## **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

### FORM 8-K

### CURRENT REPORT

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

Date of Report (Date of earliest event reported): May 13, 2021

## Progenity, Inc.

(Exact name of Registrant as Specified in Its Charter)

001-39334

Delaware (State or Other Jurisdiction of Incorporation)

(Commission File Number)

27-3950390 (IRS Employer Identification No.) 92122

(Zip Code)

4330 La Jolla Village Drive, Suite 200, San Diego, CA (Address of Principal Executive Offices)

Registrant's Telephone Number, Including Area Code: (855) 293-2639

Not Applicable

(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 (see General Instruction A.2. below):

П 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  $\boxtimes$ 

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.  $\Box$ 

### Item 2.02 Results of Operations and Financial Condition.

On May 13, 2021, Progenity, Inc. issued a press release and earnings presentation announcing its financial results for the first quarter ended March 31, 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 May 13, 2021
- 99.2 Earnings presentation, dated May 13, 2021

### 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 hereunto duly authorized.

Date: May 13, 2021

Progenity, Inc.

By: /s/ Harry Stylli, Ph.D. Harry Stylli, Ph.D. Chairman and Chief Executive Officer



#### Progenity Provides Corporate Update and Reports First Quarter 2021 Financial Results

Reports revenues of \$24.5 million in the first quarter of 2021, up 72% from prior quarter

Announced pre-validation data for its Preecludia<sup>™</sup> test showed strong performance consistent with verification study and demonstrated commercial laboratory systems readiness

Announced funding from the Crohn's and Colitis Foundation's IBD Ventures program to further develop Progenity's first-in-class oral DDS for delivery of targeted therapeutics for IBD

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

SAN DIEGO, May 13, 2021 – Progenity, Inc. (Nasdaq: PROG), a biotechnology company with an established track record of success in developing and commercializing molecular testing products, today provided a corporate update and reported financial results for the first quarter ended March 31, 2021.

Progenity made significant progress during the first quarter, both with its core molecular testing business and notably with its innovation pipeline programs. The Company recently announced another key update regarding its Preecludia<sup>™</sup> preeclampsia rule-out test, reporting that new data from a pre-validation cohort of samples tested to demonstrate commercial laboratory readiness showed test performance in the intended use population consistent with its verification study results that were presented on April 30th at the 2021 ACOG Annual Meeting. This new data showed sensitivity greater than 87% and a negative predictive value (NPV) greater than 97%. The Company continued to transition its core molecular testing business towards growth, increased its in-network position by adding regional contracts, and saw additional commercial and government payors covering average risk NIPT.

"We continue to make strong progress in our innovation pipeline as we establish a strong foundation and stabilize our core molecular testing business. We anticipate these efforts will translate into improved operating performance and revenue growth for the rest of 2021. We are on track to meet our Preecludia™ test's validation milestone by midyear and continue to target commercial launch in the second half of 2021 for the \$2-3 billion US market, the Innatal 4 platform is advancing; and we are especially excited by the accelerating progress of our GI Precision Medicine programs," said Harry Stylli, PhD, CEO, chairman of the board, and co-founder of Progenity.

### First Quarter 2021 Results and Other Corporate Highlights

- Announced and presented new data from its Preecludia<sup>™</sup> preeclampsia rule-out test verification study which was presented on April 30<sup>th</sup> at the 2021 ACOG Annual Meeting, with the test demonstrating sensitivity of 87.8% and a negative predictive value (NPV) of 97.0%.
- Announced pre-validation data for its Preecludia<sup>™</sup> test showed strong performance consistent with verification study data and demonstrated commercial laboratory systems readiness.

- Announced completion of assay testing and initiation of data analysis of clinical validation study samples for its Preecludia™ preeclampsia test.
- Entered into an agreement with Ionis Pharmaceuticals, a leader in RNA-targeted therapeutics, to evaluate the safety, tolerability and performance of Progenity's Oral Biotherapeutics Delivery System (OBDS) for oral systemic delivery of antisense oligonucleotides, developed and manufactured by Ionis.
- Announced Crohn's & Colitis Foundation IBD Ventures grant funding for DDS combination drug/device product development for IBD diseases.
- Announced that two abstracts related to Progenity's ingestible drug delivery technologies for the treatment of gastrointestinal disorders have been accepted for
  presentation at Digestive Disease Week® (DDW) taking place May 21-23, 2021.
- Announced first clinical study of the Company's oral drug delivery system (DDS) demonstrating a proprietary autonomous localization technology designed to autolocate and deliver a payload in a key region of the GI tract for drug delivery. Also announced a preclinical safety and tolerability study of PGN-600, a combination product of tofacitinib delivered by DDS.
- In February 2021, raised approximately \$25.0 million in gross proceeds from a private placement with two leading healthcare-focused investment funds.
- Increased in-network covered lives by 3.3 million with the addition of several regional plans.

