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): May 10, 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 May 10, 2022, Biora Therapeutics, Inc. issued a press release announcing its financial results for the first quarter ended March 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 May 10, 2022
99.2	Corporate presentation, dated May 10, 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: May 10, 2022

By: /s/ Aditya P. Mohanty

Aditya P. Mohanty
Chief Executive Officer

Exhibit 99.1

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

Completed transformation with the launch of Biora Therapeutics to reflect the company's focus on oral therapeutic solutions

Successfully transferred its single-molecule detection platform with launch of Enumera Molecular

Strengthened therapeutics capability and leadership with addition of Paul Shabram and opening of operations lab space

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

SAN DIEGO, May 10, 2022 – Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutics, today provided a corporate update and reported financial results for the first quarter ended March 31, 2022.

The company's launch of Biora Therapeutics is aligned with its mission to reimagine therapeutics and their 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.

Rapid induction and remission may be possible in ulcerative colitis (UC) patients through targeted delivery of therapeutics directly to the tissue of the lower GI tract. The company and its clinical collaborators presented data at several important scientific conferences during the first quarter, demonstrating the potential benefit of increasing drug concentration in GI tissue by delivering drug directly to the site of disease, which is the goal of the company's lead targeted therapeutics program.

"We are happy with the progress of the company transformation, which has culminated in the launch of Biora Therapeutics," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "The successful transfer of our single molecule detection platform is an example of how we continue to leverage our diagnostics assets while focusing resources on our oral therapeutics programs, some of which have the potential to impact the treatment of diseases with significant unmet need and representing large market opportunities." Mr. Mohanty continued, "We are on track to generate important data with our therapeutics programs this year, which should continue to demonstrate the potential of these programs."

First Quarter 2022 Results and Other Recent Corporate Highlights

- Initiated a follow-on clinical device performance study evaluating the performance of the drug delivery system (DDS) device in patients with active ulcerative colitis.
- Clinical collaborators presented patient data on indicators of efficacy in the treatment of GI disorders at the 17th Congress of the European Crohn's and Colitis Organization (ECCO), and in an oral presentation during the 34th edition of the Belgian Week of Gastroenterology.
- Clinical collaborators presented patient data exploring potential causes for the 30% of patients who are primary non-responders to anti-TNF therapies during the 17th Congress of ECCO.
- Completed the transfer of its single-molecule detection platform to newly formed Enumera Molecular, which intends to develop and commercialize the platform, and is funded initially with a $10 million investment from healthcare fund Arboretum Ventures.
- Raised $3.7 million in gross proceeds through its ATM program.
- Strengthened the management team with the appointment of Paul Shabram as Senior Vice President, Technical Operations.

First Quarter 2022 Financial Results

Comparison of Three Months Ended March 31, 2022 and December 31, 2021

The company generated $1.4 million in revenues during the first quarter, out of which $1.3 million came from discontinued operations. The company generated $7.7 million in revenues during the fourth quarter, out of which $7.2 million came from discontinued operations. Operating expenses were $20.0 million for the three months ended March 31, 2022, compared to $20.6 million for the three months ended December 31, 2021.

Net loss was $13.8 million for the three months ended March 31, 2022 and net loss per share was $0.08, compared to net loss of $92.9 million and net loss per share of $0.56 for the three months ended December 31, 2021.

Net gain from discontinued operations was $0.7 million for the three months ended March 31, 2022 with no impact to earnings per share, compared to net loss from discontinued operations of $10.1 million and net loss per share of $0.06 for the three months ended December 31, 2021.

Comparison of Three Months Ended March 31, 2022 and 2021

Operating expenses were $20.0 million for the three months ended March 31, 2022, compared to $31.6 million for the three months ended March 31, 2021.

Net loss was $13.8 million for the three months ended March 31, 2022 and net loss per share was $0.08, compared to net loss of $32.3 million and net loss per share of $0.56 for the three months ended March 31, 2021.

Net loss from discontinued operations was $0.7 million for the three months ended March 31, 2022, with no impact to earnings per share, compared to net loss from discontinued operations of $14.8 million and net loss per share for discontinued operations of $0.26 for the three months ended March 31, 2021.

Webcast and Conference Call Information

Biora Therapeutics will host a webcast and conference call to discuss the first quarter financial results and answer investment community questions today, Wednesday, May 10, 2022 at 4:30 p.m. Eastern / 1:30 p.m. Pacific.

