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

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): March 28, 2022

Progenity, 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

4330 La Jolla Village Drive, Suite 200
San Diego, California
(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	PROG	The Nasdaq Global Market

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

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

Item 2.02 Results of Operations and Financial Condition.

On March 28, 2022, Progenity, Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2021 and an updated corporate presentation. The press release and corporate presentation are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K.

As provided in General Instruction B.2 of Form 8-K, the information in this Item 2.02 and Exhibit 99.1 and 99.2 incorporated herein shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall such information or Exhibit 99.1 and 99.2 be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press release, dated March 28, 2022
99.2	Corporate presentation, dated March 28, 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.

Progenity, Inc.

Date: March 28, 2022

By: /s/ Aditya P. Mohanty

Aditya P. Mohanty
Chief Executive Officer

Exhibit 99.1

progenity®
Prepare for life.

Progenity Provides Corporate Update and Reports
Fourth Quarter and Full Year 2021 Financial Results

Accelerated Company Transformation Toward Oral Delivery of Biotherapeutics and Targeted Therapeutics Programs

Progressed Company's Targeted Therapeutics Clinical Programs with Initiation of Clinical Device Performance Study in Patients with Ulcerative Colitis

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

SAN DIEGO, March 28, 2022 – Progenity, Inc. (Nasdaq: PROG), an innovative biotechnology company, today provided a corporate update and reported financial results for the fourth quarter and full-year ended December 31, 2021.

In the fourth quarter Progenity made important progress in transforming into an innovation-led biotherapeutics company initially focused on its targeted and systemic biotherapeutics platforms.

The strategy of achieving rapid induction and remission in ulcerative colitis (UC) patients through targeted delivery of therapeutics directly to the tissue of the lower gastrointestinal (GI) tract, which cannot currently be achieved, is gaining momentum. Progenity and its associated key opinion leaders presented at important scientific conferences during the fourth quarter and, more recently, key data demonstrating the potential benefits of that therapeutic approach.

"Progenity is making great strides in its transformation into a biotherapeutics company. In the last few months we have completed the sale of our Avero affiliate, strengthened the focus of the company on our oral therapeutics programs and positioned the company to successfully deliver on its potential to impact the treatment of serious diseases," said Adi Mohanty, Chief Executive Officer of Progenity.

Mr. Mohanty continued, "We are on track to complete our transformation in the first half of 2022, and look forward to the execution of important clinical study phases of our therapeutics programs this year, which we believe will confirm our early lab and animal data. We are particularly keen to see the progress of our targeted therapeutics program in UC where there is a significant unmet need and growing recognition of the potential of our therapeutic solution as a significant step forward by key opinion leaders".

Fourth Quarter 2021 Results and Other Recent Corporate Highlights

- Completed its first clinical device performance study, which evaluated the safety and tolerability of the Drug Delivery System (DDS) capsule and validation of the device's localization and delivery function in healthy volunteers.
- Initiated a follow-on clinical device performance study evaluating the performance of the DDS device in patients with active ulcerative colitis.
- Participated in the fourth annual Inflammatory Bowel Disease (IBD) Innovate Product Development for Crohn's & Colitis conference to highlight the important developments achieved so far with the company's Targeted Therapeutics program.
- 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.
- Was granted several patents related to the company's ingestible technologies for delivery of therapeutics via the GI tract.
- Preecludia™ validation study results for preeclampsia were published in the Journal of Pharmaceutical and Biomedical Analysis.
- Raised $46 million in gross proceeds through warrant exercises and $5 million through its ATM program.
- Raised $20 million through a registered direct offering and reduced its non-affiliated debt by 38% through an exchange offer of $20.2 million of convertible notes.
- Completed the sale of its Avero affiliate and ended the year with an improved liquidity position heading into 2022. Combined with a substantially reduced cash burn, Progenity has extended cash runway to support its clinical development programs into 2023.
- Strengthened the management team and Board of Directors with the appointment of Adi Mohanty as CEO and member of the Board of Directors, and the appointment of Jill Howe as a member of the Board of Directors and chair of the Audit Committee. The company also improved its corporate governance profile with the appointment of its lead independent director, Jeffrey Alter, as Chairman of the Board of Directors.

