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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 15, 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 August 15, 2022, Biora Therapeutics, Inc. issued a press release announcing its financial results for the second quarter ended June 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 August 15, 2022
99.2	Corporate presentation, dated August 15, 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: August 15, 2022

By: /s/ Aditya P. Mohanty

Aditya P. Mohanty
Chief Executive Officer

Exhibit 99.1

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

Successfully completed PM-602 human study for its targeted therapeutics platform demonstrating promising device performance in active ulcerative colitis patients

Successfully completed PM-611 human study for its targeted therapeutics platform in healthy volunteers showing promising performance regardless of feeding schedule

Confirmed planned phase 1 IND filing in Q1 based on FDA feedback on PGN-600 program in Ulcerative Colitis

Strengthened patent position for both targeted and systemic therapeutics platforms

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

SAN DIEGO, August 15, 2022 – Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutics, today provided a corporate update and reported financial results for the second quarter ended June 30, 2022.

During the second quarter, the company completed its PM-611 device function study which assessed whether the autonomous location functionality of the ingestible devices designed for targeted drug delivery was impacted by a fed state as compared to a fasted state. The study demonstrated that all analyzed capsules indicated entry to the colon, activation, and deployment, regardless of fasted or fed schedule, with no failure modes observed in the analyzed devices. These study results suggest that the Drug Delivery System (DDS) capsule could be the first ingestible therapeutic delivery device that does not require fasting or other food restriction for use, which may be an important consideration for patients who need frequent dosing in chronic diseases like ulcerative colitis.

The company also recently announced topline results from its PM-602 device function study that assessed the safety and performance of the targeted delivery device in active ulcerative colitis patients. The study demonstrated that the device was well tolerated, and that the device performed as intended in active ulcerative colitis (UC) patients. In all seven patients, the device accurately identified entry into the colon, triggered release of a non-drug liquid payload, and achieved distribution across the entire colon. The company is not aware of any other oral drug delivery technology that accurately detects colon entry, especially in the environment of inflammation, blood and highly variable motility seen in active ulcerative colitis.

In the second quarter the company submitted a Type C filing to the United States Food and Drug Administration (FDA) asking for feedback on its proposed PGN-600 clinical development plan related to its targeted therapeutics platform. In a constructive response received recently, the FDA generally agreed with the proposed clinical trial design and provided helpful feedback on protocols. The FDA also reviewed the proposed supporting data package and confirmed the anticipated need for additional toxicology data. The company believes it will be in a position to file an IND in Q1 2023 to support the initiation of its Phase 1 clinical study.

Finally, Biora strengthened its intellectual property (IP) portfolio during the second quarter with a newly issued US patent and the allowance of two additional US patent applications. The issued US patent (No. 11,363,964) is directed to the company's targeted delivery localization technology used in the DDS device which enables detection of device entry into the colon. This builds on the company's proprietary localization technology portfolio, which includes 29 issued patents worldwide, including multiple patents issued in both the US and Europe. Related to the company's systemic therapeutics platform, the company was pleased to receive a Notice of Allowance for a US patent application covering liquid jet delivery of GLP-1 receptor agonists to the small intestine for the treatment of any disease, including Type 2 diabetes.

"We've continued to generate important human safety and performance data in support of our targeted therapeutics platform, where so far we have demonstrated that our DDS capsule functions as intended in humans, and especially in UC patients. After receiving constructive feedback from the FDA, we are now preparing to initiate our clinical program for PGN-600," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "This is an important step for this program, and we are very excited about the opportunity to improve treatment for patients with ulcerative colitis. We also continue to strengthen our IP portfolio, illustrating the innovative and proprietary aspects of our technology and platforms for both systemic and targeted drug delivery."

Second Quarter 2022 and Recent Corporate Highlights

- Completed the PM-611 device function study of the Drug Delivery System (DDS) capsule, which demonstrated that performance of the DDS device in healthy volunteers is not affected by food.
- Completed the PM-602 device function study of the DDS capsule, where the device accurately identified entry into the colon, triggered release of a non-drug liquid payload, and achieved distribution across the entire lower colon as confirmed by an independent scintigraphy imaging method.
- Received constructive feedback from the FDA on PGN-600 trial design, which will enable initiation of the Phase 1 clinical trial for PGN-600, which is now planned for Q1 2023.
- Announced a new patent issuance and allowed applications related to the company's targeted and systemic therapeutic platforms including an issued U.S. patent with claims covering the localization technology used in the targeted delivery DDS devices which enable detection of colon entry; and related to the systemic delivery platform, an allowed U.S. patent application covering delivery of a liquid formulation of any GLP-1 receptor agonist using any method of liquid jet delivery in the small intestine for any indication.

