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

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): November 10, 2021

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 200 **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	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 November 10, 2021, Progenity, Inc. issued a press release and earnings presentation announcing its financial results for the quarter ended September 30, 2021. The press release and earnings 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 Exhibits 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 Exhibits 99.1 and 99.2 be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press release, dated November 10, 2021
99.2	Earnings presentation, dated November 10, 2021
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: November 10, 2021

By: /s/ Eric d'Esparbes

Eric d'Esparbes
Chief Financial Officer

Exhibit 99.1

Progenity Provides Corporate Update and Reports
Third Quarter 2021 Financial Results

Added important patents further protecting the company's therapeutic delivery technologies

Added strong biotherapeutics capabilities to management team and board of directors

Implemented cost-cutting measures expected to result in approximately $145 million in cost savings on an annual basis[1]

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

SAN DIEGO, November 10, 2021 – Progenity, Inc. (Nasdaq: PROG), an innovative biotechnology company, today provided a corporate update and reported financial results for the third quarter ended September 30, 2021.

During the third quarter, Progenity added four patents related to its ingestible device and method technologies designed for delivery of therapeutics via the gastrointestinal (GI) tract, further strengthening one of the most robust patent portfolios of its kind.

Progenity also recently added key biotechnology and biotherapeutics leadership capabilities with proven financial leadership and extensive pharmaceutical industry experience by appointing Adi Mohanty as Chief Executive Officer and Jill Howe as a member of the Board of Directors and chair of the Audit Committee.

In the third quarter Progenity continued its strategic transformation directed at significantly reducing its cash-burn rate while accelerating its transition to an innovation-led biotherapeutics company focused on its oral delivery of biotherapeutics and its GI-targeted therapeutics platforms. As part of its strategic transformation, Progenity is in the process of implementing previously announced operating cost-cutting measures that are expected to result in cost savings of approximately $145 million on an annual run-rate basis[1], and it plans to continue to optimize its capital allocation.

"Progenity is making great strides in its transformation into a biotherapeutics company. I'm looking forward to accelerating this process, and to helping the company efficiently advance its innovation pipeline, which has great potential to impact the diagnosis and treatment of serious diseases," said Adi Mohanty, Chief Executive Officer of Progenity.

[1] Compared to Q2 2021 cash expenses annual run rate

Third Quarter 2021 Results and Other Corporate Highlights

- Added four patents related to its ingestible technologies for delivery of therapeutics via the GI tract, including methods and devices for delivery of a therapeutic agent into GI tissue for systemic uptake, methods of treating ulcerative colitis using an ingestible device that is designed to deliver a JAK inhibitor directly to the proximal part of the large intestine, and treatment of a disease of the gastrointestinal tract with a SMAD7 inhibitor and with a chemokine/chemokine receptor inhibitor.
- Entered into an additional partnership with a large pharmaceutical company to evaluate its therapeutic with Progenity's Oral Biotherapeutics Delivery System (OBDS) currently under development. This marks the company's third collaboration for the OBDS, further demonstrating industry interest in the platform's potential for the oral delivery of large molecules.
- Continued to make progress with device and manufacturing improvements for both OBDS and Drug Delivery System (DDS) programs, and further refined its animal models and its understanding of likely performance in humans.
- Held its first Inflammatory Bowel Disease Clinical Advisory Board meeting. The world-renowned advisory board members reviewed the preclinical and clinical data to date and aligned on the clinical program for the remainder of 2021 and 2022.
- Added biotechnology and biotherapeutics capabilities to the management team and Board of Directors with the appointment of Adi Mohanty as the new 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.
- Raised approximately $40 million in gross proceeds from an underwritten public offering in August 2021 and raised an additional $20 million in gross proceeds from a registered direct offering in October 2021. Progenity also received $19.6 million in gross proceeds from warrant exercises in the second half of 2021 to date.
- Engaged advisory firm and launched managed process to license the Preecludia™ test to commercial partners, with an approximately $3 billion dollar market in the US alone. Progenity also received an important patent allowance for one of the key assays, strengthening the growing IP portfolio for the test and supporting ongoing licensing efforts.