#### First Quarter 2020 Financial Results

### Comparison of Three Months Ended March 31, 2021 and December 31, 2020

Revenue was \$24.5 million in the three months ended March 31, 2021, a 72% increase compared to \$14.3 million in the three months ended December 31, 2020.

Total accessioned tests volume, which includes the company's core molecular testing and COVID-19 testing, was 78,915 in the first quarter of 2021, a decrease of 3.3% compared to accessioned tests volume in the fourth quarter of 2020, which was 81,640 tests.

Gross margin was positive 9.4% for the three months ended March 31, 2021, compared to negative 50.1% for the three months ended December 31, 2020.

Operating expenses were \$48.5 million for the three months ended March 31, 2021, compared to \$44.2 million for the three months ended December 31, 2020.

Net loss was \$32.3 million for the three months ended March 31, 2021 and basic and diluted net loss per share was \$0.56, compared to a net loss of \$75.5 million and a net loss per share of \$1.53 for the three months ended December 31, 2020.

### Comparison of Three Months Ended March 31, 2021 and 2020

Revenue was \$24.5 million in the three months ended March 31, 2021, a 46% increase compared to \$16.8 million in the three months ended March 31, 2020.

Gross margin was positive 9.4% for the three months ended March 31, 2021, compared to negative 57.9% for the three months ended March 31, 2020.

Operating expenses were \$48.5 million for the three months ended March 31, 2021, compared to \$42.8 million in the three months ended March 31, 2020.

Net loss was \$32.3 million for the three months ended March 31, 2021 and basic and diluted net loss per share was \$0.56, compared to a net loss of \$17.2 million and a net loss per share of \$3.43 for the three months ended March 31, 2020.

### COVID-19 Update

Public health measures related to the novel coronavirus are greatly impacting healthcare practices. We have responded to the COVID-19 pandemic by implementing and maintaining robust response plans, seamlessly continuing laboratory operations and maintaining pre-pandemic turnaround times. We enhanced our digital sales and support capabilities, increased proactive test reporting and remote genetic counseling capabilities, and expanded our mobile phlebotomy services, assisting our customers to continue serving their patients with the same quality care.

### Webcast and Conference Call Information

Progenity will host a webcast and conference call to discuss the first quarter financial results and answer investment community questions today, Thursday, May 13, 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: 6146238. 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 with an established track record of success in developing and commercializing molecular testing products, as well as innovating in the field of precision medicine. Progenity provides in vitro molecular tests designed to improve lives by providing actionable information that helps guide patients and physicians in making medical decisions during key life stages. The company 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 impact of the COVID-19 pandemic on our business, operations, financial results, and future performance, and the progress of our research and development efforts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements reflect our plans, estimates, and expectations, as of the date of this press release. These statements involve known and unknown risks, uncertainties, and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this press release. Such risks, uncertainties, and other factors include, among others, our ability to develop and commercialize our testing products, our ability to obtain and maintain regulatory approval or clearance of our products on 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 S

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.

Investor Contact: Robert Uhl Managing Director, Westwicke ICR ir@progenity.com (619) 228-5886

Media Contact: Kate Blom-Lowery CG Life kblomlowery@cglife.com (858) 457-2436

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

		Three Months Ended			
		March 31, 2021		December 31, 2020	
Revenues (1)	\$	24,526	\$	14,276	
Cost of sales		22,234		21,427	
Gross profit (loss)		2,292		(7,151)	
Operating expenses:					
Research and development		11,673		11,226	
Selling and marketing		14,648		12,471	
General and administrative		22,219		20,523	
Total operating expenses		48,540		44,220	
Loss from operations		(46,248)		(51,371)	
Interest and other expense, net		(3,520)		(2,699)	
Gain on warrant liability		2,650		—	
Interest and other income (expense), net		14,854		(21,294)	
Loss before income taxes		(32,264)		(75,364)	
Income tax expense		_		164	
Net loss	\$	(32,264)	\$	(75,528)	
Net loss per share, basic and diluted	\$	(0.56)	\$	(1.53)	
Weighted average number of shares outstanding used in calculating net loss per share, basic and diluted		57,493,800		49,288,579	

(1) Revenues for the three months ended March 31, 2021 and December 31, 2020 reflect an accrual of \$188 thousand and \$10.7 million, respectively, recorded as a reserve for potential payor settlements.

