share was $1.40 for the year ended December 31, 2022, compared to net loss from discontinued operations of $68.9 million and net loss per share of $17.91 for the year ended December 31, 2021.

Webcast and Conference Call Information

Biora Therapeutics will host a webcast and conference call to discuss the fourth quarter and full year 2022 financial results and answer investment community questions today, Thursday, March 30, 2023 at 4:30 PM Eastern time / 1:30 PM Pacific time.

The live call may be accessed by dialing 1-855-327-6837 (domestic) or 1-631-891-4304 (international) and entering the conference code: 10021548. 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 envisions a world where patients have access to needle-free drug delivery and better therapeutic outcomes.

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 future expectations of our research and development efforts and clinical trials and programs, the safety and efficacy profiles of our product candidates, our goals and plans regarding our IP portfolio and legacy assets and potential addressable market size, 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 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 precision medicine and develop our drug-device combinations, 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 future revenue generating opportunities with current or future pharmaceutical collaborators, our ability to raise sufficient capital to achieve our business objectives, the ongoing COVID-19 pandemic, 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	
	December 31, 2022	**September 30, 2022**
Revenues	$ 14	$ 80
Operating expenses:		
Research and development	5,767	5,820
Selling, general and administrative	8,023	8,147
Total operating expenses	13,790	13,967
Loss from operations	(13,776)	(13,887)
Interest expense, net	(2,685)	(2,773)
Gain on warrant liabilities	5,458	2,044
Other expense, net	(2,207)	(100)
Loss before income taxes	(13,210)	(14,716)
Income tax expense	259	158
Loss from continuing operations	(13,469)	(14,874)
(Loss) gain from discontinued operations	(253)	9,760
Net loss	$ (13,722)	$ (5,114)
Net loss per share from continuing operations, basic and diluted	$ (1.61)	$ (1.99)
Net (loss) gain per share from discontinued operations, basic and diluted	$ (0.03)	$ 1.31
Net loss per share, basic and diluted	$ (1.64)	$ (0.68)
Weighted average shares outstanding, basic and diluted	8,349,844	7,478,149

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Revenues	$ 14	435	$ 305	$ 1,247
Operating expenses:				
Research and development	5,767	8,485	24,049	45,785
Selling, general and administrative	8,023	12,109	38,037	73,299
Total operating expenses	13,790	20,594	62,086	119,084
Loss from operations	(13,776)	(20,159)	(61,781)	(117,837)
Interest expense, net	(2,685)	(2,186)	(10,990)	(12,636)
Gain (loss) on warrant liabilities	5,458	(48,339)	20,904	(54,157)
Other (expense) income, net	(2,207)	(12,222)	2,617	5,990
Loss before income taxes	(13,210)	(82,906)	(49,250)	(178,640)
Income tax expense (benefit)	259	(119)	(420)	(119)
Loss from continuing operations	(13,469)	(82,787)	(48,830)	(178,521)
(Loss) gain from discontinued operations	(253)	(10,087)	10,673	(68,891)
Net loss	(13,722)	(92,874)	(38,157)	(247,412)
Net loss per share from continuing operations, basic and diluted	$ (1.61)	$ (12.46)	$ (6.40)	$ (46.42)
Net (loss) gain per share from discontinued operations, basic and diluted	$ (0.03)	$ (1.52)	$ 1.40	$ (17.91)
Net loss per share, basic and diluted	$ (1.64)	$ (13.98)	$ (5.00)	$ (64.33)
Weighted average shares outstanding, basic and diluted	8,349,844	6,642,888	7,635,107	3,846,187