Third Quarter 2021 Financial Results

Comparison of Three Months Ended September 30, 2021 and June 30, 2021

The company generated $9.6 million in revenues during the third quarter, out of which $9.4 million came from discontinued operations. Operating expenses were $30.7 million for the three months ended September 30, 2021, compared to $36.1 million for the three months ended June 30, 2021.

Net loss was $43.7 million for the three months ended September 30, 2021 and net loss per share was $0.46, 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 loss from discontinued operations was $6.9 million for the three months ended September 30, 2021 and net loss per share for discontinued operations was $0.07, compared to a net loss from discontinued operations of $37.1 million and net loss per share of $0.58 for the three months ended June 30, 2021.

Comparison of Three Months Ended September 30, 2021 and 2020

Operating expenses were $30.7 million for the three months ended September 30, 2021, compared to $30.7 million for the three months ended September 30, 2020.

Net loss was $43.7 million for the three months ended September 30, 2021 and net loss per share was $0.46, compared to net loss of $47.1 million and net loss per share of $1.01 for the three months ended September 30, 2020.

Net loss from discontinued operations was $6.9 million for the three months ended September 30, 2021 and net loss per share for discontinued operations was $0.07, compared to net loss from discontinued operations of $13.9 million and net loss per share of $0.30 for the three months ended September 30, 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, Wednesday, November 10, 2021 at 4:30 p.m. Eastern / 1:30 p.m. Pacific. The live call may be accessed by dialing 833-519-1237 for domestic callers and 914-800-3810 for international callers and entering the conference code: 9763335. 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 women's health, gastrointestinal health and oral biotherapeutics. Progenity applies a multi-omics approach, combining genomics, epigenomics, proteomics, and metabolomics to its molecular testing products and to the development of a suite of investigational ingestible devices designed to provide precise diagnostic sampling and drug delivery solutions. Progenity’s vision is to transform healthcare to become more precise and personal by improving diagnoses of disease and improving patient outcomes through localized treatment with targeted therapies.

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, the strength of our intellectual property portfolio, the anticipated timing for development of our drug discovery and delivery systems, expectations regarding future cash burn, expectations regarding cost savings resulting from cost-cutting measures, the potential for partnerships with the OBDS platform and the potential performance of OBDS and DDS programs in humans 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 develop and commercialize our testing products, 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 expectations regarding our in network position, anticipated capacity for our tests, 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 period ended December 31, 2020 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	
	September 30, 2021	**June 30, 2021**
Revenues	$ 182	$ 463
Cost of sales	—	—
Gross profit	182	463
Operating expenses:		
Research and development	12,226	13,401
Selling and marketing	573	2,006
General and administrative	17,944	20,709
Total operating expenses	30,743	36,116
Loss from operations	(30,561)	(35,653)
Interest expense	(3,458)	(3,502)
Loss on warrant liability	(3,322)	(5,146)
Interest and other income, net	467	2,901
Loss from continuing operations	(36,874)	(41,400)
Loss from discontinued operations	(6,870)	(37,131)
Net loss	$ (43,744)	$ (78,531)
Net loss per share from continuing operations, basic and diluted	$ (0.38)	$ (0.65)
Net loss per share from discontinued operations, basic and diluted	$ (0.07)	$ (0.58)
Net loss per share, basic and diluted	$ (0.46)	$ (1.23)
Weighted average shares outstanding, basic and diluted	95,846,672	63,942,298

Progenity, Inc.

Condensed Consolidated Statements of Operations

(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended September 30,	
	2021	**2020**
		(1)
Revenues	$ 182	$ 56
Cost of Sales	—	—
Gross profit	182	56
Operating Expenses:		
Research and development	12,226	13,043
Selling and marketing	573	1,563
General and administrative	17,944	16,116
Total operating expenses	30,743	30,722
Loss from operations	(30,561)	(30,666)
Interest expense	(3,458)	(2,457)
Loss on warrant liability	(3,322)	—
Interest and other income (expense), net	467	(19)
Loss from continuing operations	(36,874)	(33,142)
Loss from discontinued operations	(6,870)	(13,923)
Net loss	$ (43,744)	$ (47,065)
Net loss per share from continuing operations, basic and diluted	$ (0.38)	$ (0.71)
Net loss per share from discontinued operations, basic and diluted	$ (0.07)	$ (0.30)
Net loss per share, basic and diluted	$ (0.46)	$ (1.01)
Weighted average shares outstanding, basic and diluted	95,846,672	46,632,043

1. The condensed consolidated statement of operations for the three months ended September 30, 2020 has been adjusted to reflect discontinued operations.