The live call on May 10 may be accessed by dialing 1-800-926-4402 (domestic) or 1-416-641-6700 (international) and entering the conference code: 22018599. A live webcast will be available via the Investor Relations section of the company website at bioratherapeutics.com, 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 the progress and future expectations of our research and 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 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.

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

	Three Months Ended	
	March 31, 2022	**December 31, 2021**
Revenues	$ 107	$ 435
Operating expenses:		
Research and development	6,558	8,485
Selling, general and administrative	13,457	12,109
Total operating expenses	20,015	20,594
Loss from operations	(19,908)	(20,159)
Interest (expense) income, net	(2,760)	(2,186)
Gain on warrant liability	8,989	(48,339)
Other (expense) income, net	(811)	(12,222)
Loss before income taxes	(14,490)	(82,906)
Income tax benefit	—	(119)
Loss from continuing operations	(14,490)	(82,787)
Gain (loss) from discontinued operations	682	(10,087)
Net loss	$ (13,808)	$ (92,874)
Net loss per share from continuing operations, basic and diluted	$ (0.08)	$ (0.50)
Net gain (loss) per share from discontinued operations, basic and diluted	—	$ (0.06)
Net loss per share, basic and diluted	$ (0.08)	$ (0.56)
Weighted average shares outstanding, basic and diluted	183,201,663	166,072,192

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

	Three Months Ended March 31,	
	2022	**2021**
		(1)
Revenues	$ 107	$ 167
Operating expenses:		
Research and development	6,558	11,673
Selling, general and administrative	13,457	19,958
Total operating expenses	20,015	31,631
Loss from operations	(19,908)	(31,464)
Interest (expense) income, net	(2,760)	(3,520)
Gain on warrant liability	8,989	2,650
Other (expense) income, net	(811)	14,873
Loss from continuing operations	(14,490)	(17,461)
Gain (loss) from discontinued operations	682	(14,803)
Net loss	$ (13,808)	$ (32,264)
Net loss per share from continuing operations, basic and diluted	$ (0.08)	$ (0.30)
Net gain (loss) per share from discontinued operations, basic and diluted	—	$ (0.26)
Net loss per share, basic and diluted	$ (0.08)	$ (0.56)
Weighted average shares outstanding, basic and diluted	183,201,663	57,493,800

1. The condensed consolidated statement of operations for the three months ended March 31, 2021 has been adjusted to reflect discontinued operations.

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

	March 31, 2022	December 31, 2021 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 67,234	$ 88,397
Accounts receivable, net	—	653
Prepaid expenses and other current assets	5,639	7,232
Current assets of disposal group held for sale	2,147	2,147
Total current assets	75,020	98,429
Property and equipment, net	2,742	4,012
Right-of-use assets	2,578	—
Other assets	326	326
Goodwill	6,072	6,072
Total assets	$ 86,738	$ 108,839
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 5,380	$ 8,709
Accrued expenses and other current liabilities	31,603	34,157
Warrant liability	9,742	18,731
Current portion of capital lease obligations	—	12
Total current liabilities	46,725	61,609
Convertible notes, net	126,736	126,392
Other long-term liabilities	6,462	5,814
Total liabilities	$ 179,923	$ 193,815
Stockholders' deficit:		
Common stock	148	146
Additional paid-in capital	728,243	722,646
Accumulated deficit	(802,494)	(788,686)
Treasury stock	(19,082)	(19,082)
Total stockholders' deficit	(93,185)	(84,976)
Total liabilities and stockholders' deficit	$ 86,738	$ 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 facts 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 clinical trials, the anticipated timing for 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 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.

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WHAT WE DO

Developing innovative oral biotherapeutics for gastrointestinal health and beyond

TARGETED THERAPEUTICS

Targeted delivery of therapeutics to the site of disease in the gastrointestinal tract could improve outcomes for patients with IBD.

DDS
Targeted Drug Delivery System

PGN-600	PGN-001
Tofacitinib + DDS	Adalimumab variant + DDS

SYSTEMIC THERAPEUTICS

Capsule technology designed for systemic delivery of biotherapeutics, replacing injection with needle-free, oral delivery technology.