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

	December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 30,486	$ 88,397
Accounts receivable, net	—	653
Income tax receivable	828	—
Prepaid expenses and other current assets	4,199	7,232
Current assets of disposal group held for sale	2,603	2,493
Total current assets	38,116	98,775
Property and equipment, net	1,654	3,666
Right-of-use assets	1,482	—
Other assets	6,201	326
Goodwill	6,072	6,072
Total assets	$ 53,525	$ 108,839
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 3,606	$ 8,709
Accrued expenses and other current liabilities	16,161	34,157
Warrant liabilities	3,538	18,731
Current portion of capital lease obligations	—	12
Total current liabilities	23,305	61,609
Convertible notes, net	127,811	126,392
Other long-term liabilities	4,696	5,814
Total liabilities	$ 155,812	$ 193,815
Stockholders' deficit:		
Common stock	8	6
Additional paid-in capital	743,626	722,782
Accumulated deficit	(826,843)	(788,686)
Treasury stock	(19,078)	(19,078)
Total stockholders' deficit	(102,287)	(84,976)
Total liabilities and stockholders' deficit	$ 53,525	$ 108,839

Exhibit 99.2

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

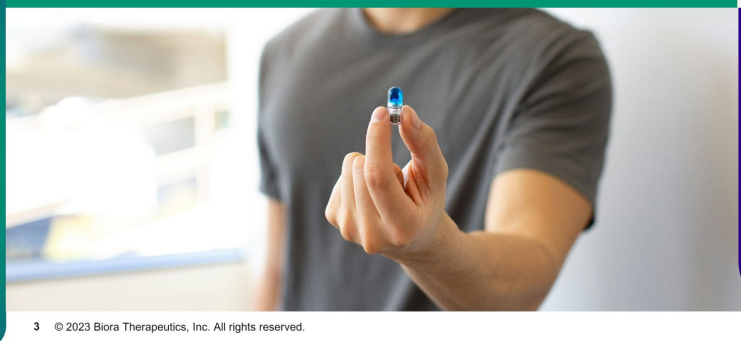
Innovating smart capsule technologies to deliver the right dose to the right place, safely

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

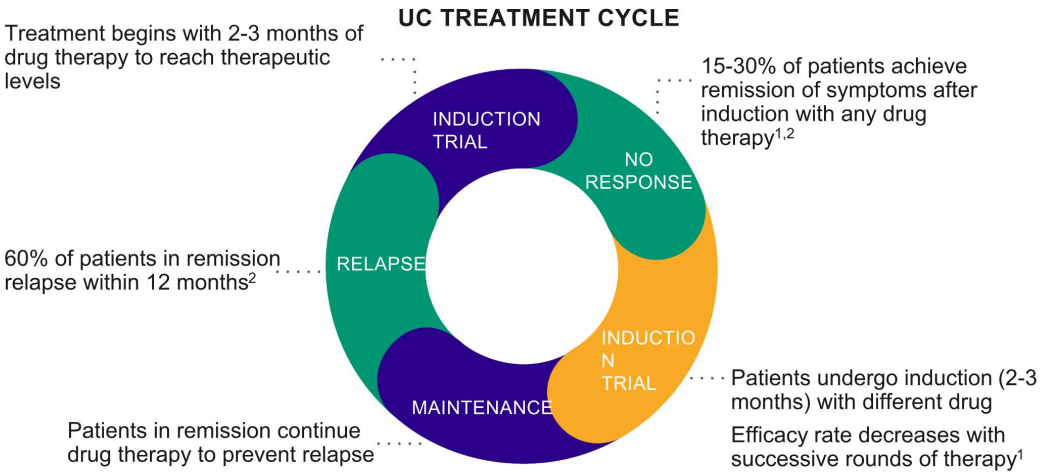
	PROGRAM	INDICATION	DESIGN/FEASIBILITY	PRECLINICAL	CLINICAL
TARGETED THERAPEUTICS	**NaviCap™** Targeted Oral Delivery Platform	--			
	BT-600 NaviCap + tofacitinib	UC			
	BT-001 NaviCap + adalimumab variant	UC			
SYSTEMIC THERAPEUTICS	**BioJet™** Systemic Oral Delivery Platform	--			
	BT-200 BioJet + GLP-1 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			