Progenity, Inc.

Condensed Consolidated Balance Sheets

(Unaudited)

(In thousands)

	September 30, 2021	December 31, 2020 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 54,136	$ 91,520
Accounts receivable, net	1,917	6,634
Prepaid expenses and other current assets	10,372	8,107
Current assets of disposal group held for sale	26,545	20,077
Total current assets	92,970	126,338
Property and equipment, net	4,564	8,106
Other assets	147	169
Long-term assets of disposal group held for sale	—	19,827
Total assets	$ 97,681	$ 154,440
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 7,989	$ 12,657
Accrued expenses and other current liabilities	40,850	51,206
Warrant liability	42,402	—
Current portion of mortgages payable and capital lease obligations	110	338
Current liabilities of disposal group held for sale	11,922	8,469
Total current liabilities	103,273	72,670
Mortgages payable and capital lease obligations, net of current portion	1,219	1,317
Convertible notes, net	156,045	158,886
Embedded derivative liability	—	18,370
Other long-term liabilities	14,110	8,239
Long-term liabilities of disposal group held for sale	—	1,952
Total liabilities	$ 274,647	$ 261,434
Stockholders' deficit:		
Common stock	83	59
Additional paid-in capital	537,548	452,992
Accumulated deficit	(695,813)	(541,274)
Treasury stock	(18,784)	(18,771)
Total stockholders' deficit	(176,966)	(106,994)
Total liabilities and stockholders' deficit	$ 97,681	$ 154,440

1. The condensed consolidated balance sheet data at December 31, 2020 has been derived from the audited consolidated financial statements, with adjustments to reflect the assets and liabilities held for sale.

Exhibit 99.2

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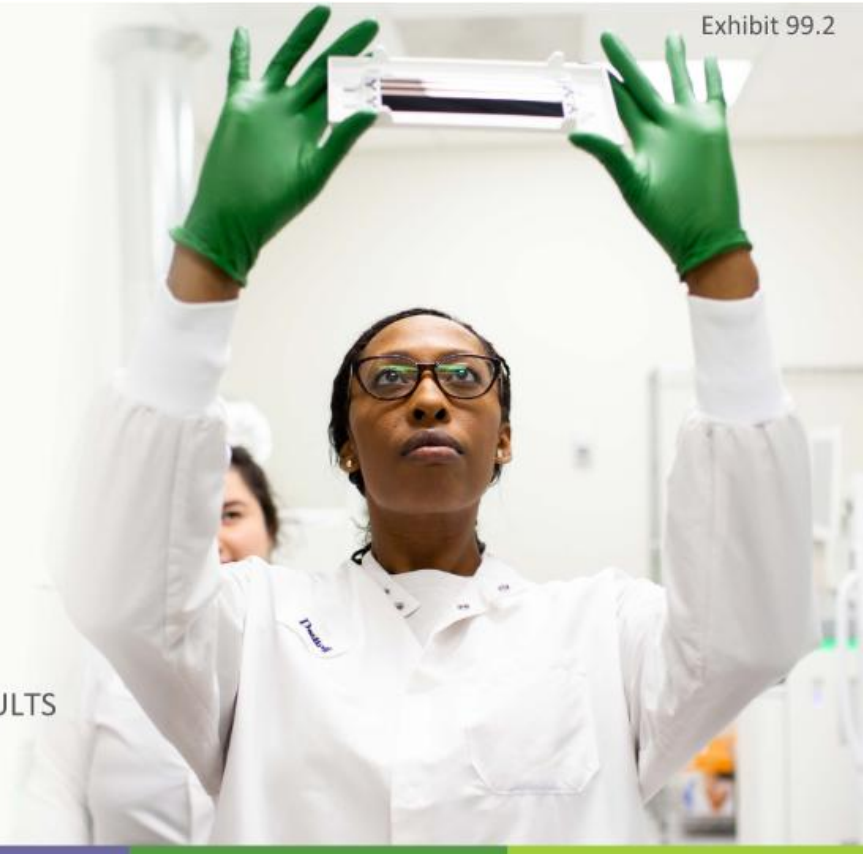
Prepare for life.