OBDS
Systemic Oral Biotherapeutics Delivery System

PGN-OB1	PGN-OB2
Adalimumab variant + OBDS	GLP-1 agonist + OBDS

Ionis	Large Pharma	Large Pharma
Antisense therapy + OBDS	Undisclosed drug + OBDS	Undisclosed drug + OBDS

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BIORA Therapeutics

THERAPEUTICS PIPELINE

	PROGRAM	INDICATION	DESIGN/FEASIBILITY	PRECLINICAL	CLINICAL
TARGETED THERAPEUTICS	DDS	IBD	Targeted Therapeutics Device		
	PGN-600	Ulcerative Colitis	Tofacitinib + Device		
	PGN-001	Ulcerative Colitis	Adalimumab variant + Device		
SYSTEMIC THERAPEUTICS	OBDS	–	Systemic Therapeutics Device		
	PGN-OB1	Autoimmune	Adalimumab variant + Device		
	PGN-OB2	Diabetes	GLP-1 agonist + Device		
	–	Undisclosed	Antisense Therapy + Device	in partnership with IONIS	
	–	Undisclosed	Undisclosed Drug + Device	in partnership with LARGE PHARMA 1	
	–	Undisclosed	Undisclosed Drug + Device	in partnership with LARGE PHARMA 2	

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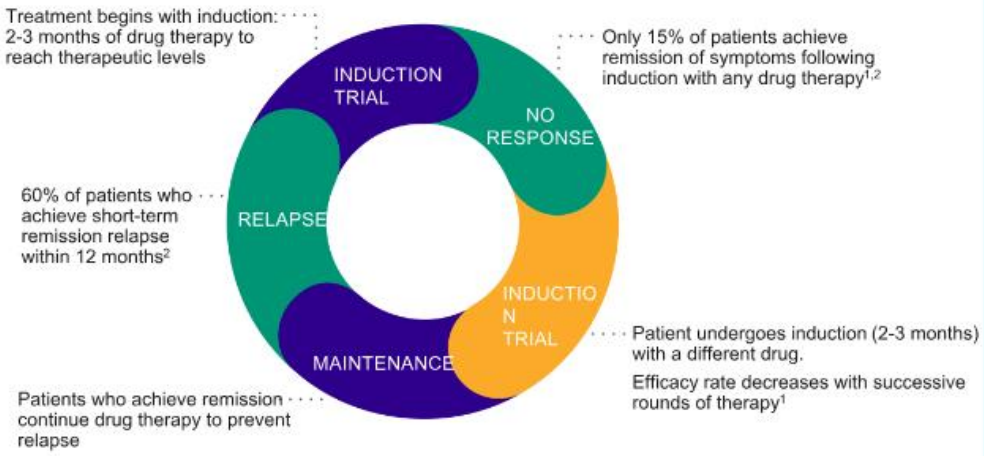
TARGETED THERAPEUTICS

ULCERATIVE COLITIS: THE TREATMENT GAP

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

UC TREATMENT CYCLE



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(8):857-863.

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TREATMENT OBJECTIVE

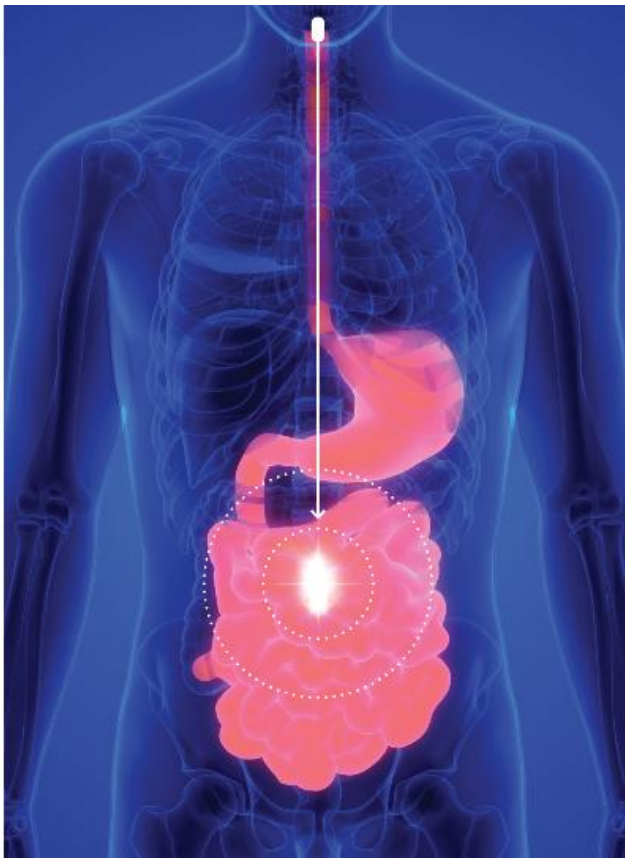
- The goal is deep remission: a combination of symptom remission and endoscopic healing