Second Quarter 2022 Financial Results

Comparison of Three Months Ended June 30, 2022 and March 31, 2022

The company generated $0.9 million in revenues during the second quarter, out of which $0.8 million came from discontinued operations. The company generated $1.4 million in revenues during the first quarter, out of which $1.3 million came from discontinued operations. Operating expenses were $14.3 million for the three months ended June 30, 2022, compared to $20.0 million for the three months ended March 31, 2022.

Net loss was $5.5 million and net loss per share was $0.03 for the three months ended June 30, 2022, compared to net loss of $13.8 million and net loss per share of $0.08 for the three months ended March 31, 2022.

Net gain from discontinued operations was $0.5 million for the three months ended June 30, 2022 with no impact to loss per share, compared to net gain from discontinued operations of $0.7 million with no impact to loss per share for the three months ended March 31, 2022.

Comparison of Three Months Ended June 30, 2022 and 2021

Operating expenses were $14.3 million for the three months ended June 30, 2022, compared to $36.1 million for the three months ended June 30, 2021.

Net loss was $5.5 million and net loss per share was $0.03 for the three months ended June 30, 2022, compared to net loss of $78.5 million and net loss per share of $1.23 for the three months ended June 30, 2021.

Net gain from discontinued operations was $0.5 million for the three months ended June 30, 2022, with no impact to loss per share, compared to net loss from discontinued operations of $37.1 million and net loss per share for discontinued operations of $0.58 for the three months ended June 30, 2021.

Webcast and Conference Call Information

Biora Therapeutics will host a webcast and conference call to discuss the second quarter financial results and answer investment community questions today, Monday, August 15, 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 therapeutics. 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, 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, 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.

Investor Contact
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Exhibit 99.1

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

	Three Months Ended	
	June 30, 2022	**March 31, 2022**
Revenues	$ 104	$ 107
Operating expenses:		
Research and development	5,904	6,558
Selling, general and administrative	8,410	13,457
Total operating expenses	14,314	20,015
Loss from operations	(14,210)	(19,908)
Interest expense, net	(2,772)	(2,760)
Gain (loss) on warrant liability	4,413	8,989
Other income (expense), net	5,735	(811)
Loss before income taxes	(6,834)	(14,490)
Income tax benefit	(837)	—
Loss from continuing operations	(5,997)	(14,490)
Gain (loss) from discontinued operations	484	682
Net loss	$ (5,513)	$ (13,808)
Net loss per share from continuing operations, basic and diluted	$ (0.03)	$ (0.08)
Net loss per share from discontinued operations, basic and diluted	$ —	$ —
Net loss per share, basic and diluted	$ (0.03)	$ (0.08)
Weighted average shares outstanding, basic and diluted	184,371,626	183,201,663

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

	Three Months Ended June 30,	
	2022	**2021**
Revenues	$ 104	$ 463
Operating expenses:		
Research and development	5,904	13,401
Selling, general and administrative	8,410	22,715
Total operating expenses	14,314	36,116
Loss from operations	(14,210)	(35,653)
Interest expense, net	(2,772)	(3,502)
Gain (loss) on warrant liability	4,413	(5,146)
Other income, net	5,735	2,901
Loss before income taxes	(6,834)	(41,400)
Income tax benefit	(837)	—
Loss from continuing operations	(5,997)	(41,400)
Gain (loss) from discontinued operations	484	(37,131)
Net loss	$ (5,513)	$ (78,531)
Net loss per share from continuing operations, basic and diluted	$ (0.03)	$ (0.65)
Net loss per share from discontinued operations, basic and diluted	$ —	$ (0.58)
Net loss per share, basic and diluted	$ (0.03)	$ (1.23)
Weighted average shares outstanding, basic and diluted	184,371,626	63,942,298

