UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 14, 2022

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: (855) 293-2639

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

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

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

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

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

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

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

Item 2.02 Results of Operations and Financial Condition.

On November 14, 2022, Biora Therapeutics, Inc. issued a press release announcing its financial results for the second quarter ended September 30, 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 November 14, 2022
99.2	Corporate presentation, dated November 14, 2022
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

SIGNATURES

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

Biora Therapeutics, Inc.

Date: November 14, 2022

By: /s/ Aditya P. Mohanty

Aditya P. Mohanty
Chief Executive Officer

Exhibit 99.1

Biora Therapeutics Provides Corporate Update and Reports Third Quarter 2022 Financial Results

Presented results of human study at the American College of Gastroenterology annual meeting, demonstrating promising device performance in active ulcerative colitis patients

Executed a registered direct capital raise of $9.75 million

Presented preclinical results demonstrating the possibilities for systemic delivery of large molecules using the company's systemic delivery platform

Received key patent for oral delivery of GLP-1 receptor agonist

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

SAN DIEGO, November 14, 2022 – Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutic delivery, today provided a corporate update and reported financial results for the third quarter ended September 30, 2022.

During the third quarter, the company shared the results of its PM-602 device function study, which assessed the safety and performance of the company's targeted delivery device in active ulcerative colitis patients, at the American College of Gastroenterology annual meeting. In the study, the device accurately identified entry into the colon, triggered release of a non-drug liquid payload, and achieved distribution across the entire colon in seven patients. These results demonstrate the potential of the targeted therapeutics platform to transform management of ulcerative colitis by improving efficacy through increased drug concentration in the colon, while potentially minimizing the harmful side effects associated with high systemic drug uptake.

Additionally, the company recently announced a registered direct financing raising $9.75 million in total, with $6 million in gross proceeds from an existing investor and $3.75 million reinvested by Athyrium from the interest on convertible notes held by the firm, demonstrating continued commitment by existing investors to support Biora's key programs. These funds, combined with cash on hand, will help the company work toward important clinical milestones coming up in 2023.

Biora also shared preclinical results from its systemic therapeutics program, demonstrating promising device performance using liquid jet injection to the small intestine in animal models. The company successfully demonstrated ≥83% deployment accuracy in the canine small intestine and average bioavailability of 22% (up to 55%) for a variant of adalimumab in swine where drug was detected in blood. Results were presented at the Controlled Release Society Annual Meeting, the Parenteral Drug Association Universe of Pre-Filled Syringes and Injection Devices Conference, and the American College of Gastroenterology Annual Scientific Meeting.

Biora continued to strengthen its intellectual property portfolio during the third quarter with a newly-issued patent covering jet delivery of any glucagon-like peptide-1 (GLP-1) receptor agonist formulation to the small intestine for treatment of any disease, including type 2 diabetes.

According to leading analytics firm GlobalData, the GLP-1 receptor agonist market is forecasted to be well over $20 billion by 2025.

“We are extremely pleased with the ongoing development of our targeted drug delivery platform and have demonstrated that our device functions as intended in ulcerative colitis patients, which is a key step in advancing our PGN-600 program. We are on track to initiate clinical studies for our drug-device combination early next year” said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. “We are very excited about the opportunity to improve treatment for patients with ulcerative colitis. We also continue to progress our systemic therapeutics platform, strengthen our IP portfolio, and seek to find ways to monetize legacy assets to generate value for our investors.”

Third Quarter 2022 and Recent Corporate Highlights

- Presented results of the company's PM-602 study for its targeted therapeutics platform at the American College of Gastroenterology annual meeting, demonstrating successful device performance in active ulcerative colitis patients
- Executed a registered direct financing raise of $9.75 million
- Presented results of preclinical studies for the company's systemic therapeutics platform, demonstrating promising bioavailability and device performance in animal models
- Received a key patent for oral delivery of any GLP-1 receptor agonist for the systemic therapeutics platform
- Announced sale of patent rights related to methods for determining the origin of cell-free DNA to Roche Diagnostics, as Biora continues generating value from legacy assets

Third Quarter 2022 Financial Results

Comparison of Three Months Ended September 30, 2022 and June 30, 2022

The company generated $10.0 million in revenues during the third quarter, out of which $9.9 million came from discontinued operations, primarily due to a partial reversal of prior period accruals. The company generated $0.9 million in revenues during the second quarter, out of which $0.8 million came from discontinued operations. Operating expenses were $14.1 million for the three months ended September 30, 2022, compared to $14.6 million for the three months ended June 30, 2022, out of which $0.2 million and $0.3 million, respectively came from discontinued operations.