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]

TARGETED THERAPEUTICS: A POTENTIAL SOLUTION FOR UNMET NEED IN UC

CURRENT THERAPEUTIC CHALLENGES FOR UC	TARGETED THERAPEUTIC DELIVERY: POTENTIAL SOLUTIONS
1 UC drugs have systemic toxicity issues that may limit daily dosage	Reduced systemic uptake should reduce toxicity and adverse events
2 Achieving sufficient drug levels at the site of disease is difficult with systemic delivery.	Increased drug levels in tissue are correlated with improved endoscopic outcomes[1]
3 Only 1 in 4 UC patient achieves short-term response[2]	Targeted delivery could enable rapid induction, which should improve patient response
4 UC has multiple pathways,[3] but current protocols target single pathways due to toxicity concerns	Targeted delivery could enable combination therapy to target multiple inflammatory pathways simultaneously[3]



1. Verstockt B, Alsoud D, van Oostrom J, et al. Tofacitinib tissue exposure correlates with endoscopic outcome. Oral presentation at the 34th edition of the Belgian Week of Gastroenterology, February 9, 2022.
2. 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. doi:10.1016/S2468-1253(21)00065-0
3. Van Oostrom J, Hanzel J, Verstockt B, et al. Pharmacokinetic stratification of cytokine profiles during anti-TNF induction treatment in moderate-to-severe ulcerative colitis. Poster presented at the 17th Congress of the European Crohn's and Colitis Organisation (ECCO); February 18, 2022.

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OUR IBD SOLUTION: TARGETED THERAPEUTICS

Targeted drug delivery to the GI tract designed to improve efficacy and safety

ADVANTAGES OF OUR APPROACH

- Targeted delivery designed to improve endoscopic outcomes by increasing drug levels at the site of disease
- Payload delivery method designed to minimize systemic uptake, potentially reducing adverse effects
- Reduced systemic toxicity could finally enable combination therapy

Research in partnership with: CROHN'S & COLITIS FOUNDATION

ORAL ADMINISTRATION

- Oral capsule approximately the size of a fish oil capsule for patient convenience

FLEXIBLE FORMULATION

- Delivers a payload of ~500µl liquid or solid formulation to the desired location

ACCURATE DELIVERY

- Proprietary autolocation in the GI tract for accurate drug delivery

watch activation video

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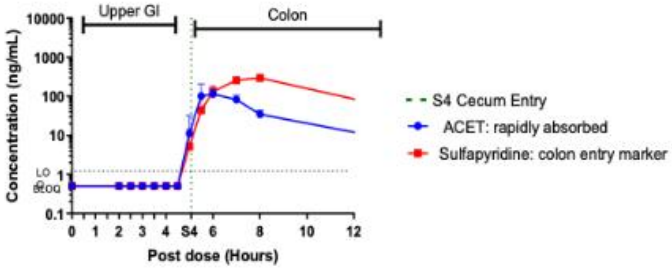
BIORA Therapeutics

TARGETED THERAPEUTICS: PRECLINICAL RESULTS

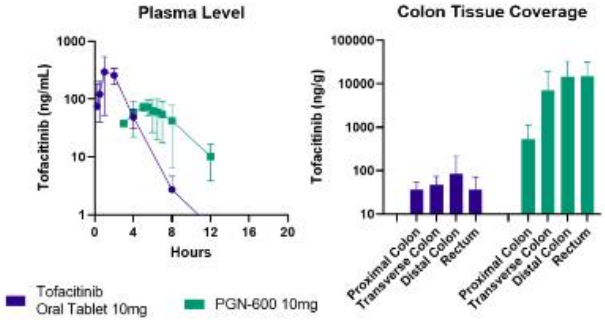
ACCURATE DELIVERY TO THE COLON



Pharmacokinetic data from two marker drugs administered in canine model indicated:

- Successful delivery to colon via DDS
- No early release of drug
- No drug absorption in upper GI tract

BETTER PK EFFECT & COVERAGE



Standard oral dose vs. PGN-600 (tofacitinib delivered via DDS capsule) in canine model demonstrated:

- Reduced drug levels in blood vs. standard oral dose
- Tissue drug levels at least 25x higher along the length of the colon vs. standard oral dose