THIRD QUARTER 2021 – FINANCIAL RESULTS

November 2021

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, future revenues or performance, financing needs, plans or intentions relating to product candidates, estimates of market size, estimates of market growth, business trends, expected testing supply and demand, the anticipated timing, design and conduct of our planned clinical trials, the development of our product candidates, including the timing and likelihood of regulatory filings and approvals for our product candidates, our ability to commercialize our product candidates, if approved, the pricing and reimbursement of our product candidates, if approved, the potential to develop future product candidates, the potential benefits of strategic collaborations and our intent to enter into any strategic 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, 2020, 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 (SEC).

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.

RECENT HIGHLIGHTS

ORAL DELIVERY OF BIOTHERAPEUTICS

- Initiated preclinical studies of PGN-OB1 (variant of adalumimab) and PGN-OB2 (GLP-1 agonist)
- Promising initial data with average bioavailability of approx. 15% of IV for PGN-OB1 following a single dose[1]
- Signed third pharma partnership to test their molecule with the OBDS
- Obtained a patent related to OBDS device

GI-TARGETED THERAPEUTICS

- Ongoing clinical study in ulcerative colitis patients using adalimumab delivered by enema as proxy for PGN-001 (variant of adalumimab)
- Designing first clinical study for PGN-600 (tofacitinib)
- Established IBD Clinical Advisory Board
- Obtained three patents related to therapeutic technologies
- DDS article published in Crohn's & Colitis 360

STRATEGIC TRANSFORMATION

- Company transformation into focused biotherapeutics platform company progressing as planned
- Already achieved $110M reduction in annual operating expenses annual run rate; targeting total $145M reduction post transformation
- Maintaining Avero Diagnostics while pursuing divestiture

PREECLUDIA™ TEST

- Submitted validation study data from Preecludia™ rule-out test for preeclampsia for publication in peer-reviewed journal
- Awarded patent for one of the key assays
- Engaged advisory firm and launched a managed process to license the test to potential commercial partners

1. In animals where significant drug was detected

INNOVATION PIPELINE UPDATE

THERAPEUTICS PROGRAMS

drug-device combinations

ORAL DELIVERY OF BIOTHERAPEUTICS

For drugs that today must be injected, our ingestible capsule technology could enable needle-free, oral delivery and systemic uptake of large molecules.