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

		Three Months Ended March 31,		
		2021		2020
Revenues (1)	\$	24,526	\$	16,828
Cost of Sales		22,234		26,570
Gross profit (loss)	_	2,292		(9,742)
Operating Expenses:				
Research and development		11,673		11,240
Selling and marketing		14,648		14,436
General and administrative		22,219		17,108
Total operating expenses		48,540		42,784
Loss from operations		(46,248)		(52,526)
Interest expense		(3,520)		(2,302)
Gain on warrant liability		2,650		_
Interest and other income (expense), net		14,854		(20)
Loss before income taxes		(32,264)		(54,848)
Income tax expense (benefit)		_		(37,696)
Net loss	\$	(32,264)	\$	(17,152)
Net loss per share, basic and diluted	\$	(0.56)	\$	(3.43)
Weighted average number of shares outstanding used in calculating net loss per share, basic and diluted		57,493,800		4,993,393

(1) Revenues for the three months ended March 31, 2021 reflect an accrual of \$188 thousand recorded as a reserve for potential payor settlements. Revenues for the three months ended March 31, 2020 reflect an accrual of \$13.2 million related to the settlement with the DOJ and the participating State AGS.

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

	March 31, 2021		December 31, 2020 (1)	
Assets				
Current assets:				
Cash and cash equivalents	\$ 65,276	\$	92,076	
Accounts receivable, net	13,206		12,682	
Inventory	12,377		12,219	
Prepaid expenses and other current assets	 10,312		9,361	
Total current assets	101,171		126,338	
Property and equipment, net	17,377		17,842	
Goodwill and other intangible assets	9,830		10,062	
Other assets	 199		198	
Total assets	\$ 128,577	\$	154,440	
Liabilities and Stockholders' Deficit				
Current liabilities:				
Accounts payable	\$ 15,625	\$	17,410	
Accrued expenses and other current liabilities	53,783		54,677	
Warrant liability	10,154		_	
Current portion of mortgages payable and capital lease obligations	 500		583	
Total current liabilities	 80,062		72,670	
Mortgages payable and capital lease obligations, net of current portion	2,741		2,841	
Convertible notes, net	159,204		158,886	
Embedded derivative liability	3,542		18,370	
Other long-term liabilities	 8,535		8,667	
Total liabilities	\$ 254,084	\$	261,434	
Stockholders' deficit:				
Common stock	63		59	
Additional paid-in capital	466,740		452,992	
Accumulated deficit	(573,538)		(541,274)	
Treasury stock	 (18,772)		(18,771)	
Total stockholders' deficit	(125,507)		(106,994)	
Total liabilities and stockholders' deficit	\$ 128,577	\$	154,440	

(1) The condensed consolidated balance sheet data at December 31, 2020 has been derived from the audited consolidated financial statements



# progenity®

First Quarter 2021 Financial Results

May 13, 2021

## **Forward Looking Statements**

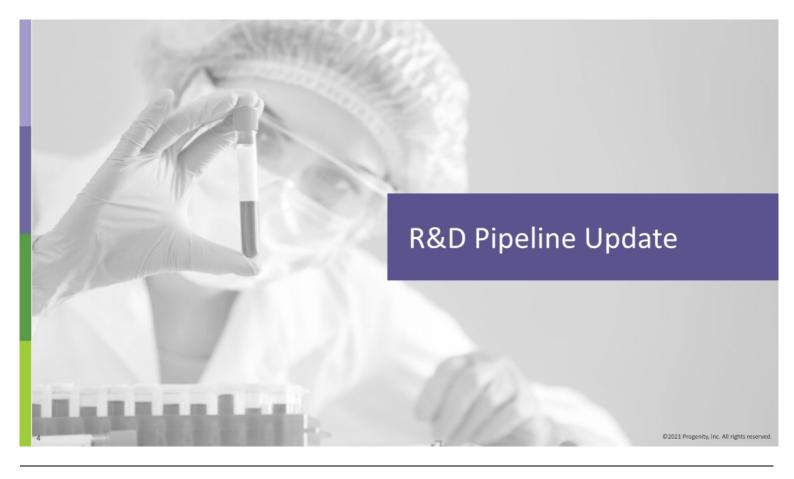
This presentation contains "forward-looking statements" within the meaning of the federal securities laws, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this presentation, 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 in approved, the pricing and reimbursement of 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 results or 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 our Quarterly Reports on Form 10-Q, filed with the <u>U.S. Securities and Exchange Commission (SEC</u>).