Net loss was $5.1 million and net loss per share was $0.03 for the three months ended September 30, 2022, compared to net loss of $5.5 million and net loss per share of $0.03 for the three months ended June 30, 2022.

Net gain from discontinued operations was $9.8 million and net gain per share was $0.05 for the three months ended September 30, 2022, compared to net gain from discontinued operations of $0.5 million with no impact to loss per share for the three months ended June 30, 2022.

Comparison of Three Months Ended September 30, 2022 and 2021

The company generated $10.0 million in revenues for three months ended September 30, 2022, out of which $9.9 million came from discontinued operations primarily due to a partial reversal of prior period accruals. The company generated $9.7 million in revenues for the three months ended September 30, 2021, out of which $9.5 million came from discontinued operations. Operating expenses were $14.1 million for the three months ended September 30, 2022, compared to $37.0 million for the three months ended September 30, 2021, out of which $0.2 million and $6.3 million, respectively, came from discontinued operations.

Net loss was $5.1 million and net loss per share was $0.03 for the three months ended September 30, 2022, compared to net loss of $43.7 million and net loss per share of $0.46 for the three months ended September 30, 2021.

Net gain from discontinued operations was $9.8 million and net gain per share was $0.05 for the three months ended September 30, 2022, compared to net loss from discontinued operations of $6.9 million and net loss per share of $0.07 for the three months ended September 30, 2021.

Webcast and Conference Call Information

Biora Therapeutics will host a webcast and conference call to discuss the third quarter financial results and answer investment community questions today, Monday, November 14, 2022 at 4:30 p.m. Eastern / 1:30 p.m. Pacific.

The live call may be accessed by dialing 1-877-423-9813 (domestic) or 1-201-689-8573 (international) and entering the conference code: 13731511. 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, 2021 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.

Exhibit 99.1

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

Media Contact
media@bioratherapeutics.com

Exhibit 99.1

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

	Three Months Ended	
	September 30, 2022	June 30, 2022
Revenues	$ 80	$ 104
Operating expenses:		
Research and development	5,820	5,904
Selling, general and administrative	8,147	8,410
Total operating expenses	13,967	14,314
Loss from operations	(13,887)	(14,210)
Interest expense, net	(2,773)	(2,772)
Gain on warrant liability	2,044	4,413
Other (expense) income, net	(100)	5,735
Loss before income taxes	(14,716)	(6,834)
Income tax (expense) benefit	(158)	837
Loss from continuing operations	(14,874)	(5,997)
Gain from discontinued operations	9,760	484
Net loss	$ (5,114)	$ (5,513)
Net loss per share from continuing operations, basic and diluted	$ (0.08)	$ (0.03)
Net gain per share from discontinued operations, basic and diluted	$ 0.05	$ —
Net loss per share, basic and diluted	$ (0.03)	$ (0.03)
Weighted average shares outstanding, basic and diluted	186,953,741	184,371,626

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

	Three Months Ended September 30,	
	2022	**2021**
Revenues	$ 80	$ 182
Operating expenses:		
Research and development	5,820	12,226
Selling, general and administrative	8,147	18,517
Total operating expenses	13,967	30,743
Loss from operations	(13,887)	(30,561)
Interest expense, net	(2,773)	(3,458)
Gain (loss) on warrant liability	2,044	(3,322)
Other (expense) income, net	(100)	467
Loss before income taxes	(14,716)	(36,874)
Income tax expense	(158)	—
Loss from continuing operations	(14,874)	(36,874)
Gain (loss) from discontinued operations	9,760	(6,870)
Net loss	$ (5,114)	$ (43,744)
Net loss per share from continuing operations, basic and diluted	$ (0.08)	$ (0.38)
Net gain (loss) per share from discontinued operations, basic and diluted	$ 0.05	$ (0.07)
Net loss per share, basic and diluted	$ (0.03)	$ (0.46)
Weighted average shares outstanding, basic and diluted	186,953,741	95,846,672