Fourth Quarter and Full Year 2021 Financial Results

Comparison of Three Months Ended December 31, 2021 and September 30, 2021

The company generated $7.7 million in revenues during the fourth quarter, out of which $7.2 million came from discontinued operations. The company generated $9.7 million in revenues during the third quarter, out of which $9.5 million came from discontinued operations. Operating expenses were $20.6 million for the three months ended December 31, 2021, compared to $30.7 million for the three months ended September 30, 2021.

Net loss was $92.9 million for the three months ended December 31, 2021 and net loss per share was $0.56, 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 loss from discontinued operations was $10.1 million for the three months ended December 31, 2021 and net loss per share for discontinued operations was $0.06, 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.

Comparison of Three Months Ended December 31, 2021 and 2020

Operating expenses were $20.6 million for the three months ended December 31, 2021, compared to $28.5 million for the three months ended December 31, 2020.

Net loss was $92.9 million for the three months ended December 31, 2021 and net loss per share was $0.56, compared to net loss of $75.5 million and net loss per share of $1.53 for the three months ended December 31, 2020.

Net loss from discontinued operations was $10.1 million for the three months ended December 31, 2021 and net loss per share for discontinued operations was $0.06, compared to net loss from discontinued operations of $23.0 million and net loss per share for discontinued operations of $0.47 for the three months ended December 31, 2020.

Comparison of Full Year Ended December 31, 2021 and 2020

The company generated $60.6 million in revenues during the year ended December 31, 2021, of which $59.4 million were generated from discontinued operations. The company generated $74.3 million in revenues during the year ended December 31, 2020, of which $74.2 million were generated from discontinued operations. Operating expenses were $119.1 million for the year ended December 31, 2021, compared to $107.8 million for the year ended December 31, 2020.

Net loss was $247.4 million for the year ended December 31, 2021 and net loss per share was $2.57, compared to net loss of $192.5 million and net loss per share of $7.00 for the year ended December 31, 2020.

Net loss from discontinued operations was $68.9 million for the year ended December 31, 2021 and net loss per share for discontinued operations was $0.72, compared to net loss from discontinued operations of $87.4 million and net loss per share for discontinued operations of $3.18 for the year ended December 31, 2020.

Webcast and Conference Call Information

Progenity will host a webcast and conference call to discuss the third quarter financial results and answer investment community questions today, Monday, March 28, 2022 at 4:30 p.m. Eastern / 1:30 p.m. Pacific. The live call may be accessed by dialing 877-423-9813 for domestic callers and 201-689-8573 for international callers and entering the conference code: 13727360. A live webcast and archive of the call will be available online from the investor relations section of the company website at www.progenity.com.

About Progenity

Progenity, Inc. is a biotechnology company innovating in the fields of gastrointestinal health and oral biotherapeutics and is developing a suite of investigational ingestible devices designed to provide precise drug delivery solutions and diagnostic sampling. Progenity's vision is to transform healthcare to become more precise and personal by improving patient outcomes through localized treatment with targeted therapies and improving disease diagnoses.

For more information, visit www.progenity.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, expectations regarding future cash burn and cash burn and expectations regarding cost savings resulting from cost-cutting measures 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 test volumes and revenues, 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 Progenity's Annual Report on Form 10-K for the year ended December 31, 2021 to be filed with the SEC and other subsequent documents, including Quarterly Reports, that we file with the SEC.