Exhibit 99.1

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

	June 30, 2022	December 31, 2021 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 48,506	$ 88,397
Accounts receivable, net	—	653
Income tax receivable	817	—
Prepaid expenses and other current assets	8,675	7,232
Current assets of disposal group held for sale	2,147	2,147
Total current assets	60,145	98,429
Property and equipment, net	2,454	4,012
Right-of-use assets	2,203	—
Other assets	6,227	326
Goodwill	6,072	6,072
Total assets	$ 77,101	$ 108,839
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 4,315	$ 8,709
Accrued expenses and other current liabilities	30,940	34,157
Warrant liability	5,329	18,731
Current portion of capital lease obligations	—	12
Total current liabilities	40,584	61,609
Convertible notes, net	127,086	126,392
Other long-term liabilities	5,537	5,814
Total liabilities	$ 173,207	$ 193,815
Stockholders' deficit:		
Common stock	150	146
Additional paid-in capital	730,833	722,646
Accumulated deficit	(808,007)	(788,686)
Treasury stock	(19,082)	(19,082)
Total stockholders' deficit	(96,106)	(84,976)
Total liabilities and stockholders' deficit	$ 77,101	$ 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

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.

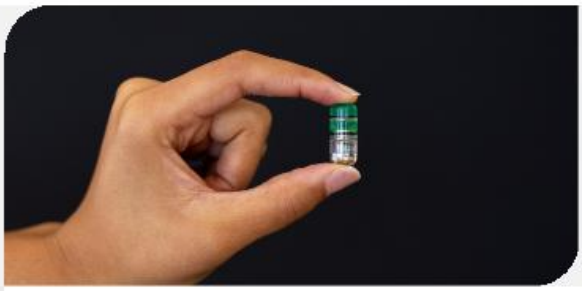
ABOUT BIORA THERAPEUTICS

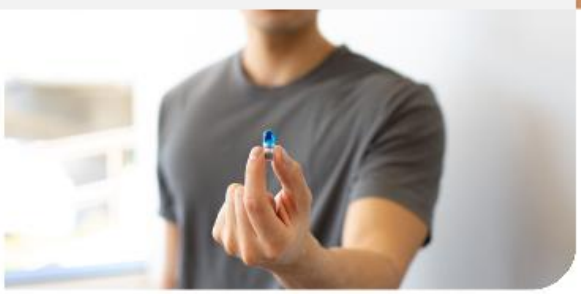
Our mission is to reimagine therapeutics and their delivery

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

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 improved management of chronic diseases

THERAPEUTIC PIPELINE

	PROGRAM	INDICATION	DESIGN/FEASIBILITY	PRECLINICAL	CLINICAL
TARGETED THERAPEUTICS	**DDS** Device	--			
	PGN-600 Tofacitinib + Device	UC			
	PGN-001 Adalimumab + 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			