Exhibit 99.1

BIORA Therapeutics

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

	September 30, 2022	December 31, 2021 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 37,060	$ 88,397
Accounts receivable, net	—	653
Income tax receivable	828	—
Prepaid expenses and other current assets	6,259	7,232
Current assets of disposal group held for sale	2,213	2,147
Total current assets	46,360	98,429
Property and equipment, net	2,112	4,012
Right-of-use assets	1,843	—
Other assets	6,227	326
Goodwill	6,072	6,072
Total assets	$ 62,614	$ 108,839
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 2,356	$ 8,709
Accrued expenses and other current liabilities	21,750	34,157
Warrant liability	3,285	18,731
Current portion of capital lease obligations	—	12
Total current liabilities	27,391	61,609
Convertible notes, net	127,445	126,392
Other long-term liabilities	5,221	5,814
Total liabilities	$ 160,057	$ 193,815
Stockholders' deficit:		
Common stock	153	146
Additional paid-in capital	734,607	722,646
Accumulated deficit	(813,121)	(788,686)
Treasury stock	(19,082)	(19,082)
Total stockholders' deficit	(97,443)	(84,976)
Total liabilities and stockholders' deficit	$ 62,614	$ 108,839

(1) The condensed consolidated balance sheet data as of December 31, 2021 has been derived from the audited consolidated financial statements

Exhibit 99.2


BIORA™
Therapeutics
CORPORATE
PRESENTATION
November 2022

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 difficulties in managing changes to our organization due to our strategic transformation; 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, 2021, 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

TARGETED ORAL DELIVERY OF BIOTHERAPEUTICS

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

SYSTEMIC ORAL DELIVERY OF BIOTHERAPEUTICS

Ingestible technology designed to enable needle-free, systemic delivery of large molecules for better management of chronic diseases

THERAPEUTIC PIPELINE

	PROGRAM	INDICATION	DESIGN/FEASIBILITY	PRECLINICAL	CLINICAL
TARGETED THERAPEUTICS	**DDS** Device	--			
	PGN-600 Tofacitinib + Device	UC			
	PGN-001 Adalimumab variant + Device	UC			
SYSTEMIC THERAPEUTICS	**OBDS** Device	--			
	PGN-OB2 GLP-1 agonist + Device	Diabetes			
	PGN-OB1 Adalimumab variant + Device	Autoimmune			
	Ionis Collaboration Antisense therapy + Device	Undisclosed			
	Large Pharma 1 Collaboration Undisclosed drug + Device	Undisclosed			
	Large Pharma 2 Collaboration Undisclosed drug + Device	Undisclosed			

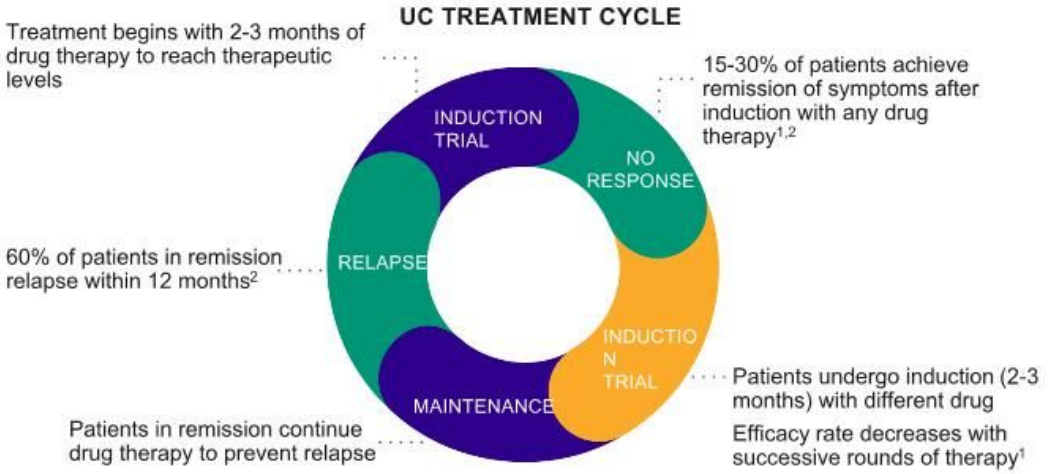
BIORA Therapeutics

TARGETED THERAPEUTICS

ULCERATIVE COLITIS: THE TREATMENT GAP

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

UC TREATMENT CYCLE



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]

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.