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.

# Q1 2021 & Other Recent Corporate Highlights

D	Announced pre-validation data for PREECLUDIA <sup>™</sup> test showing performance consiste with verification study	nt 🔊	Signed agreement with Ionis Pharmaceuticals to evaluate OBDS for oral systemic delivery of their antisense oligonucleotides
Ø	Completed PREECLUDIA validation study sample testing/initiating analysis; planning for targeted commercial launch 2H 2021	Ø	Announced two abstracts accepted for DDW in May 2021 related to ingestible drug delivery technology for treatment of GI disorders
D	Q1 Revenue up 72% vs. Q4 2020, with improving ASPs	♦	Announced first clinical data supporting oral DDS, its proprietary auto-location technology in the GI tract and payload delivery; and first preclinical data of PGN-600 (tofacitinib + DDS)
3	Continued to increase our INN position by 3.3M lives, reaching 149M total covered lives	•	Announced Crohn's & Colitis Foundation IBD Ventures grant funding for DDS combination product development



# Preeclampsia Rule-Out Test: Preecludia™ **Innovative Test to Address Unmet Need**

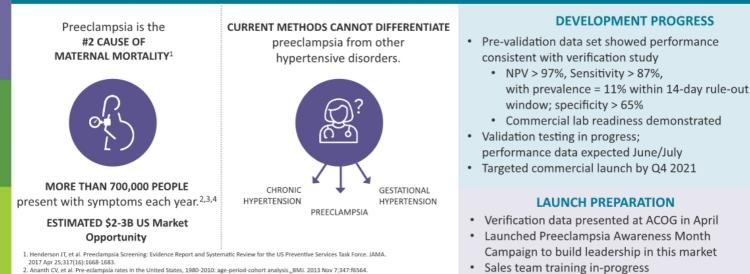
**UNMET NEED** 

3. https://www.sciencedirect.com/topics/medicine-and-dentistry/gestational-hypertension 4. Center for Disease Control and Prevention. Births: Final Data for 2018 (In press). https://www.cdc.gov/nchs/nvss/births.htm

preeclampsia rule-out test

preecludia

## PROJECT UPDATES



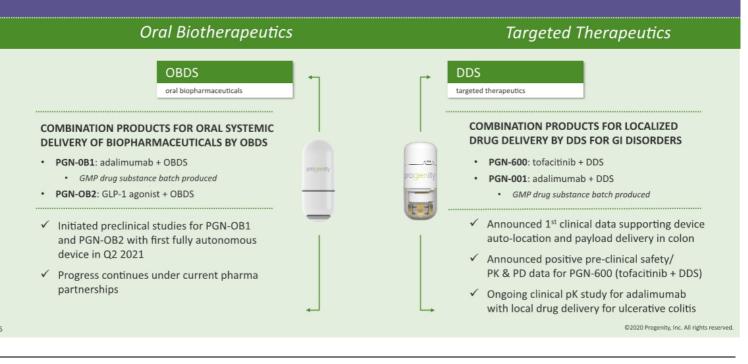
**CLINICAL DILEMMA** 

Sales team training in-progress

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# **GI Precision Medicine Programs**