NAVI*cap*™

TARGETED ORAL DELIVERY PLATFORM

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

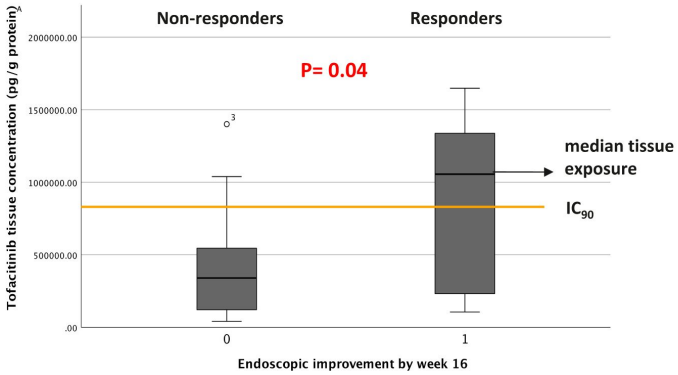
Tissue drug concentration correlates with endoscopic outcomes in UC

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

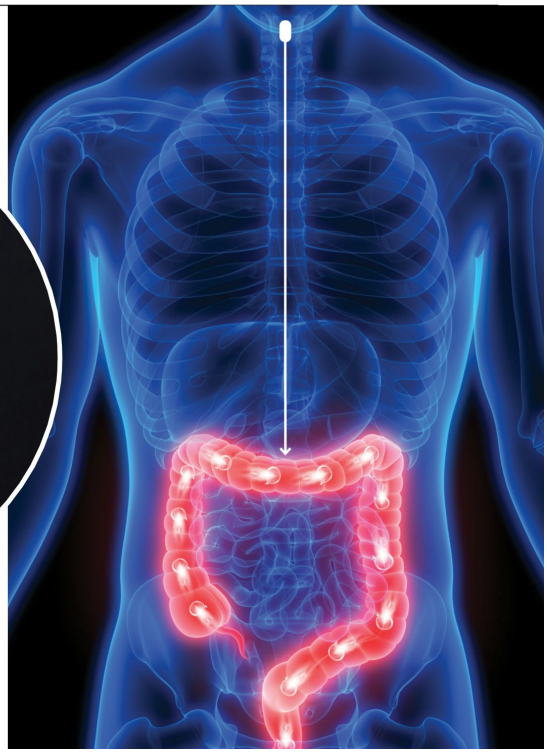
- Convenient oral capsule the size of a fish-oil pill

AUTONOMOUS LOCATION

- Proprietary GITrac™ autolocation technology for accurate drug delivery regardless of fasted or fed state[1]

TARGETED DRUG DELIVERY

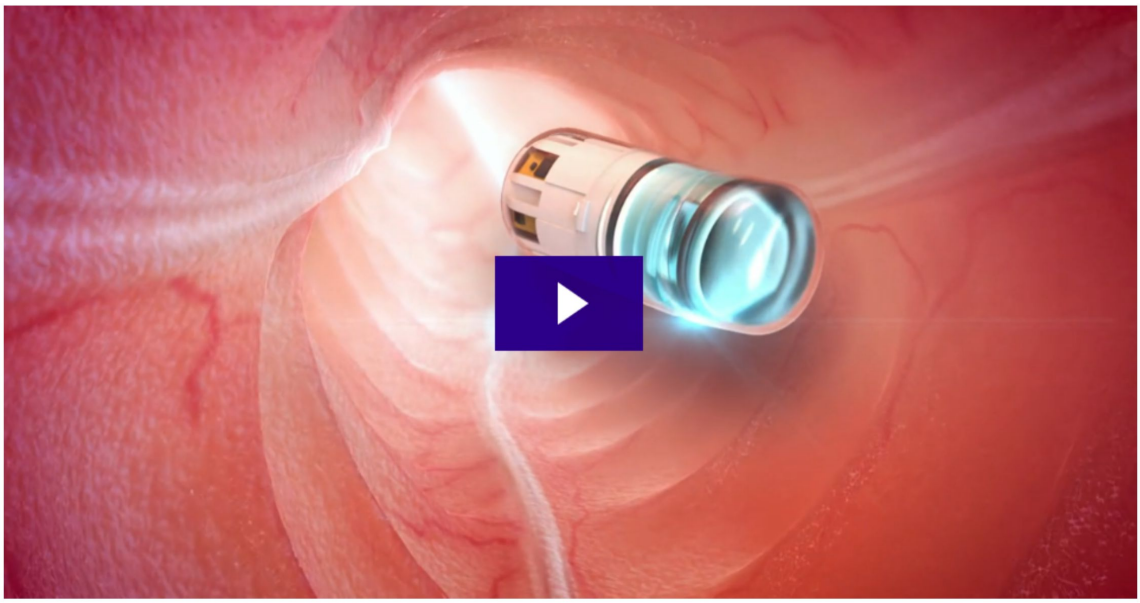
- Method designed to coat the length of the colon with liquid formulation, minimizing systemic uptake