UNMET NEED IN ULCERATIVE COLITIS

TARGETED THERAPEUTICS

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]

Research 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.

Tissue drug concentration correlates with endoscopic outcomes in UC

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

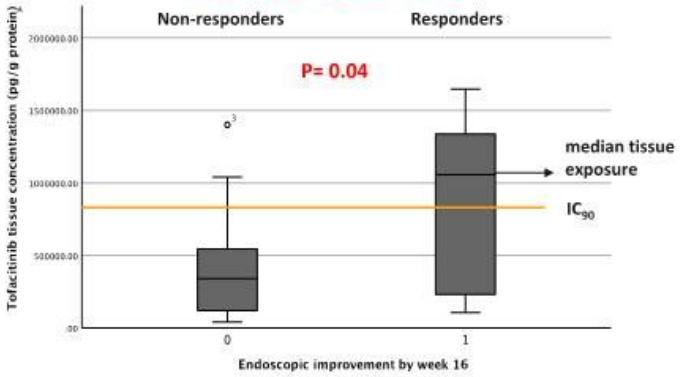
RESULTS

- 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:

KU LEUVEN IBD Leuven Amsterdam UMC University Medical Centers

TOFACITINIB TISSUE EXPOSURE EXCEEDED IC_{90} IN RESPONDERS



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

TARGETED THERAPEUTIC DELIVERY FOR IBD

TARGETED THERAPEUTICS

Needle-free, oral drug delivery to the colon

ORAL ADMINISTRATION

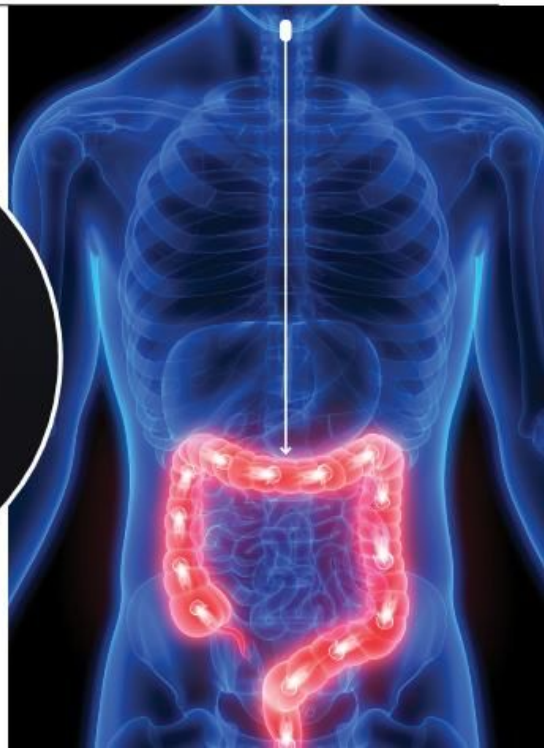
- Convenient oral capsule the size of a fish-oil pill

AUTONOMOUS LOCATION

- Proprietary autolocation in the GI tract 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