Drug/Device Combination Products and Drug Delivery Systems

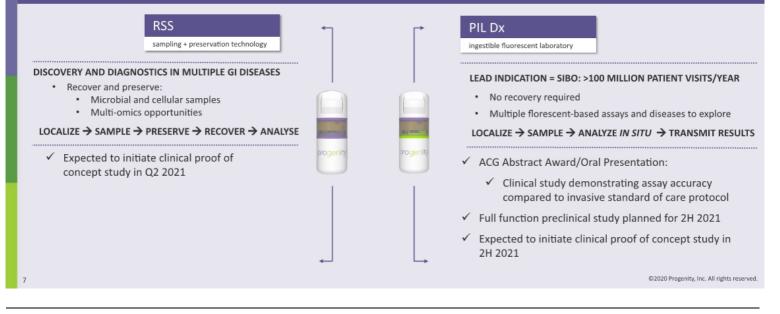


# **GI Precision Medicine Programs**

## Ingestible GI Diagnostic Platforms

### Recoverable Sampling System

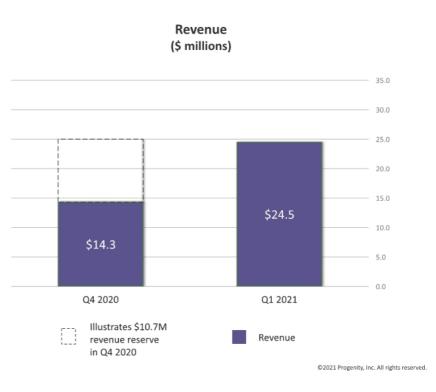
### Ingestible Lab-in-a-Capsule





## Q1 Revenues Grow 72%

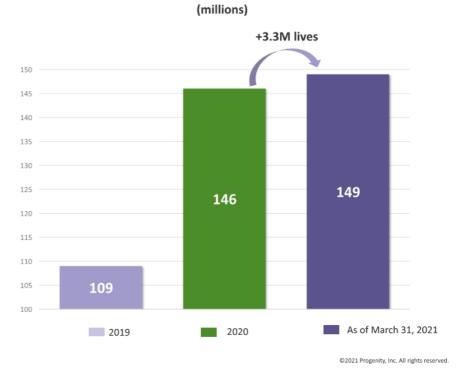
- Q1 2021 revenues are up 72% vs. Q4 2020, consistent with prior guidance
- ASPs continuing to improve
- Maintaining 2021 core products revenue guidance range of \$115-125M



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# Expanding the In-Network Footprint

- Added 3.3 million regional plan covered lives in Q1
- Expanding government and commercial payer coverage for average risk NIPT
- Continuing discussions for INN contracts with national and other regional plans



In-Network Lives - Progenity

### 10

# **Financial Overview**

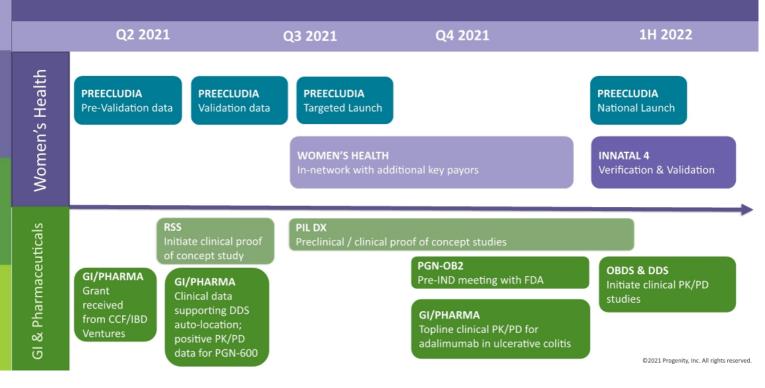
\$ in millions

	Q4 2020	FY 2020	Q1 2021
Revenues	\$14.3 <sup>1</sup>	\$74.3 <sup>1</sup>	\$24.5
ASP (\$/test)	\$174.9 <sup>1</sup>	\$232.6 <sup>1</sup>	\$310.8
COGS	21.4	93.4	22.2
SG&A	33.0	128.3	36.9
R&D	11.2	47.7	11.7
Net Loss	(75.5) <sup>2</sup>	(192.5) <sup>2</sup>	(32.3)
<b>Operating Cash Flows</b>	(70.1)	(165.7)	(48.9)
Cash & Cash Equivalents	92.1	92.1	65.3
Indebtedness <sup>3</sup>	171.6	171.6	171.5

Includes \$10.7M reserve for estimated future payor settlements
 Included \$13.8M expense related to change in fair value of derivative liability
 Consists principally of \$168.5M convertible notes debt

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# Near-Term Potential Catalysts



# progenity®

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