UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): August 12, 2021

Progenity, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-39334 Commission File Number) 27-3950390 (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 fili	ng obligation of the registrant under any of the following provisions:				
\square Written communications pursuant to Rule 425 under the Se	ecurities Act (17 CFR 230.425)				
\square Soliciting material pursuant to Rule 14a-12 under the Exch	nange Act (17 CFR 240.14a-12					
\square Pre-commencement communications pursuant to Rule 14d	-2(b) under the Exchange Act	(17 CFR 240.14d-2(b))				
\square Pre-commencement communications pursuant to Rule 13e-	-4(c) under the Exchange Act ((17 CFR 240.13e-4(c))				
Securities	registered pursuant to Section	on 12(b) of the Act:				
	Trading					
Title of each class	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 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter). Emerging growth company ⊠	company as defined in Rule 40	05 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of				
If an emerging growth company, indicate by check mark if the registra accounting standards provided pursuant to Section 13(a) of the Exchange \Box		xtended transition period for complying with any new or revised financial				

Item 2.02 Results of Operations and Financial Condition.

On August 12, 2021, Progenity, Inc. issued a press release and earnings presentation announcing its financial results for the quarter ended June 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 August 12, 2021
- 99.2 <u>Earnings presentation, dated August 12, 2021</u>
- 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: August 12, 2021 By: /s/ Harry Stylli, Ph.D.

Harry Stylli, Ph.D.

Chairman and Chief Executive Officer



Progenity Provides Corporate Update and Reports Second Quarter 2021 Financial Results

Announced successful completion of the validation study PRO-104 for the PreecludiaTM rule out test for preeclampsia and achievement of the primary endpoint of the study protocol

Recently achieved promising results with the prototype autonomous Oral Biotherapeutics Delivery System in a single oral dose study in a porcine model for lead candidate PGN-OB1

Implemented cost-cutting measures expected to result in approximately \$97 million of cost savings on an annual run-rate basis

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

SAN DIEGO, August 12, 2021 – Progenity, Inc. (Nasdaq: PROG), a biotechnology company innovating in the fields of gastrointestinal health and oral biotherapeutics, today provided a corporate update and reported financial results for the second quarter ended June 30, 2021.

In the second quarter Progenity initiated a strategic transformation directed at significantly reducing its cash burn rate whilst accelerating its transition to an innovation-led biotech company focused on its oral delivery of biomolecules and its GI-IBD platforms. The company has implemented cost-cutting measures that are expected to result in cost savings of approximately \$97 million on an annual run-rate basis, and it plans to continue to evaluate and implement further cost-saving measures.

The company also recently announced the successful completion of the validation study, PRO-104, for its PreecludiaTM rule out test for preeclampsia. Importantly, PreecludiaTM achieved the primary endpoint of the study protocol and demonstrated strong performance consistent with what was achieved in the PRO-129 verification study and pre-validation set.

Separately, during the second quarter the company initiated preclinical studies of its lead candidates PGN-OB1 (adalimumab a monoclonal) and PGN-OB2 (liraglutide, a GLP 1 agonist) utilizing for the first time its prototype autonomous Oral Biotherapeutics Delivery System (OBDS) in a swine model. Data from a recent study demonstrated that, in animals with significant drug detected, average bioavailability levels were approximately 15% with maximum levels up to 44% of IV for adalimumab following a single dose, highlighting the vast potential for this program.

"Our GI innovation pipeline is progressing with both the Oral Biotherapeutics Delivery System and the Drug Delivery System now available as fully autonomous prototype devices that will enable key studies to be performed to advance our programs and provide potential partnership opportunities. I'm also excited by the successful outcome for the PreecludiaTM PRO-104 validation study results, which we expect the independent PIs to publish soon, and we are making good progress with our single molecule platform. I'm also pleased with the implementation and execution of our company transformation with substantial costs savings already being achieved and with more anticipated in the coming months. We are projecting multiple key catalysts in the next quarter and beyond, and we look forward to sharing those results in the near future," said Harry Stylli, PhD. CEO, chairman of the board, and co-founder of Progenity.