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

	Three Months Ended	
	December 31, 2021	**September 30, 2021**
Revenues	$ 435	$ 182
Cost of sales	—	—
Gross profit	435	182
Operating expenses:		
Research and development	8,485	12,226
Selling and marketing	321	573
General and administrative	11,788	17,944
Total operating expenses	20,594	30,743
Loss from operations	(20,159)	(30,561)
Interest income (expense), net	(2,186)	(3,458)
Loss on warrant liability	(48,339)	(3,322)
Other income (expense), net	(12,222)	467
Loss before income taxes	(82,906)	(36,874)
Income tax benefit	(119)	—
Loss from continuing operations	(82,787)	(36,874)
Loss from discontinued operations	(10,087)	(6,870)
Net loss	$ (92,874)	$ (43,744)
Net loss per share from continuing operations, basic and diluted	$ (0.50)	$ (0.38)
Net loss per share from discontinued operations, basic and diluted	$ (0.06)	$ (0.07)
Net loss per share, basic and diluted	$ (0.56)	$ (0.46)
Weighted average shares outstanding, basic and diluted	166,072,192	95,846,672

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Revenues	$ 435	106	$ 1,247	$ 162
Cost of sales	—	—	—	—
Gross profit	435	106	1,247	162
Operating expenses:				
Research and development	8,485	11,226	45,785	47,743
Selling and marketing	321	1,151	4,758	5,949
General and administrative	11,788	16,110	68,541	54,089
Total operating expenses	20,594	28,487	119,084	107,781
Loss from operations	(20,159)	(28,381)	(117,837)	(107,619)
Interest income (expense), net	(2,186)	(2,687)	(12,636)	(9,915)
Loss on warrant liability	(48,339)	—	(54,157)	—
Other income (expense), net	(12,222)	(21,294)	5,990	(25,084)
Loss before income taxes	(82,906)	(52,362)	(178,640)	(142,618)
Income tax benefit	(119)	164	(119)	(37,532)
Loss from continuing operations	(82,787)	(52,526)	(178,521)	(105,086)
Loss from discontinued operations	(10,087)	(23,002)	(68,891)	(87,442)
Net loss	(92,874)	(75,528)	(247,412)	(192,528)
Dividend paid to preferred stockholders	—	—	—	(268)
Net loss attributable to common stockholders	$ (92,874)	$ (75,528)	$ (247,412)	$ (192,796)
Net loss per share from continuing operations, basic and diluted	$ (0.50)	$ (1.07)	$ (1.86)	$ (3.82)
Net loss per share from discontinued operations, basic and diluted	$ (0.06)	$ (0.47)	$ (0.72)	$ (3.18)
Net loss per share, basic and diluted	$ (0.56)	$ (1.53)	$ (2.57)	$ (7.00)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.56)	$ (1.53)	$ (2.57)	$ (7.01)
Weighted average shares outstanding, basic and diluted	166,072,192	49,288,579	96,154,672	27,512,876

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 88,397	$ 92,076
Accounts receivable, net	653	6,634
Prepaid expenses and other current assets	7,232	8,632
Current assets of disposal group held for sale	2,147	18,996
Total current assets	98,429	126,338
Property and equipment, net	4,012	8,106
Other assets	326	169
Goodwill	6,072	6,072
Long-term assets of disposal group held for sale	—	13,755
Total assets	$ 108,839	$ 154,440
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 8,709	$ 17,379
Accrued expenses and other current liabilities	34,157	54,437
Warrant liability	18,731	—
Current portion of mortgages payable and capital lease obligations	12	338
Current liabilities of disposal group held for sale	—	516
Total current liabilities	61,609	72,670
Mortgages payable and capital lease obligations, net of current portion	—	1,317
Convertible notes, net	126,392	158,886
Embedded derivative liability	—	18,370
Other long-term liabilities	5,814	8,667
Long-term liabilities of disposal group held for sale	—	1,524
Total liabilities	$ 193,815	$ 261,434
Stockholders' deficit:		
Common stock	146	59
Additional paid-in capital	722,646	452,992
Accumulated deficit	(788,686)	(541,274)
Treasury stock	(19,082)	(18,771)
Total stockholders' deficit	(84,976)	(106,994)
Total liabilities and stockholders' deficit	$ 108,839	$ 154,440