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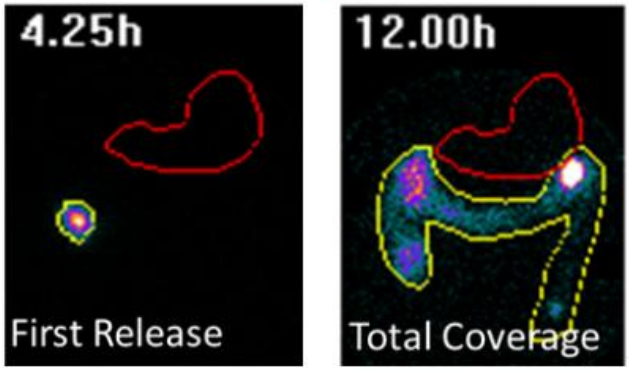
TARGETED THERAPEUTICS: CLINICAL DEVICE PERFORMANCE

Accurate localization and delivery demonstrated in humans

DEVICE LOCALIZATION AND DELIVERY TO COLON



Successful clinical device validation for localization
and delivery function using scintigraphic imaging:

- Safety and tolerability in normal healthy volunteers; devices recovered intact
- 83% accuracy of localization function (10/12)
- No early release before colon detection

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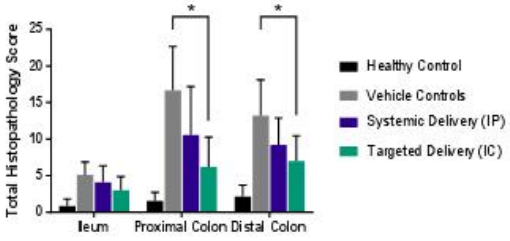
TARGETED DELIVERY: SUPERIOR PHARMACODYNAMICS IN MULTIPLE MOLECULES

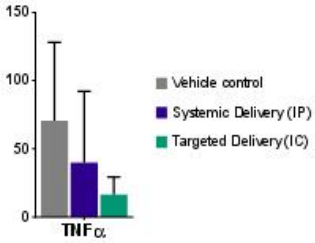
Anti-TNFα in animal models

IMPROVED HISTOPATHOLOGY SCORE



*Pair-wise comparisons by two-tailed Mann-Whitney *U*-Test; $p<0.05$

REDUCED INFLAMMATORY CYTOKINES



REDUCED T-CELL COUNTS

T-Cell Immunohistochemistry (CD4+)

Systemic Delivery (IP) of anti-TNFα to Proximal Colon

Targeted Delivery (IC) of anti-TNFα to Proximal Colon

Systemic delivery via intraperitoneal injection (IP) vs. targeted intracecal delivery (IC) of anti-TNFα in mouse model of T-cell transfer colitis demonstrated:

- Significantly improved histopathology score vs. systemic delivery
- Significantly reduced inflammatory cytokines vs. systemic delivery
- T-cell counts reduced in proximal colon (decrease in inflammation) vs. systemic delivery

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BIORA Therapeutics

TARGETED THERAPEUTICS CLINICAL PLAN

FUNCTION STUDIES	TOX STUDY	PHASE 1 CLINICAL STUDIES	PHASE 1B/2A CLINICAL STUDIES

PM-601 Device Function Study in Normal Healthy Volunteers
• Device was well tolerated
• Achieved pan-colon distribution of payload
• Accurately identified entry into the colon (10/12); no early deployment
 	
PM-602 Device Function Study in Patients with Active Ulcerative Colitis
• Recruiting
	PGN-600 Tox GLP
	• Up to 30 animals in three groups:
	  ◦ Oral pill
	  ◦ Device only (10 mg)
	  ◦ Device + drug (25 mg)
	• 8 weeks/QD
		PGN-600 Phase 1 SAD/MAD Study to Evaluate Safety, Tolerability, and PK/PD in Normal Healthy Volunteers
		• 48 total subjects (24 SAD / 24 MAD)
		• 8 days
			PGN-600 Safety and Efficacy in Subjects with Moderate to Severe Ulcerative Colitis Who Have Been Previously Exposed to TNF Antagonist

OBJECTIVES • Scintigraphy confirmation of device location, drug release, and colon coverage	**OBJECTIVES** • Confirmation of device location, drug release, and colon coverage **Previous Tox Study (2021)** • 7 days/QD in canines • No safety signals were observed	**OBJECTIVES** • Safety & tolerability of PGN-600 by assessing treatment-related AEs, ECGs, vital signs, and clinical laboratory values	**OBJECTIVES** • Demonstrate safety & tolerability, PK/PD of PGN-600 in UC patients • Estimate % of patients with clinical remission after 8 weeks treatment with PGN-600