Second Q	nuarter 2021 Results and Other Corporate Highlights
	Successful completion of the validation study for the Preecludia™ rule-out test for preeclampsia. Achieved the primary endpoint of the study protocol. Demonstrated strong performance and a high NPV consistent with what was achieved in the PRO-129 verification study and pre-validation set.
	Completed closure of Ann Arbor laboratory and refocus of resources toward innovation pipeline. Operating expenses reduction plan is on track to achieve target.
	Initiated preclinical studies of PGN-OB1 (adalimumab + OBDS) and PGN-OB2 (GLP 1 agonist + OBDS). Initial data is promising with average bioavailability of approximately 15% in animals where significant drug was detected, and reaching up to 44%. Existing pharma partnerships advancing as expected.
	Announced the formation of its Inflammatory Bowel Disease Clinical Advisory Board. The advisory board includes respected researchers and clinicians who are thought leaders in the research and treatment of inflammatory bowel disease (IBD).
	Ongoing clinical study in ulcerative colitis patients using adalimumab delivered by enema as proxy for PGN-001 (adalimumab + Drug Delivery System (DDS)). First four subjects have completed dosage regimen with promising initial results Clinical advisory board to meet next month to review data and help finalize design of the first human feasibility study delivering Humira with the DDS.
	Announced the appointment of Surbhi Sarna to its board of directors effective July 1, 2021. Ms. Sarna's medical device experience and her focus on development of strategic partnerships will prove valuable as the company advances its innovation pipeline.
	In June 2021, raised approximately \$40.0 million in gross proceeds from a private placement with two leading healthcare-focused investment funds.

Second Quarter 2021 Financial Results

Comparison of Three Months Ended June 30, 2021 and March 31, 2021

Operating expenses were \$36.1 million for the three months ended June 30, 2021, compared to \$31.6 million for the three months ended March 31, 2021.

Net loss was \$78.5 million for the three months ended June 30, 2021 and net loss per share was \$1.23, compared to a net loss of \$32.3 million and a net loss per share of \$0.56 for the three months ended March 31, 2021.

Net loss from discontinued operations was \$37.1 million for the three months ended June 30, 2021 and net loss per share for discontinued operations was \$0.58, compared to a net loss from discontinued operations of \$14.8 million and a net loss per share of \$0.26 for the three months ended March 31, 2021.

Comparison of Three Months Ended June 30, 2021 and 2020

Operating expenses were \$36.1 million for the three months ended June 30, 2021, compared to \$26.5 million for the three months ended June 30, 2020.

Net loss was \$78.5 million for the three months ended June 30, 2021 and net loss per share was \$1.23, compared to a net loss of \$53.1 million and a net loss per share of \$6.11 for the three months ended June 30, 2020.

Net loss from discontinued operations was \$37.1 million for the three months ended June 30, 2021 and net loss per share for discontinued operations was \$0.58, compared to a net loss from discontinued operations of \$20.1 million and a net loss per share of \$2.31 for the three months ended June 30, 2020.

Webcast and Conference Call Information

Progenity will host a webcast and conference call to discuss the second quarter financial results and answer investment community questions today, Thursday, August 12, 2021 at 4:30 p.m. ET / 1:30 p.m. PT. 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: 8635609. 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 additional information about Progenity, please visit the company's website at www.progenity.com.