Exhibit 99.2

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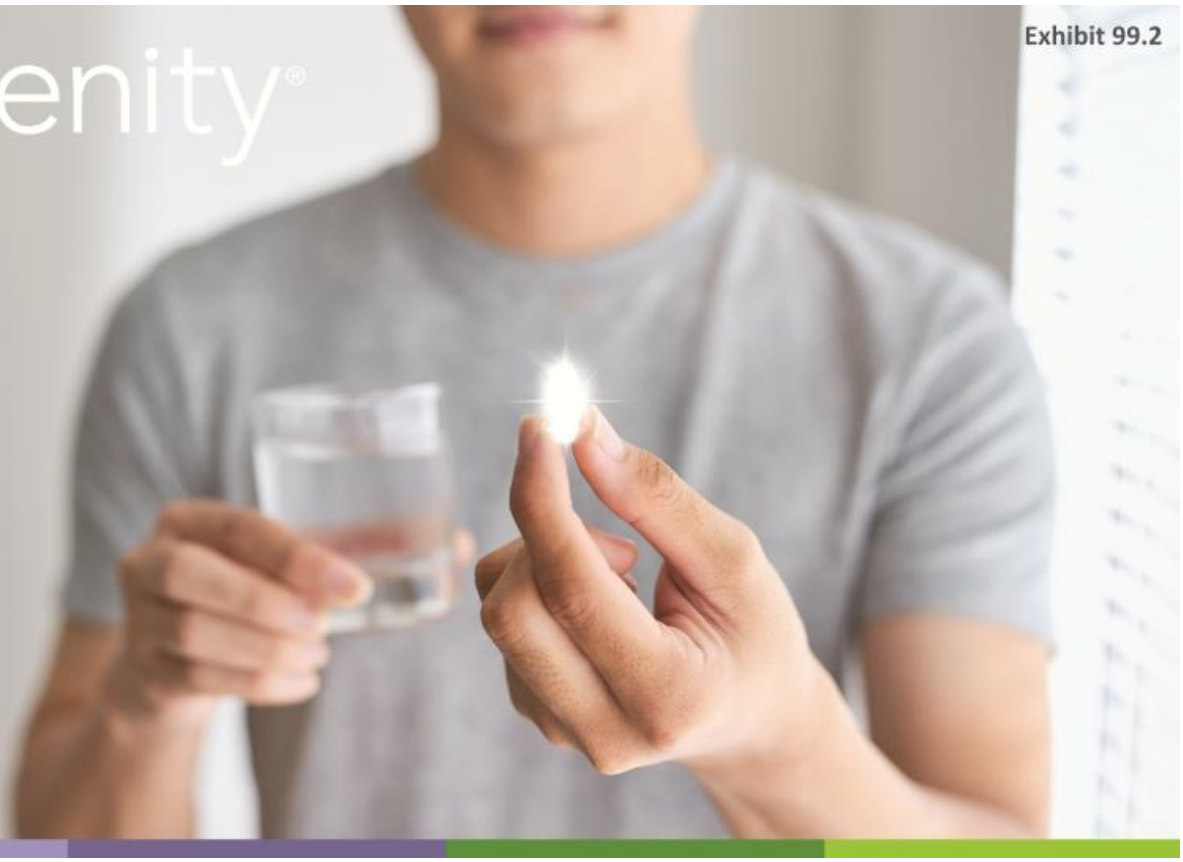
CORPORATE PRESENTATION

March 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 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.