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SYSTEMIC THERAPEUTICS

NEEDLE AVERSION LEADS TO POOR PATIENT ADHERENCE

Patients prefer oral delivery of medication

20% of adults avoid medical treatment due to fear of needles[1]

42% of patients fail to maintain injectable treatment due to needle aversion[3]

among diabetes patients initiating treatment with injectable GLP-1 agonist

88% of patients prefer a daily oral capsule to bi-weekly injection[3]

among rheumatoid arthritis patients undergoing anti-TNFα therapy

1. Wright S, Yelland M, Heathcote K, Ng SK, Wright G. Fear of needles--nature and prevalence in general practice. Aust Fam Physician. 2009;38(3):172-176.
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
3. Frost & Sullivan research commissioned by Rani Therapeutics Holdings, Inc. https://ir.ranitherapeutics.com/static-files/b1f080bf-a860-4136-87cb-d6f7c49c1502

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SYSTEMIC THERAPEUTICS DELIVERY SYSTEM

Needle-free, oral delivery to small intestine designed for optimal systemic uptake

ADVANTAGES OF SYSTEMIC ORAL BIOTHERAPEUTICS

- Needle-free, liquid jet administration to intestinal tissue for enhanced systemic uptake
- More frequent administration vs. injection may improve outcomes
- Versatile platform can deliver a range of large molecules, including:
  - Monoclonal antibodies
  - Peptides
  - Nucleic acids

RESEARCH PARTNERSHIPS

- Large Pharma 1
- Large Pharma 2
- IONIS

LIQUID FORMULATION

- Delivers a payload of ~400µl liquid drug with little to no reformulation

PRECISE DELIVERY

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

NEEDLE-FREE ADMINISTRATION

- Capsule about the size of a multivitamin for pain-free oral administration

watch activation video

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SYSTEMIC THERAPEUTICS: PRECISION DELIVERY

Preclinical studies demonstrate precise and reliable release of payload

STUDY DESIGN

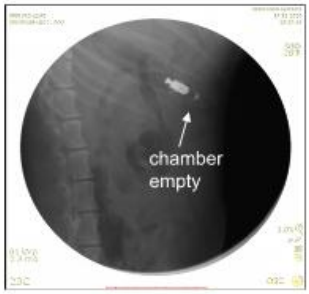
- Capsule loaded with a radio-opaque marker (iohexal)
- Two different enteric triggers evaluated
- Sequential imaging as the capsule transits through the GI tract in canines

RESULTS

- Reliable triggering and iohexal release
- Ability to optimize timing of trigger release
- No safety issues observed

ACCURATE DELIVERY IN SMALL INTESTINE

Immediately after dosing in the stomach



After deployment in the small intestine

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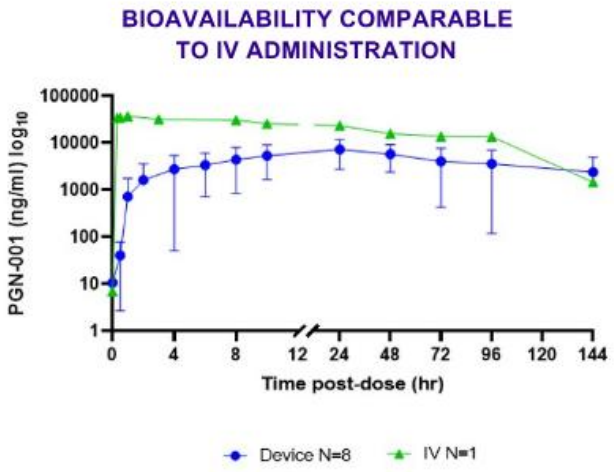
EXCELLENT SYSTEMIC UPTAKE FOR ORALLY DELIVERED LARGE MOLECULES

Demonstrated up to 67% bioavailability for monoclonal antibodies



- Multiple studies in swine model with endoscopically placed, autonomous device compared to IV administration
- Achieved up to 67% bioavailability for a variant of adalimumab[1]
- Most recent study had an average of 22% bioavailability in animals where drug was detected in blood[1]
  - For comparison, commercially available oral large molecules achieve bioavailability of 1% or less

1. Biora Therapeutics internal data

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MILESTONES & CORPORATE HIGHLIGHTS

DEVELOPMENT TIMELINE

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