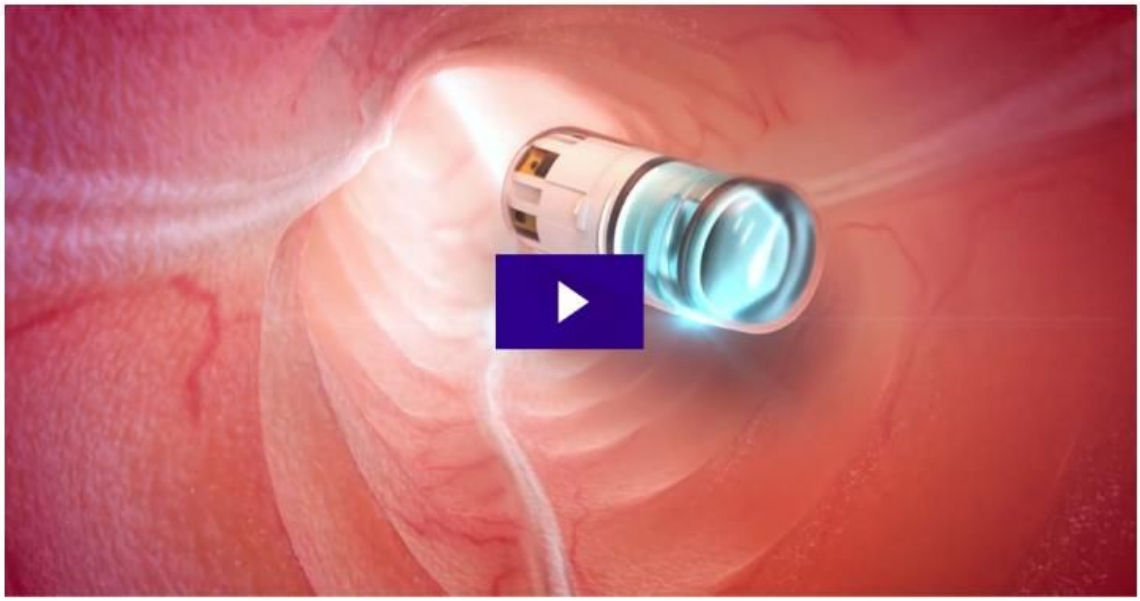


1. Biora Therapeutics internal data

TARGETED THERAPEUTIC DELIVERY FOR IBD

Autonomous location and delivery to the colon

TARGETED THERAPEUTICS



SCAN ME

https://biora.wistia.com/medias/n65935rbqa

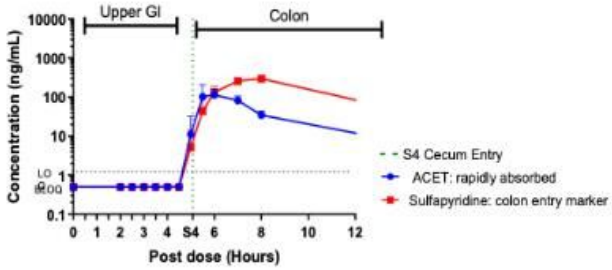
BIORA Therapeutics

Demonstrated accurate localization and delivery to colon

TARGETED THERAPEUTICS

ACCURATE DELIVERY TO COLON IN CANINES

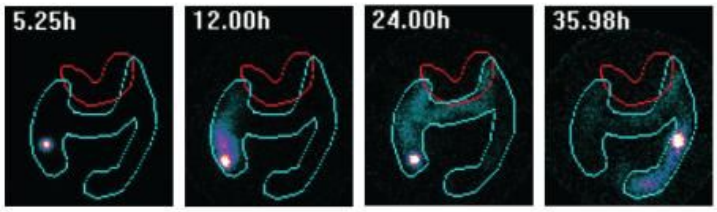
Pharmacokinetic data from two marker drugs administered in canine model



- Successful delivery to colon via DDS
- 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

TARGETED THERAPEUTICS

Three successful studies demonstrating device function in humans

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 indicated entry to the colon, activation, and deployment, and were unaffected by food (39/39)[2] • No failure modes observed in the analyzed devices[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. Biora Therapeutics internal data
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

PGN-600 PRECLINICAL STUDY RESULTS

TARGETED THERAPEUTICS

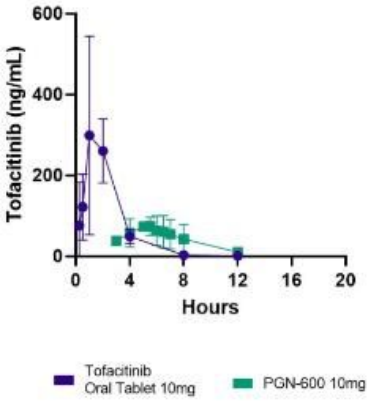
Reduced systemic uptake, better PK effect and coverage