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

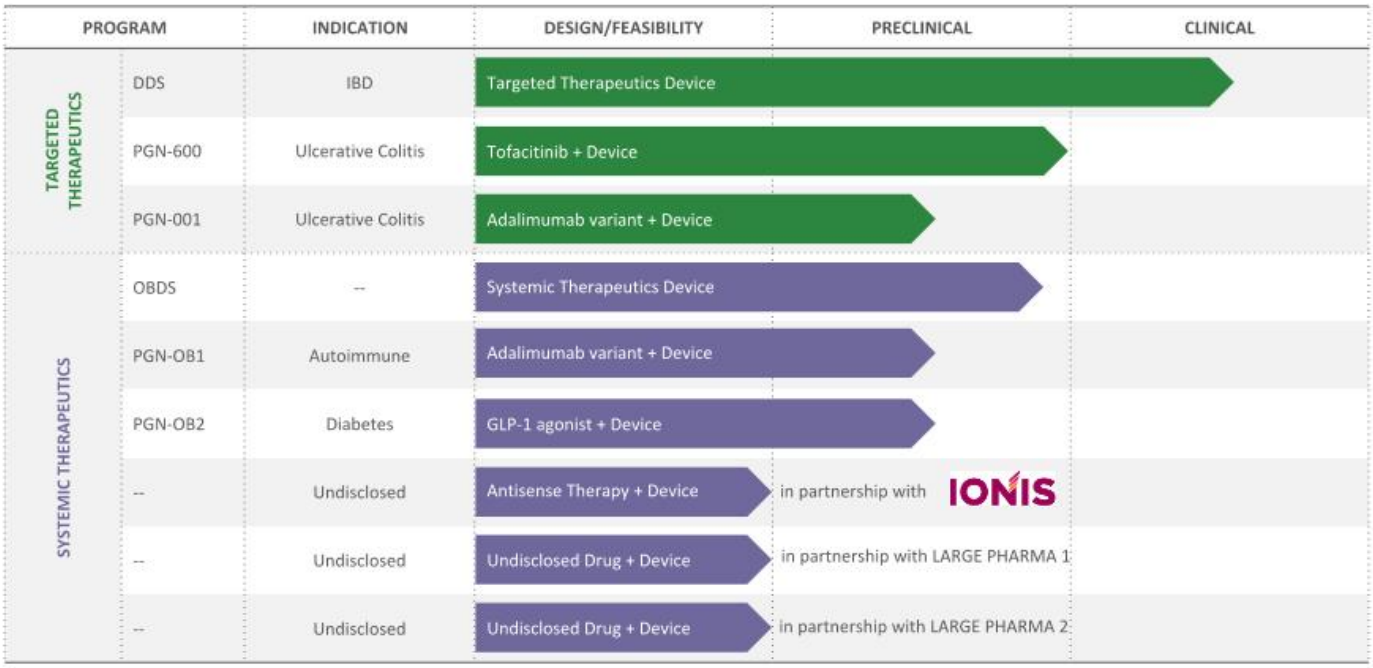
Capsule technology designed for systemic delivery of biotherapeutics, replacing injection with needle-free, oral delivery technology.

OBDS
Systemic Oral Biotherapeutics Delivery System

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

Ionis Pharma	Large Pharma 1	Large Pharma 2
Antisense therapy + OBDS	Undisclosed drug + OBDS	Undisclosed drug + OBDS

THERAPEUTICS PIPELINE

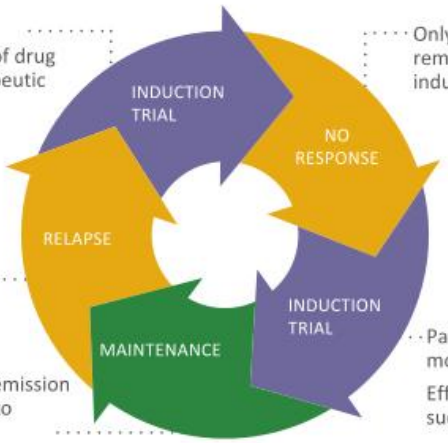


TARGETED THERAPEUTICS

ULCERATIVE COLITIS: THE TREATMENT GAP

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

UC TREATMENT CYCLE



Treatment begins with induction: 2-3 months of drug therapy to reach therapeutic levels

Only 15% of patients achieve remission of symptoms following induction with any drug therapy[1,2]

Patient undergoes induction (2-3 months) with a different drug.

Efficacy rate decreases with successive rounds of therapy[1]

Patients who achieve remission continue drug therapy to prevent relapse

60% of patients who achieve short-term remission relapse within 12 months[2]

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.

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 17 th Congress of the European Crohn's and Colitis Organisation (ECCO); February 18, 2022.