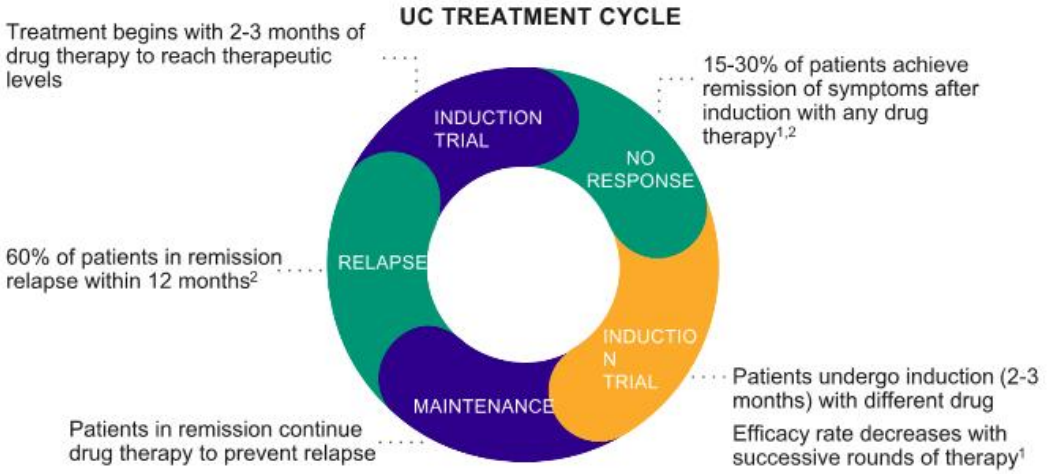
BIORA Therapeutics

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

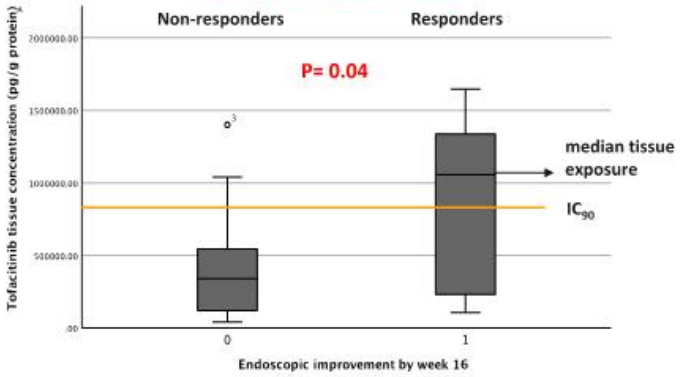
RESULTS

- 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

Needle-free, oral drug delivery to the colon

TARGETED THERAPEUTICS

ORAL ADMINISTRATION

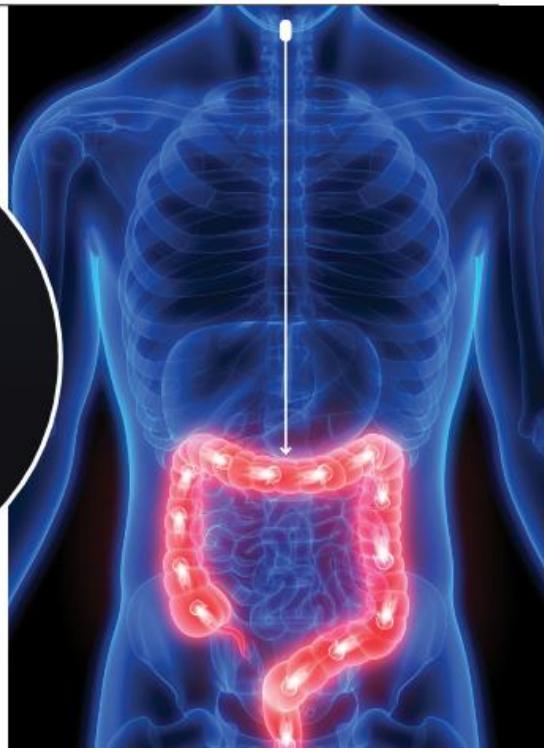
- Convenient oral capsule the size of a fish oil pill

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



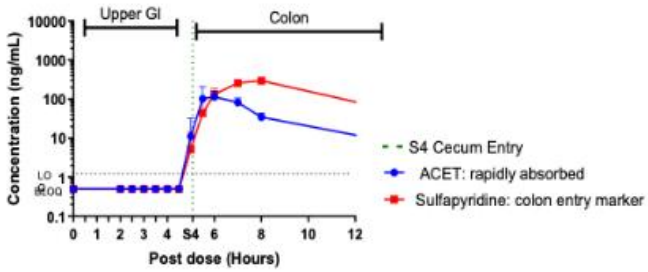
1. Biora Therapeutics internal data

Demonstrated accurate localization and delivery to colon

TARGETED THERAPEUTICS

ACCURATE DELIVERY TO COLON IN CANINES

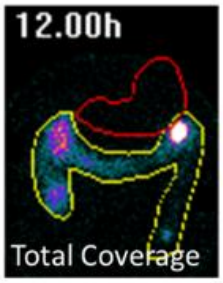
Pharmacokinetic data from two marker drugs administered in canine model



- 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 normal, healthy volunteers



- Achieved distribution across the entire colon

Biora Therapeutics internal data

BIORA Therapeutics

TARGETED THERAPEUTICS

Three successful human studies show device functions with and without food, and in active UC patients

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) • **Achieved distribution of payload across the entire colon** • No early deployment before colon detection • Presenting data at upcoming conference	• 100% of analyzed devices indicated entry to the colon, activation, and deployment, **and were unaffected by food** (39/39) • No failure modes observed in the analyzed devices • No serious adverse events reported	• 100% of devices accurately identified entry into the colon, triggered release of a liquid payload, and achieved distribution across the entire colon (7/7) • **Device was well tolerated and performed as intended in active ulcerative colitis patients** • Presenting data at upcoming conference