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

NAVICAP™ TARGETED DRUG DELIVERY PLATFORM

Autonomous location and delivery to the colon



SCAN ME

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

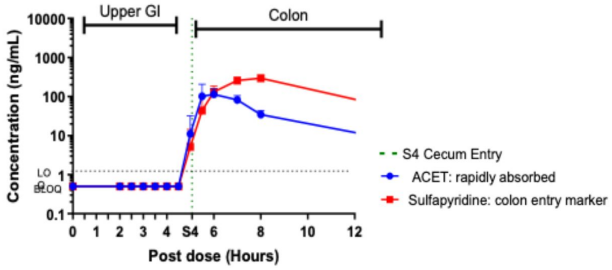
DEVICE FUNCTION STUDIES

Demonstrated accurate localization and delivery to colon

NAVIcap™

ACCURATE DELIVERY TO COLON IN CANINES

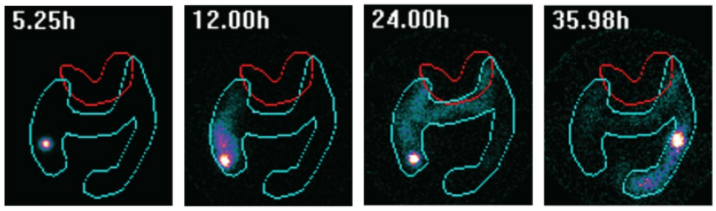
Pharmacokinetic data from two marker drugs administered in canine model



- 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

Three successful studies demonstrating device function in humans

NAVIcap™

PM-601 Device Function Study in Healthy Volunteers – Fasted State	PM-611 Device Function Study in Healthy Volunteers – Fasted and Fed	PM-602 Device Function Study in Patients with Active UC
• 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 analyzed devices successfully identified entry to the colon and activated H2 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] • No serious adverse events reported[2]	• 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] • Device was well tolerated and performed as intended in active ulcerative colitis patients[3]
DEVICE FUNCTION IN HEALTHY VOLUNTEERS ✓	**DEVICE FUNCTION WITH / WITHOUT FOOD** ✓	**DEVICE FUNCTION IN ACTIVE UC PATIENTS** ✓

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.

BIORA Therapeutics

BT-600 (NAVICAP™ + TOFACITINIB) PRECLINICAL STUDY RESULTS

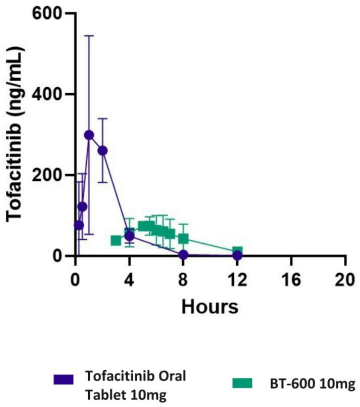
Reduced systemic uptake, better PK effect and coverage

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)