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

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

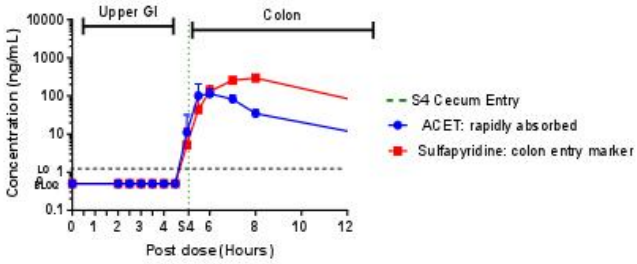
- Proprietary autolocation in the GI tract for accurate drug delivery

Research in partnership with: CROHN'S & COLITIS FOUNDATION

watch activation video

TARGETED THERAPEUTICS: PRECLINICAL RESULTS

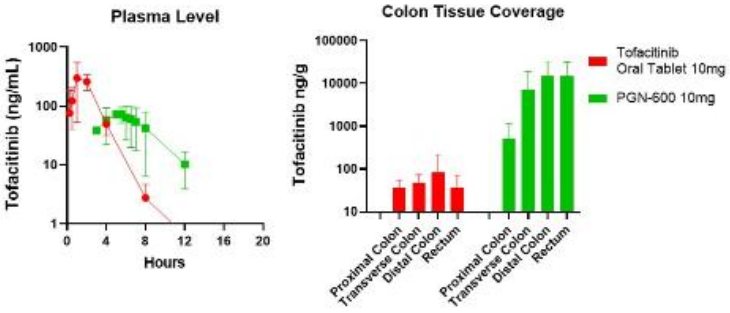
ACCURATE DELIVERY TO THE COLON



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



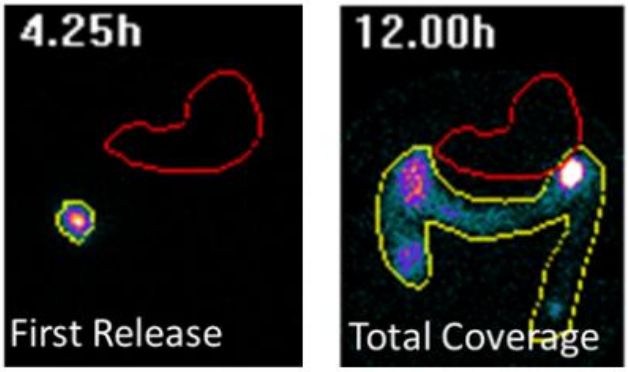
Standard oral dose vs. PGN-600 (tofacitinib delivered via DDS capsule) in canine model demonstrated:

- 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

TARGETED THERAPEUTICS: CLINICAL DEVICE PERFORMANCE

Accurate localization and delivery demonstrated in humans

DEVICE LOCALIZATION AND DELIVERY TO COLON



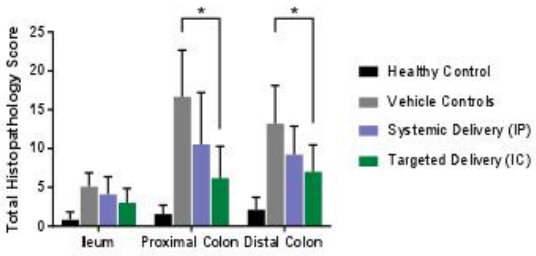
Successful clinical device validation for localization and delivery function using scintigraphic imaging:

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

TARGETED DELIVERY: SUPERIOR PHARMACODYNAMICS IN MULTIPLE MOLECULES

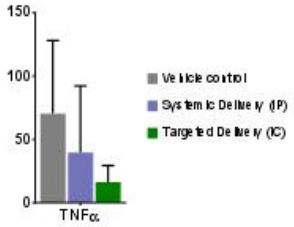
Anti-TNFα in animal models

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

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 **OBJECTIVES** ▶ Scintigraphy confirmation of device location, drug release, and colon coverage	**PGN-600 Tox GLP** ▶ Up to 30 animals in three groups: ▶ Oral pill ▶ Device only (10 mg) ▶ Device + drug (25 mg) ▶ 8 weeks/QD **OBJECTIVES** ▶ Confirmation of device location, drug release, and colon coverage **Previous Tox Study (2021)** 7 days/QD in canines ▶ No safety signals were observed	**PGN-600 Single & Multiple Dose in Healthy Volunteers** ▶ Up to 50 total subjects (25 single dose / 25 multiple dose) ▶ 1 week **OBJECTIVES** ▶ Scintigraphy confirmation of device location, drug release, and colon coverage	**PGN-600 Safety and Efficacy in Subjects with Moderate to Severe Ulcerative Colitis Who Have Been Previously Exposed to TNF Antagonist** **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