Biora Therapeutics internal data

BIORA Therapeutics

PGN-600 PRECLINICAL TOX STUDY RESULTS

Reduced systemic uptake, better PK effect and coverage

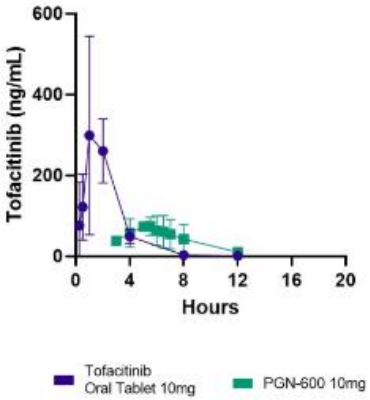
TARGETED THERAPEUTICS

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

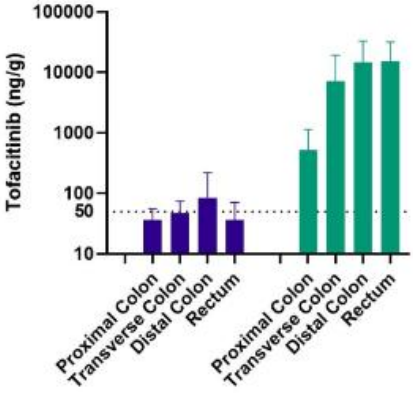
RESULTS

- 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

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PGN-600 (TOFACITINIB + DDS DEVICE)

Clinical Development Plan

TARGETED THERAPEUTICS

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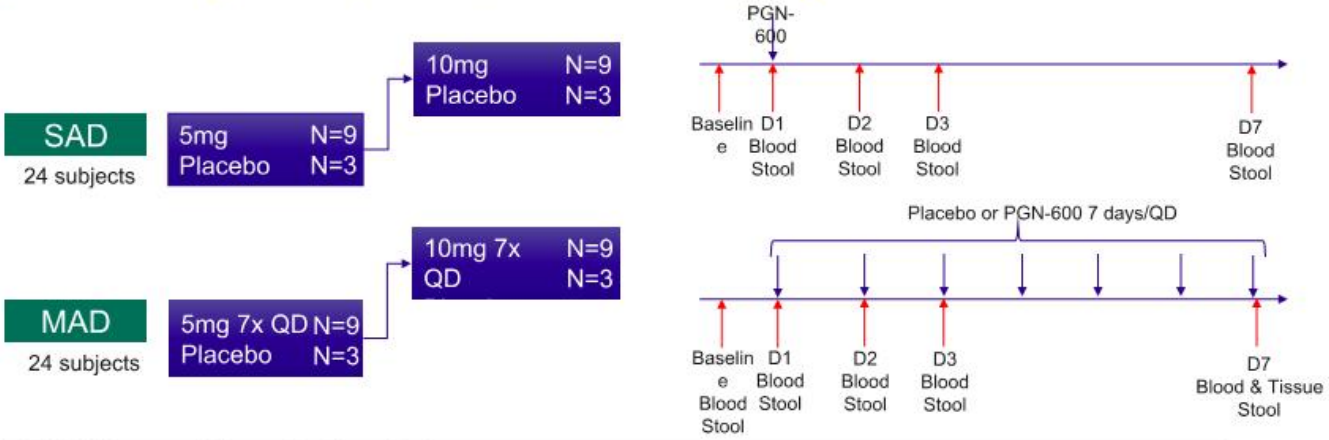
PHASE 1: SINGLE AND MULTIPLE ASCENDING DOSE STUDIES

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.