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," "cauld," "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		
	June 30, 2021		March 31, 2021	
Revenues	\$	463	\$	167
Cost of sales		_		_
Gross profit		463		167
Operating expenses:				
Research and development		13,401		11,673
Selling and marketing		2,006		1,858
General and administrative		20,709		18,100
Total operating expenses		36,116		31,631
Loss from operations		(35,653)		(31,464)
Interest expense		(3,502)		(3,520)
(Loss) gain on warrant liability		(5,146)		2,650
Interest and other income, net		2,901		14,873
Loss from continuing operations		(41,400)		(17,461)
Loss from discontinued operations		(37,131)		(14,803)
Net loss	\$	(78,531)	\$	(32,264)
Net loss per share from continuing operations, basic and diluted	\$	(0.65)	\$	(0.30)
Net loss per share from discontinued operations, basic and diluted	\$	(0.58)	\$	(0.26)
Net loss per share, basic and diluted	\$	(1.23)	\$	(0.56)
Weighted average number of shares outstanding used in calculating net loss per share, basic and diluted		63.942.298		57.493.800

Progenity, Inc.

Condensed Consolidated Statements of Operations (Unaudited)

(In thousands, except share and per share amounts)
Progenity, Inc.

Three Months Ended June 30,

		June 30,		
	-	2021	ī-	2020
Revenues	\$	463	\$	_
Cost of Sales		_		_
Gross profit		463		_
Operating Expenses:				
Research and development		13,401		12,234
Selling and marketing		2,006		1,547
General and administrative		20,709		12,702
Total operating expenses		36,116		26,483
Loss from operations		(35,653)		(26,483)
Interest expense		(3,502)		(2,489)
Loss on warrant liability		(5,146)		_
Interest and other income (expense), net		2,901		(3,751)
Loss from continuing operations		(41,400)		(32,723)
Loss from discontinued operations		(37,131)		(20,060)
Net loss		(78,531)		(52,783)
Dividend paid to preferred shareholders		<u> </u>		(268)
Net loss attributable to common stockholders	\$	(78,531)	\$	(53,051)
Net loss per share from continuing operations, basic and diluted	\$	(0.65)	\$	(3.77)
Net loss per share from discontinued operations, basic and diluted	\$	(0.58)	\$	(2.31)
Net loss per share attributable to common stockholders, basic and diluted	\$	(1.23)	\$	(6.11)
Weighted average number of shares outstanding used in calculating net loss per share, basic and diluted		63,942,298		8,687,250

Condensed Consolidated Balance Sheets (Unaudited) (In thousands)

	J	June 30, 2021		December 31, 2020	
				(1)	
Assets					
Current assets:					
Cash and cash equivalents	\$	65,991	\$	91,520	
Accounts receivable, net		5,047		6,634	
Prepaid expenses and other current assets		13,107		8,107	
Current assets of disposal group held for sale		30,181		20,077	
Total current assets		114,326		126,338	
Property and equipment, net		5,474		8,660	
Other assets		146		169	
Long-term assets of disposal group held for sale				19,273	
Total assets	\$	119,946	\$	154,440	
Liabilities and Stockholders' Deficit					
Current liabilities:					
Accounts payable	\$	14,560	\$	12,657	
Accrued expenses and other current liabilities		58,172		51,206	
Current portion of mortgages payable and capital lease obligations		202		338	
Current liabilities of disposal group held for sale		12,703		8,469	
Total current liabilities		85,637	_	72,670	
Mortgages payable and capital lease obligations, net of current portion		1,238		1,317	
Convertible notes, net		157,533		158,886	
Embedded derivative liability		388		18,370	
Other long-term liabilities		14,759		8,239	
Long-term liabilities of disposal group held for sale		_		1,952	
Total liabilities	\$	259,555	\$	261,434	
Stockholders' deficit:					
Common stock		82		59	
Additional paid-in capital		531,156		452,992	
Accumulated deficit		(652,069)		(541,274)	
Treasury stock		(18,778)		(18,771)	
Total stockholders' deficit		(139,609)		(106,994)	
Total liabilities and stockholders' deficit	\$	119,946	\$	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.