SYSTEMIC THERAPEUTICS

NEEDLE AVERSION LEADS TO POOR PATIENT ADHERENCE

Patients prefer oral delivery of medication

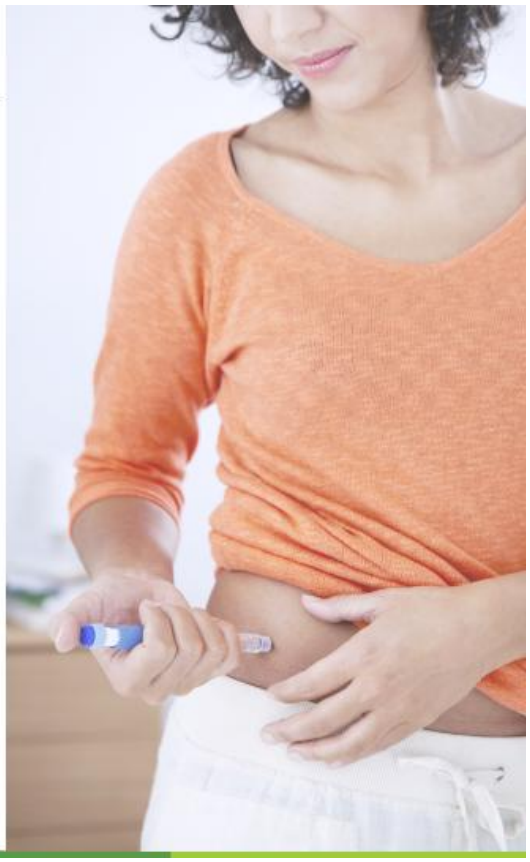
20% of adults avoid medical treatment due to fear of needles[1]