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

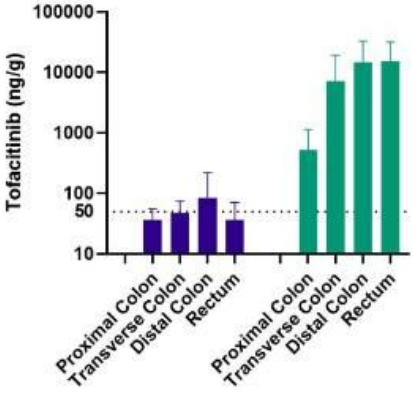
RESULTS

- 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



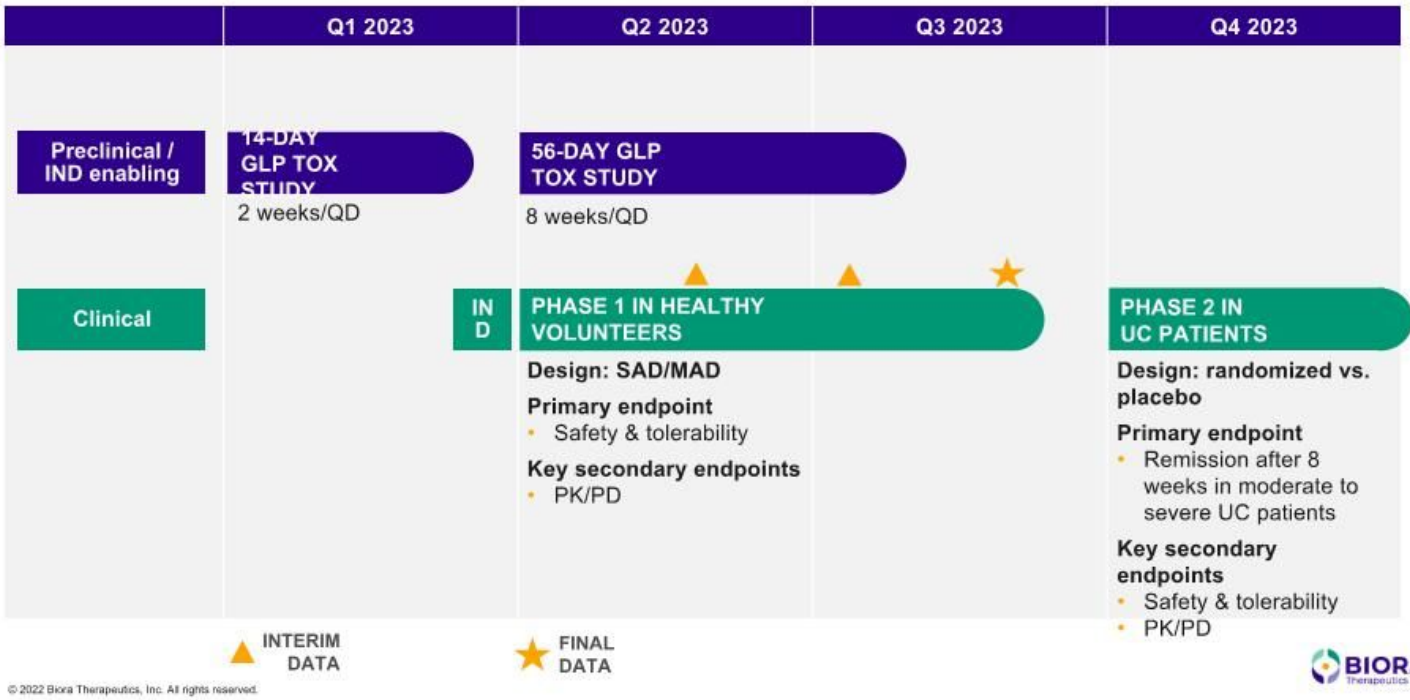
Biora Therapeutics internal data

BIORA Therapeutics

PGN-600 (TOFACITINIB + DDS DEVICE)

Clinical Development Plan

TARGETED THERAPEUTICS

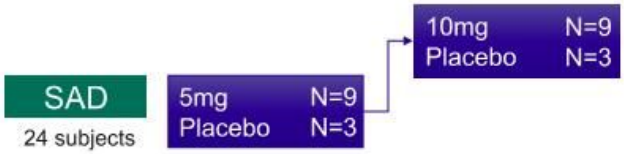


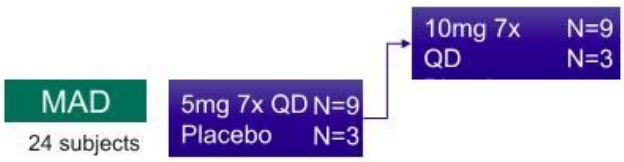
BIORA Therapeutics

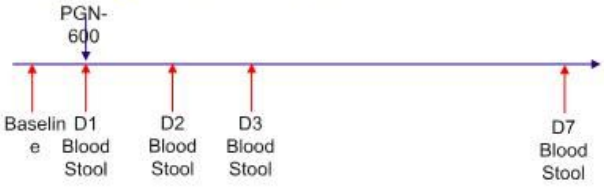
PHASE 1: SINGLE AND MULTIPLE ASCENDING DOSE STUDIES