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," "covid," "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

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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RECENT HIGHLIGHTS

WOMEN'S HEALTH

- ➤ Successful completion of the validation study for the Preecludia™ rule-out test for preeclampsia
- Achieved the primary endpoint of the study protocol
- Demonstrated strong performance and a high NPV in line with target in a broad use population
- Proceeding toward publication in peer-reviewed journal

STRATEGIC TRANSFORMATION

- Completed closure of Ann Arbor laboratory; refocused resources toward innovation pipeline
- Opex reduction plan on track to achieve target
- Already achieved \$97 reduction in annual operating expenses annual run rate
- Maintaining Avero Diagnostics while pursuing divestiture

ORAL BIOTHERAPEUTICS

- Initiated preclinical studies of PGN-OB1 (adalumimab) and PGN-OB2 (GLP 1 agonist)
- Goal is to demonstrate bioavailability of drug candidates in comparison to parenteral administration
- Initial data is promising with average bioavailability of approximately 15% and reaching up to 44%¹
- Existing Pharma partnerships advancing as expected

Animals where significant drug was detected.

GASTROINTESTINAL HEALTH

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

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INNOVATION PIPELINE UPDATE

PREECLUDIA™ RULE-OUT TEST FOR PREECLAMPSIA

Test developed with >3,700 patient samples, targeting NPV >95%

PREECLAMPSIA IS THE #2 CAUSE

of maternal mortality1

CURRENT METHODS CANNOT DIFFERENTIATE

VERIFICATION STUDY: PRO-129

samples from 400 patients

days in the target population

Prospective, cohort study producing blinded

Results support a rule-out window up to 14

SPECIFICITY

73.3%

(68.1% - 78.0%)

*NPV calculated at a 10% prevalence representing the expected prevalence

preeclampsia from other hypertensive disorders

>700,000 PATIENTS present with symptoms each year2,3,4

UP TO \$3 BILLION

NPV

98.2%*

(95.5% - 99.3%)

estimated market opportunity in the United States

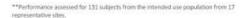
CLINICAL VALIDATION: PRO-104

- · Achieved primary endpoint of validation study protocol (hazard ratio)
- · Demonstrated strong performance and a high NPV level
 - · In line with target
 - · At high prevalence rate and in a broad use population
- · Proceeding toward publication of results in peer reviewed journal





- PRE-VALIDATION DATA SET N = 356 enrolled subjects**
- Demonstrated commercial laboratory systems readiness
- Performance consistent with verification study
- NPV >97%, sensitivity >87%, with prevalence =11% within 14 day rule-out window; specificity >65%





- · Market education and development
- · Initiate trials with partner to evaluate clinical utility
- · Develop health economics data
- · Targeted publication of key data

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SENSITIVITY

88.0%

(78.2% - 94.4%)

- Henderson IT, et al. Preeclampsia Scree JAMA. 2017 Apr 25;317[16]:1668-1683.

- https://www.sciencedirect.com/topics/medicine-and-dentistry/gestational-hypertension
 Center for Disease Control and Prevention. Births: Final Data for 2018 (in press). https://www.cdc.gov/nchs/nvss/births.ht

DRUG PROGRAMS

Drug/Device Combination Products and Drug Delivery Systems

ODBS Oral biotherapeutics delivery system

ORAL BIOTHERAPEUTICS

programy

Ionis Pharmaceuticals Antisense therapy + OBDS

Large Pharma Co
Drug + OBDS

Animals where significant drug was detected
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ORAL SYSTEMIC DELIVERY OF

► PGN-0B1: adalimumab + OBDS

BIOTHERAPEUTICS

- GMP drug substance batch produced
- ► PGN-OB2: GLP-1 agonist + OBDS
- ▶ Recently achieved preclinical avg. bioavailability levels of approx. 15% and maximum levels up to 44% of IV for adalumimab following a single dose¹
- Progress continues under current pharma partnerships