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

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

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

RESEARCH PARTNERSHIPS

Large Pharma 1

Large Pharma 2

IONIS

watch activation video

SYSTEMIC THERAPEUTICS: PRECISION DELIVERY

Preclinical studies demonstrate precise and reliable release of payload

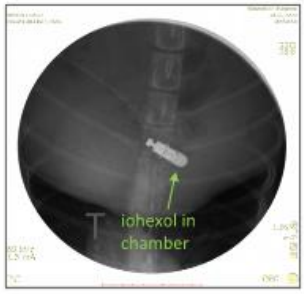
STUDY DESIGN

- 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

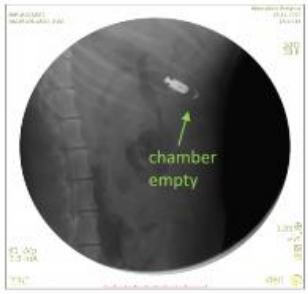
RESULTS

- 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



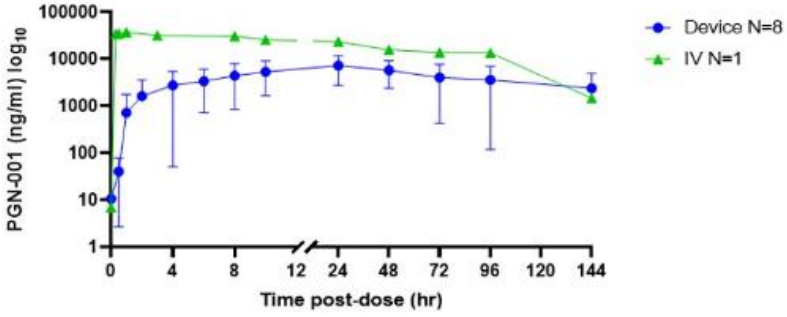
After deployment in the small intestine

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

BIOAVAILABILITY COMPARABLE TO IV ADMINISTRATION



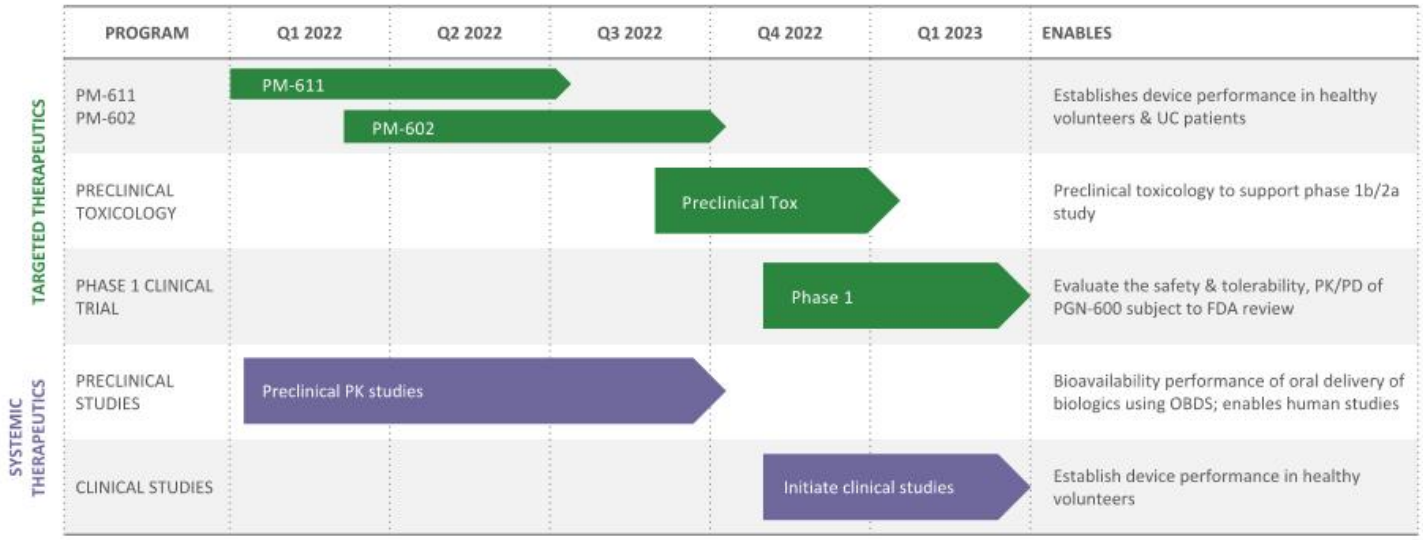
1. Progenity internal data

MILESTONES & CORPORATE HIGHLIGHTS

OTHER PLATFORMS IN DEVELOPMENT

PLATFORM	DESCRIPTION	DEVELOPMENT PLANS
RSS: RECOVERABLE SAMPLING SYSTEM	Ingestible capsule designed to autonomously identify locations in the GI tract, collect and preserve a sample for recovery and analysis.	▶ Presenting microbiome sampling data at DDW 2022 ▶ Continuing device development
PIL Dx	Ingestible capsule designed to sample, measure, and transmit results. Potential for on-board fluorescent assays measuring bacteria, proteins, and drugs, plus additional detection modalities.	▶ Continuing device development and preclinical research
PREECLUDIA™ TEST **SINGLE-MOLECULE DETECTION PLATFORM**	For patients with symptoms of possible preeclampsia, the Preecludia test assesses risk by evaluating multiple pathophysiological pathways. Novel, single-molecule counting assay, initially for NIPT. Potentially applicable to known genomic, epigenomic, and proteomic targets.	▶ Validation study results were published in the Journal of Pharmaceutical and Biomedical Analysis ▶ Further development of diagnostic testing has been discontinued at Progenity; managed process for licensing to potential commercial partners is ongoing

NEAR-TERM POTENTIAL CATALYSTS

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