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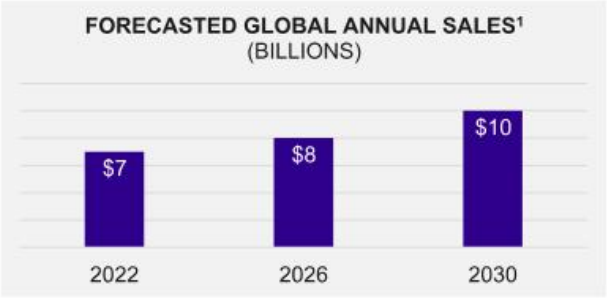
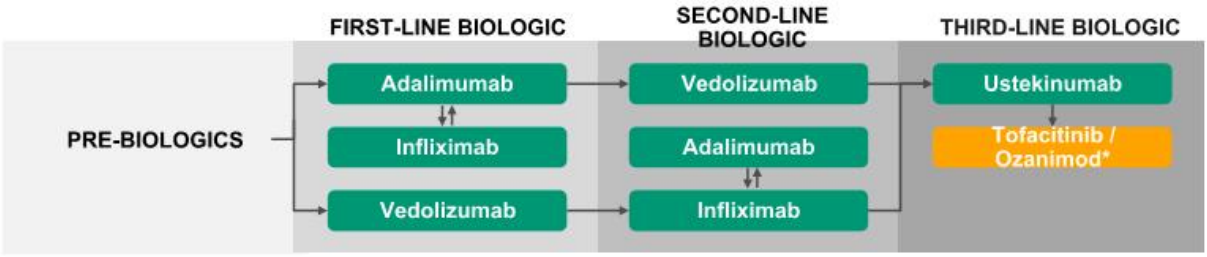
TARGETED THERAPEUTICS

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

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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

IONIS COLLABORATIONS

-
- Large Pharma 1
- Large Pharma 2

SYSTEMIC THERAPEUTICS

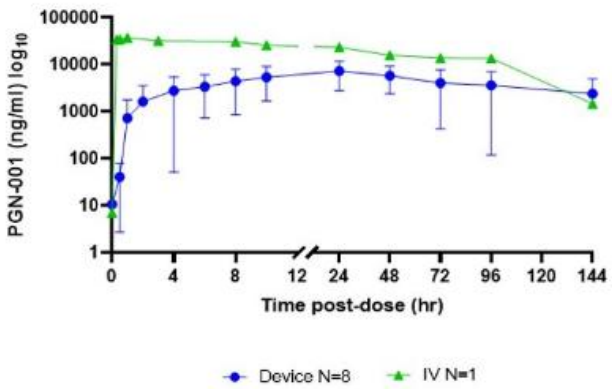
Excellent systemic uptake for orally delivered large molecules demonstrated in animal models

Multiple studies in swine model with endoscopically placed, autonomous device compared to IV administration

RESULTS

- In multiple studies in swine model, an average of ~22% bioavailability was observed in animals where drug was detected in blood[1]
- Achieved up to 67% bioavailability for a variant of adalimumab[1]
  - *For comparison, commercially available oral large molecules achieve 1% or less bioavailability*
- Precise and reliable release of payload in small intestine demonstrated in canine studies
- No issues observed with safety or tolerability of the device

BIOAVAILABILITY COMPARABLE TO IV



1. Biora Therapeutics, Inc. Data on file.
See also Lee SN, Stork C, Smith J, et al. Assessing the performance of an oral biotherapeutic delivery system (OBDS) using intra-duodenal endoscopy delivery in Yucatan minipigs. Poster presented at: *Controlled Release Society Annual Meeting*, July 13-14, 2022, Montreal, Canada.
Lee SN, Stork C, Smith J, et al. Development of ex-vivo and in-vivo models to assess the performance of an oral biotherapeutic delivery system (OBDS) capsule. Poster presented at: *Controlled Release Society Annual Meeting*, July 13-14, 2022, Montreal, Canada.

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DEVELOPMENT TIMELINE

DEVELOPMENT TIMELINE

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**. 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**. Presented at DDW 2021.
4. **Development of a novel drug delivery system for treatment of Ulcerative Colitis**. Presented 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**. Presented at ECCO 2022 and DDW 2022.
7. **Pharmacokinetic stratification of cytokine profiles during anti-TNF induction treatment in moderate-to-severe UC**. Presented at ECCO 2022 and DDW 2022.

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1. **Development of *ex-vivo* and *in-vivo* models to assess the performance of an oral biotherapeutic delivery system (OBDS) capsule**. Poster presented at: *Controlled Release Society Annual Meeting*, July 13-14, 2022, Montreal, Canada.
2. **Assessing the performance of an oral biotherapeutic delivery system (OBDS) using intra-duodenal endoscopy delivery in *Yucatan* minipigs**. Poster presented at: *Controlled Release Society Annual Meeting*, July 13-14, 2022, Montreal, Canada.

INTELLECTUAL PROPERTY PORTFOLIO

Diverse patent portfolio with 82 distinct patent families[1]

DEVICES
37 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
28 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
17 patent families covering:

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

1. Approximately **170 issued patents and 170 pending applications** in major countries and regions around the world


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Therapeutics