TARGETED THERAPEUTICS

DDS Drug delivery system



PGN-600 Tofacitinib + DDS

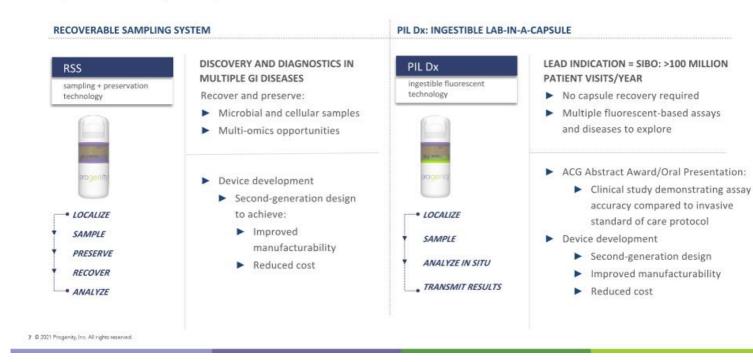
PGN-001 Adalimumab + DDS

LOCALIZED DRUG DELIVERY FOR GI DISORDERS

- ► PGN-600: tofacitinib + DDS
- ► PGN-001: adalimumab + DDS
- Announced first clinical data supporting device auto-location and payload delivery in colon
- Announced positive pre-clinical safety/PK & PD data for PGN-600 (tofacitinib + DDS)
- Ongoing clinical PK study for adalimumab with local drug delivery for ulcerative colitis

GASTROINTESTINAL HEALTH - DIAGNOSTICS

Ingestible GI diagnostic platforms



SINGLE-MOLECULE DETECTION PLATFORM

Novel, single-molecule counting assay, initially for NIPT

Potentially applicable to known genomic, epigenomic, and proteomic targets



QUALITY RESULTS Maintain premium clinical value and reliability



FASTER RESULTS

Enables 3-day laboratory turnaround time



COST EFFECTIVENESS

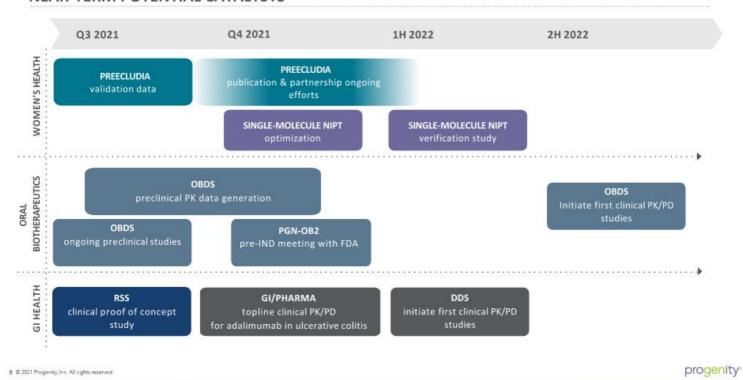
Chemistry greatly reduces assay cost vs. NGS



- Achieved development milestone demonstrating potential to "quantify" fetal fraction
- Made critical advancement by finalizing probe pool design and testing
- Anticipated optimization exit
- · Anticipated validation exit

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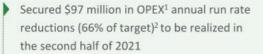
NEAR-TERM POTENTIAL CATALYSTS





OPERATING EXPENSES

OPEX REDUCTIONS

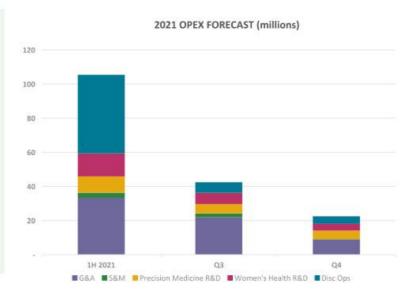


Expecting additional \$50 million in OPEX annual run rate reduction by end of Q4 20212

Monthly expense run rate reducing from \$15 million in 1H'21 to <\$7 million by end of 2021

Focusing stage-gated capital allocation on innovation pipeline





progenity^{*}