ODBS

Oral Biotherapeutics Delivery System

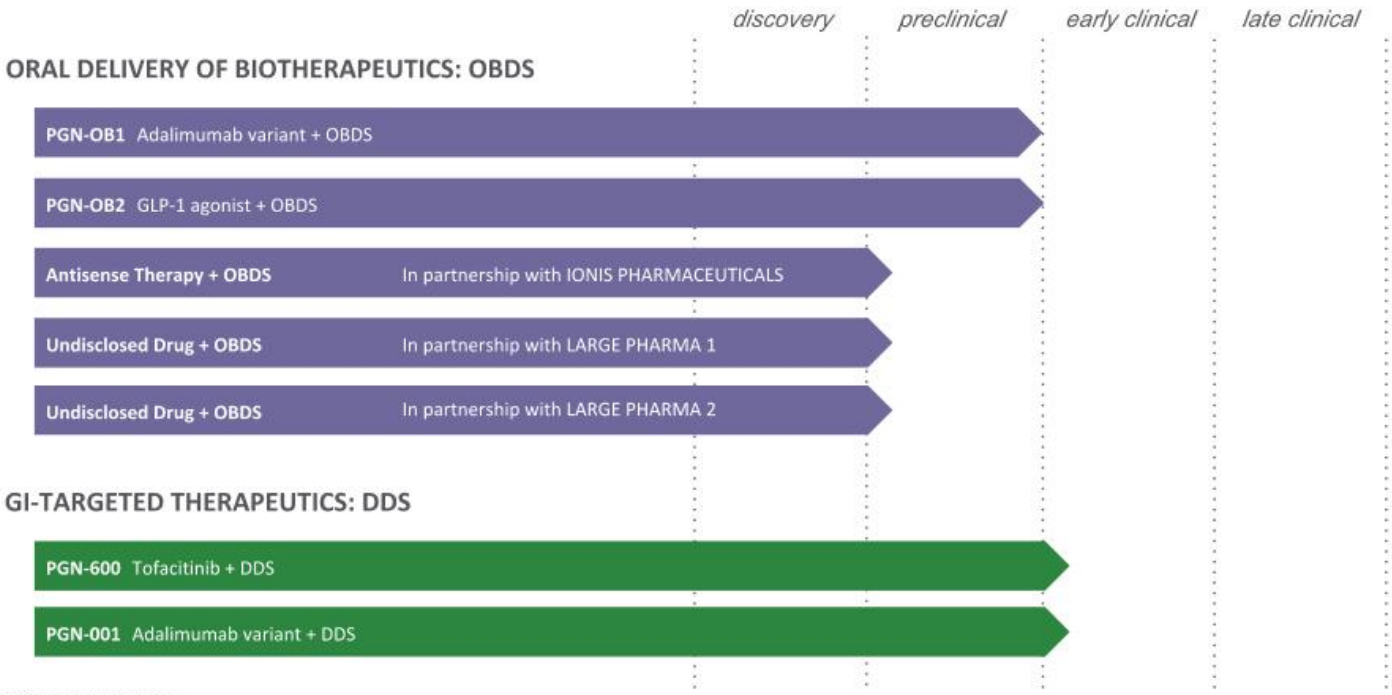
GI-TARGETED THERAPEUTICS

For people who suffer from gastrointestinal diseases, delivering therapeutics directly to the site of disease could enable safer and more effective drug therapies.

DDS

Drug Delivery System

THERAPEUTICS PIPELINE



THERAPEUTICS PROGRAMS

Program updates – Q3

ORAL DELIVERY OF BIOTHERAPEUTICS

- Initiated preclinical studies of PGN-OB1 (variant of adalumimab) and PGN-OB2 (GLP-1 agonist)
- Promising initial data with average bioavailability of approximately 15% of IV for PGN-OB1 following a single dose[1]
- Signed third pharma partnership to test their molecule with the OBDS
- Obtained a patent related to OBDS device

GI-TARGETED THERAPEUTICS

- Ongoing clinical study in ulcerative colitis patients using adalimumab delivered by enema as proxy for PGN-001 (variant of adalumimab)
- Designing first clinical study for PGN-600 (tofacitinib)
- Established IBD Clinical Advisory Board
- Obtained three patents related to therapeutic technologies
- DDS article published in Crohn's & Colitis 360