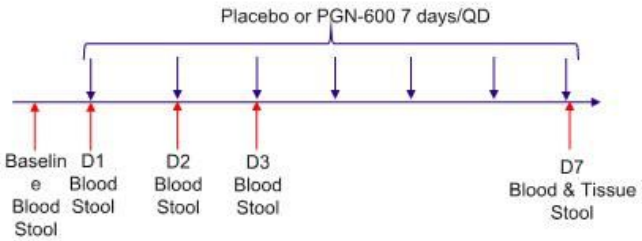
TARGETED THERAPEUTICS

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









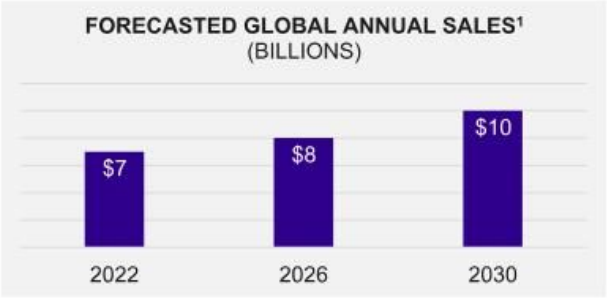
PATIENT POPULATION	Normal healthy volunteers Total of 48 subjects (24 SAD and 24 MAD subjects)
STUDY DESIGN	Randomized, double-blind (participant and site), placebo-controlled study to evaluate the safety, tolerability, and PK/PD of SAD and MAD doses of PGN-600 in healthy subjects
OBJECTIVES	Demonstrate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

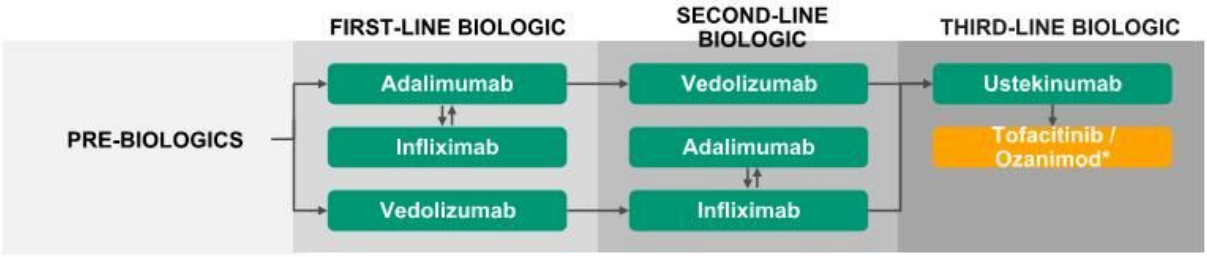
BIORA Therapeutics

TARGETED THERAPEUTICS

Potential for market-leading efficacy in tofacitinib creates sizeable opportunity