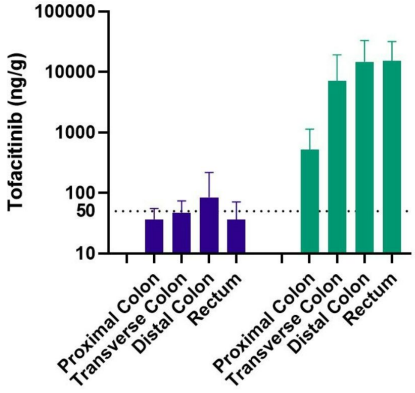
RESULTS

- 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

PLASMA LEVEL CMAX ~5X LOWER



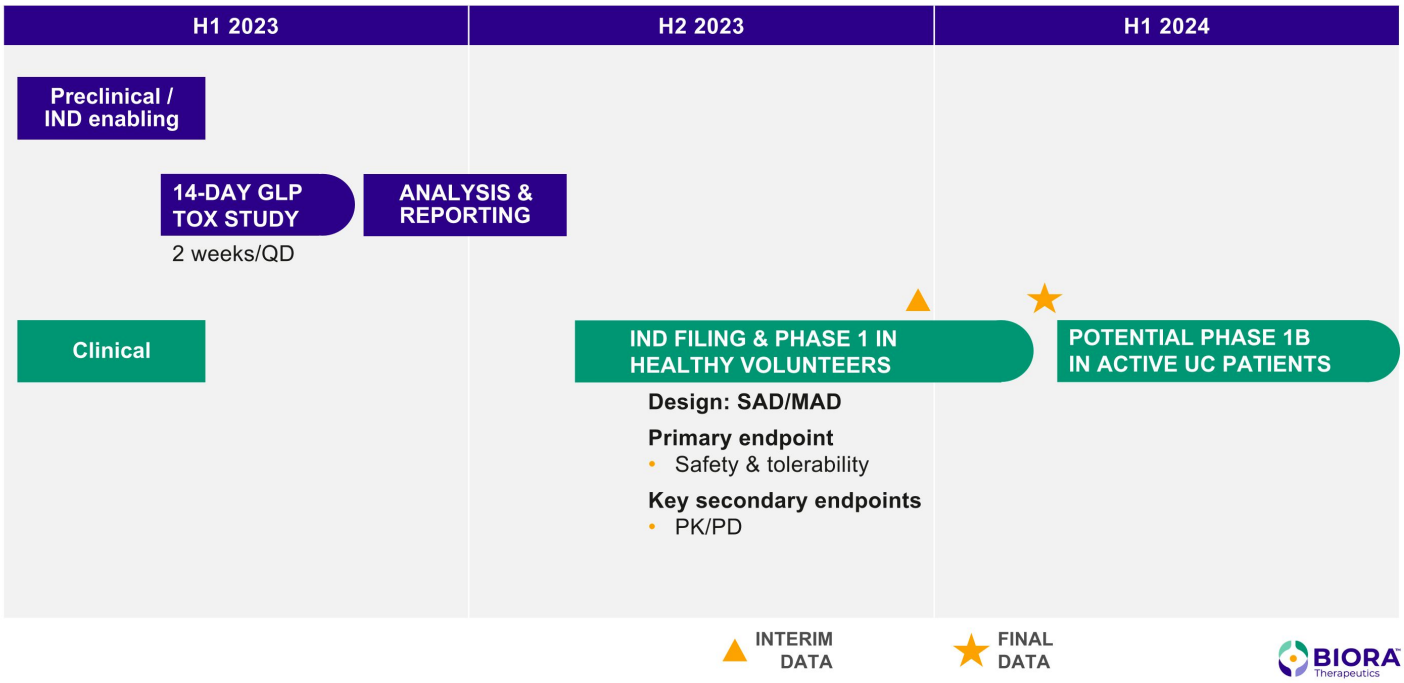
COLON TISSUE COVERAGE ~100X HIGHER



Biora Therapeutics internal data

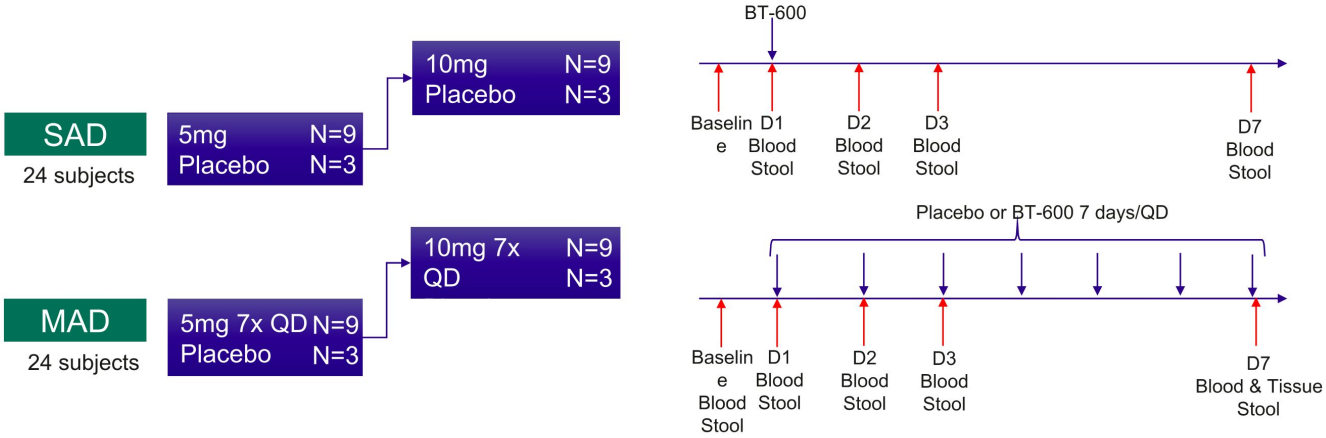
BT-600 (NAVICAP™ + TOFACITINIB)

Clinical Development Plan



PHASE 1: SINGLE AND MULTIPLE ASCENDING DOSE STUDIES

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