1. In animals where significant drug was detected

PREECLUDIA™ TEST

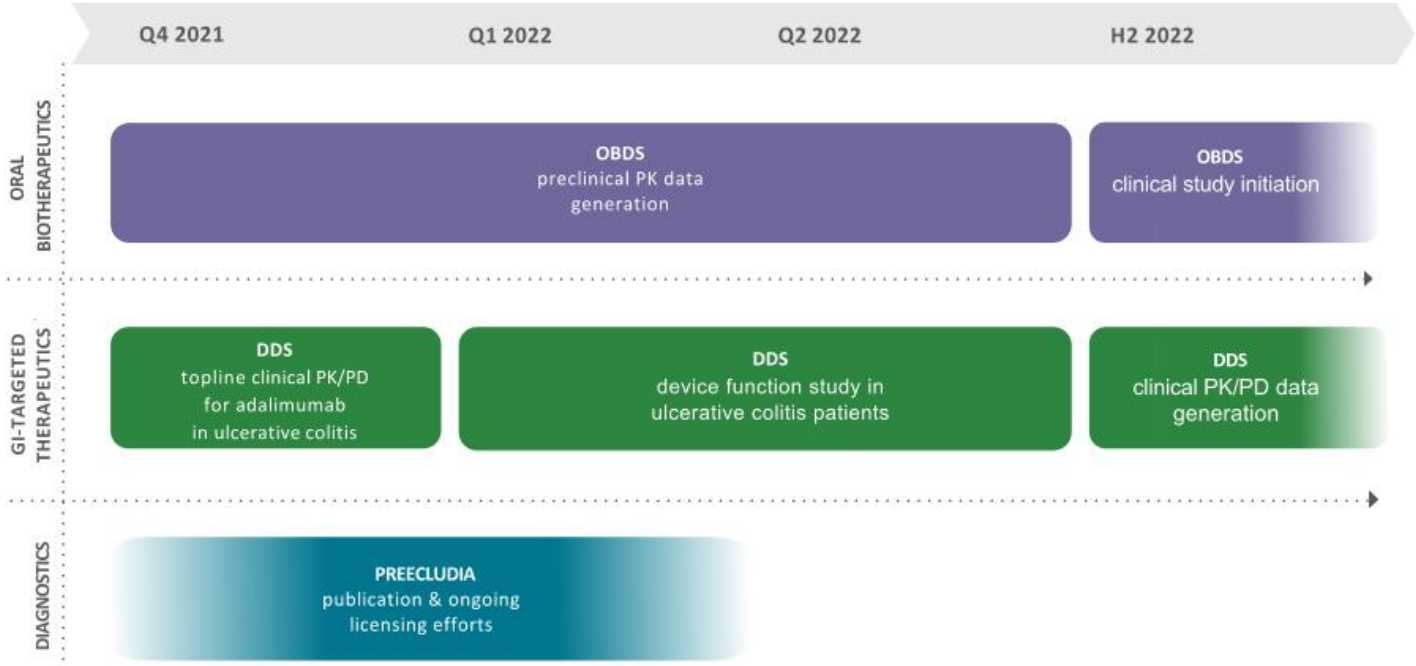
Program updates – Q3

RULE-OUT TEST FOR PREECLAMPSIA

For patients with symptoms of possible preeclampsia, the Preecludia test is potentially the first blood test designed to assess risk by evaluating multiple pathophysiological pathways.

- Submitted PRO-104 validation study manuscript publication in peer-reviewed journal; data is under embargo until publication
- Awarded patent for one of the key assays
- Engaged advisory firm and launched managed process to license the test to potential commercial partners

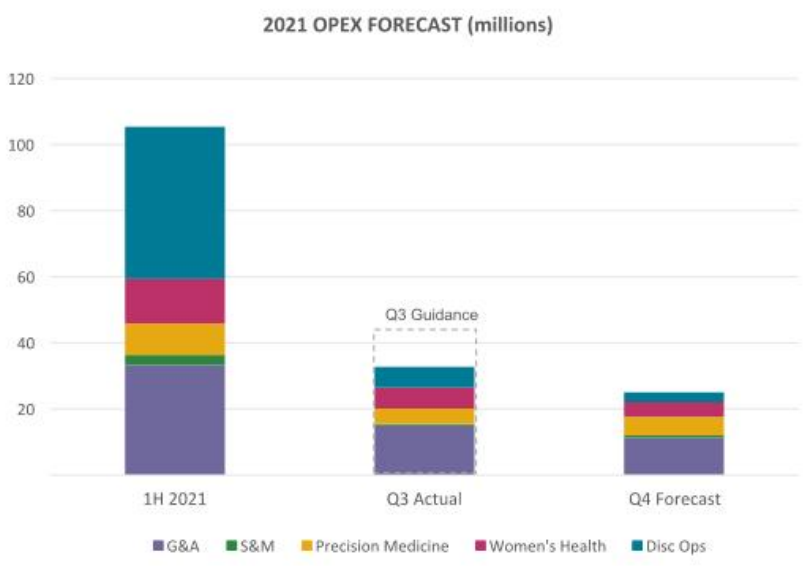
NEAR-TERM POTENTIAL CATALYSTS



OPERATING EXPENSES

OPEX REDUCTIONS

- Secured $110 million in OPEX[1] annual run rate reductions from Q2 2021
- Expecting ~$145 million[2] total OPEX annual run rate reduction post company transformation
- Confirming target range of $5 to $6 million monthly cash burn run-rate post transformation
- Raised ~$79 million during H2 2021, providing cash runway extending into Q3 2022.
- Focusing stage-gated capital allocation on innovation pipeline



[1] Operating expenses before stock-based compensation accruals
[2] Assumes sale of Avero by end of 2021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