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





1. Source: Evaluate Pharma; GlobalData

*Non-biologic drug therapies

BIORA Therapeutics


SYSTEMIC THERAPEUTICS

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

ORAL BIOTHERAPEUTICS DELIVERY SYSTEM

Needle-free, oral delivery to small intestine

SYSTEMIC THERAPEUTICS

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

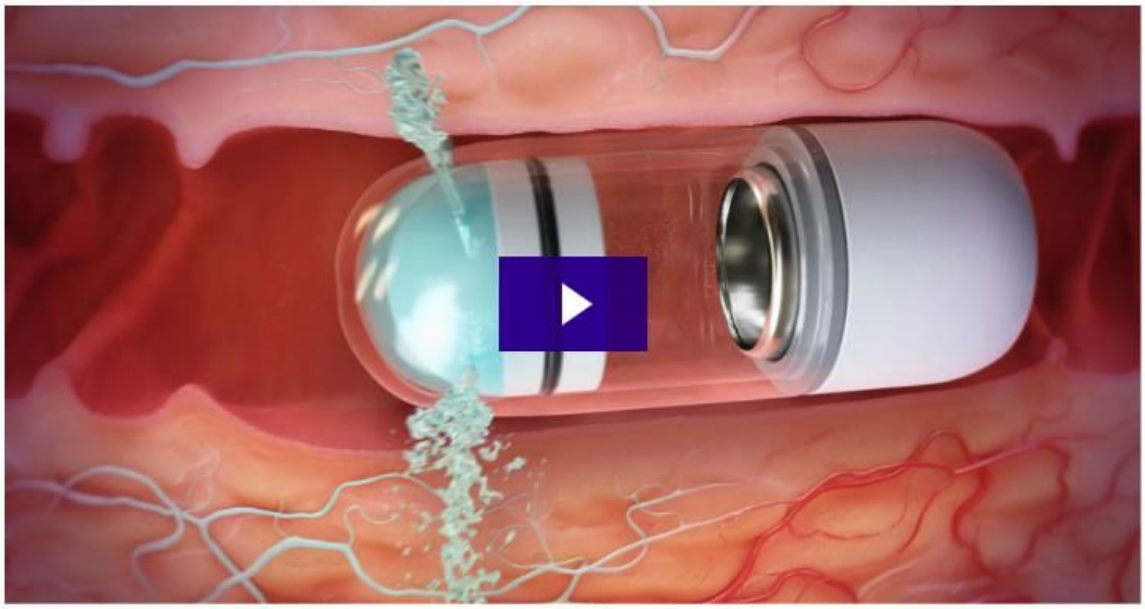
RE IONIS I COLLABORATIONS

-
- Large Pharma 1
- Large Pharma 2

ORAL BIOTHERAPEUTICS DELIVERY SYSTEM

Liquid jet delivery to the small intestine

SYSTEMIC THERAPEUTICS



SCAN ME

https://biora.wistia.com/medias/smbr15eh3a

BIORA Therapeutics

SYSTEMIC THERAPEUTICS

Excellent systemic uptake for orally delivered large molecules demonstrated in animals

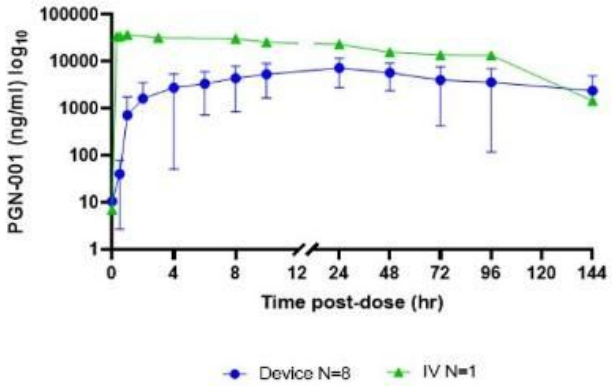
Preclinical studies in (1) swine model with endoscopically placed, autonomous device compared to IV administration of a variant of adalimumab (PGN-001) and (2) canine model with autonomous device to evaluate device function and safety

RESULTS

Recently published data demonstrated:

- Average bioavailability of 22% (up to 55%) for PGN-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, J.H., 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. Rybelsus® oral Semaglutide delivered as an oral tablet.
3. Biora Therapeutics internal data

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DEVELOPMENT TIMELINE

Systemic Therapeutics Platform Milestones

SYSTEMIC THERAPEUTICS

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

Reimagining therapeutic delivery

BIORA Therapeutics

TARGETED THERAPEUTICS

- Clinical-ready device
- Entering the clinic

SYSTEMIC THERAPEUTICS

- Refining preclinical models
- Data generation and partnership

APPENDIX

TARGETED THERAPEUTICS PUBLICATIONS

bioratherapeutics.com/publications

TARGETED THERAPEUTICS

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.

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 74 distinct patent families[1]

DEVICES
39 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
25 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
10 patent families covering:

- GI sample preservation
- GI analyte detection & quantification systems
- Complementary diagnostic markers
- Protein and nucleic acid markers & assays

1. Approximately **144 issued patents and 160 pending applications** in major countries and regions around the world


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Therapeutics