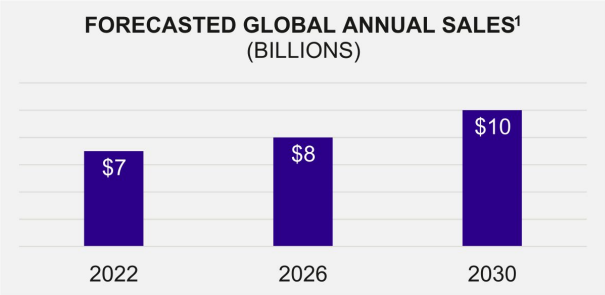


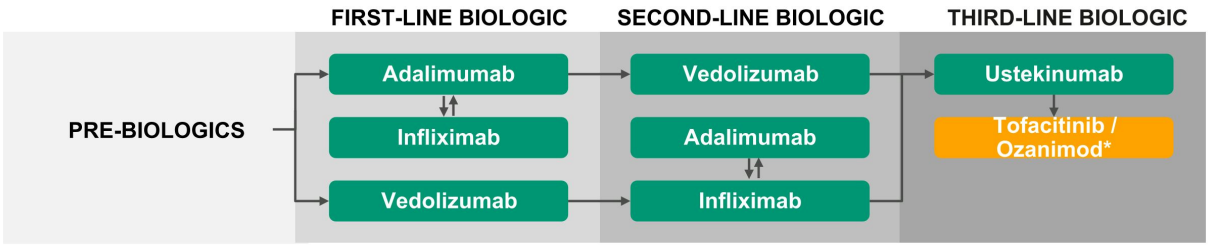
PATIENT POPULATION	Normal healthy volunteers Total of 48 subjects (24 SAD and 24 MAD subjects)
STUDY DESIGN	Randomized, double-blind (participant and site), placebo-controlled study to evaluate the safety, tolerability, and PK/PD of SAD and MAD doses of BT-600 in healthy subjects
OBJECTIVES	Demonstrate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

ULCERATIVE COLITIS: TREATMENT LANDSCAPE

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

BIO*jet*™

SYSTEMIC ORAL DELIVERY PLATFORM

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

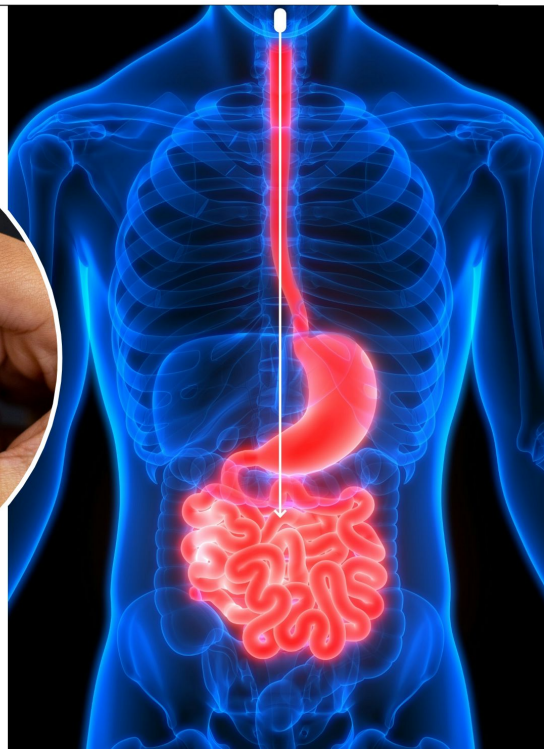
Enteric trigger for precise timing of drug delivery to the small intestine

NEEDLE-FREE ADMINISTRATION

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

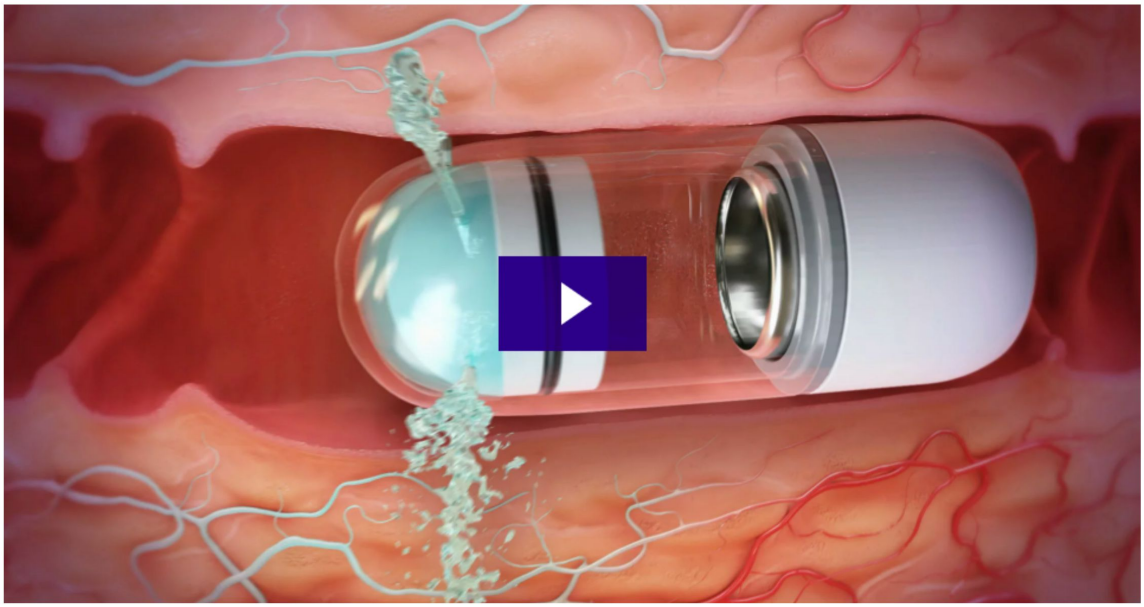
RESEARCH COLLABORATIONS

- 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

BT-200 PRECLINICAL PERFORMANCE

Excellent systemic uptake for orally delivered large molecules demonstrated in animals

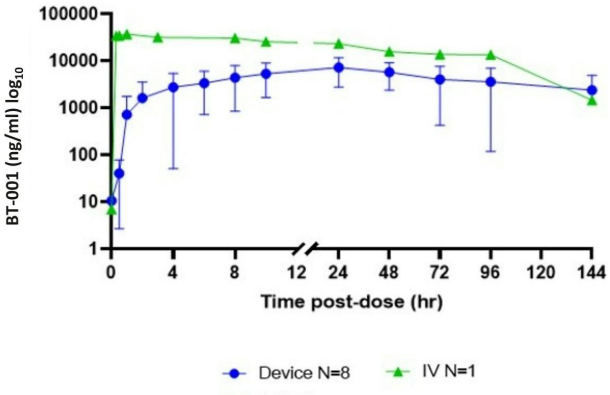
Preclinical studies in (1) swine model with endoscopically placed, autonomous device compared to IV administration of a variant of adalimumab (BT-001) and (2) canine model with autonomous device to evaluate device function and safety

RESULTS

Recently published data demonstrated:

- Average bioavailability of 22% (up to 55%) for BT-001 in swine where drug was detected in blood[1]
  - *For comparison, commercially available oral large molecules achieve 1% or less bioavailability*[2]
- In canines, ≥ 83% deployment accuracy and consistent deployment time post gastric emptying in the small intestine, with no early deployment[1]
- No issues observed with safety or tolerability of the device[3]

BIOAVAILABILITY COMPARABLE TO IV



1. Lee SN, Stork C, Smith J, et al. Development of a submucosal injection device for an oral biotherapeutic delivery system. Poster presented at: *Parenteral Drug Association Universe of Pre-Filled Syringes and Injection Devices Conference*. October 18-19, 2022. Palm Springs, CA.
2. 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.
3. Biora Therapeutics internal data

PRECLINICAL RESULTS

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

BIOjet™

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[1]

COMPARISON

- *15% target bioavailability[2]*
- *1% bioavailability in humans for commercially available oral semaglutide[4]*

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. 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.

BIORA Therapeutics

DEVELOPMENT TIMELINE

Systemic Therapeutics Platform Milestones

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

Our mission is to reimagine therapeutic delivery

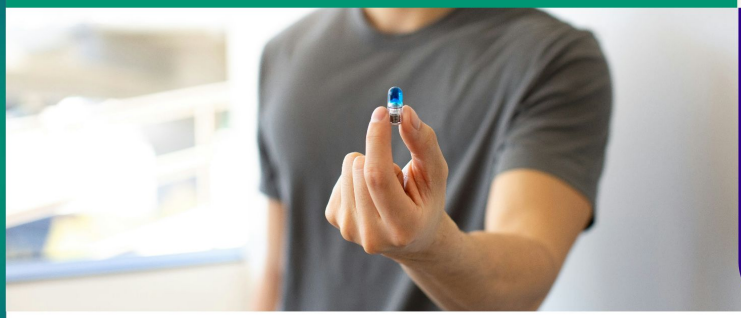
Innovating smart capsule technologies to deliver the right dose to the right place, safely

BIORA™ Therapeutics

NAVI*cap*™

TARGETED ORAL DELIVERY

- Completing tox study analysis
- Preparing to file IND and enter the clinic



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.

INTELLECTUAL PROPERTY PORTFOLIO

Diverse patent portfolio with 68 distinct patent families[1]

DEVICES
36 patent families covering:

- Device designs, materials, components & manufacturing
- GI localization
- Devices for targeted delivery to GI tract
- Devices for targeted GI sampling systems
- Devices for jet delivery into GI tissue

THERAPEUTICS
26 patent families covering:

- Treatment via ingestible device
- GI delivery PK/PD profiles
- GI delivery dosing regimens
- GI delivery drug combinations
- Liquid drug formulations

SAMPLING & DIAGNOSTICS
6 patent families covering:

- GI sample preservation
- GI analyte detection & quantification systems
- Complementary diagnostic markers

1. Approximately **165 issued patents** and **137 pending applications** in major countries and regions around the world


BIORA™
Therapeutics