1	ROBERT V. PRONGAY (#270796)					
2	rprongay@glancylaw.com					
3	CASEY E. SADLER (#274241) csadler@glancylaw.com					
4	GARTH A. SPENCER (#335424)					
5	gspencer@glancylaw.com GLANCY PRONGAY & MURRAY LLF					
	1925 Century Park East, Suite 2100					
6	Los Angeles, California 90067					
7	Telephone: (310) 201-9150 Facsimile: (310) 201-9160					
8	201 7100					
9	Attorneys for Lead Plaintiffs					
10						
11	UNITED STATES	DISTRICT COURT				
12	SOUTHERN DISTRICT OF CALIFORNIA					
13	IN DE DOCENITY INC	Case No. 3:20-cv-01683-RBM-AHG				
14	IN RE PROGENITY, INC. SECURITIES LITIGATION	Case No. 5.20-cv-01065-RDWI-AITO				
15		THIRD AMENDED CLASS ACTION COMPLAINT FOR				
16		VIOLATION OF THE SECURITIES				
17		ACT OF 1933				
18		JURY TRIAL DEMANDED				
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						

Case No. 20cv01683

THIRD AMENDED COMPLAINT

TABLE OF CONTENTS 1 2 NATURE OF THE ACTION...... 3 II. JURISDICTION AND VENUE......7 4 PARTIES & RELEVANT NON-PARTIES8 III. 5 Lead Plaintiffs8 Α. 6 B. Corporate Defendant8 7 Individual Defendants......9 C. 8 D. 9 E. 10 IV. STATEMENT OF RELEVANT FACTS17 11 Α. 12 1. 13 Progenity Depended On Its Core Business From The Preparent and Innatal Testing Products To Generate 2. 14 15 3. Test Volumes and Average Selling Prices Were Key 16 17 Progenity Was Able To Reconcile Its Billed Tests To Its 4. 18 5. Progenity Depended On Billing Government Health Care Programs And Commercial Health Insurance Providers To 19 20 Progenity Agreed To A \$49 Million Settlement For Improperly Billing Government Health Care Programs For Innatal Tests And Illegally Waiving Patient Payments.......22 6. 21 22 Waiving Patient Payment Amounts Violates Federal Laws 7. 23 24 Progenity Repeatedly Negotiated Payor Refunds, and Accounted For Such Refunds Prior To The Final 8. 25 26 The 2018 Introduction of the 81443 CPT Code Applicable to Preparent Tests29 9. 27 28

1 2		10.	Reimbursement Rates for the 81443 Code Were Lower Than Reimbursement For Its Predecessor Billing Codes, And Some Payors Did Not Reimburse The 81443 Code At All	30
3 4		11.	Government Health Care Programs Required Correct Coding and Use of the 81443 Code As Of January 1, 2019	
5	B.	Undisclosed Adverse Facts Existing At The Time Of Progenity's June 2020 IPO		34
6 7		1.	Progenity Had Improperly Billed Government Payors For Preparent Tests And Likely Received A Material Amount of Overpayments Through "Early 2020"	34
8 9		2.	In February 2020 Progenity Discontinued The Illegal Marketing Practice On Which Its Business Depended	
10		3.	Progenity Suffered From Declining Test Volumes At The Time of the IPO	57
11 12		4.	Progenity Suffered From Declining Test Average Selling Prices At The Time of the IPO	60
13		5.	Progenity Suffered From Declining Revenues At The Time of the IPO	61
14	C.	Progenity's June 2020 IPO		63
15 16	D.	Inves Plum	stors Learn The Truth And Progenity's Stock Price	64
17		1.	August 13-14, 2020 Disclosures	64
18		2.	September 10, 2020 Disclosures	69
19		3.	October 29, 2020 Disclosures	70
20		4.	November 9, 2020 Disclosures	72
21		5.	November 18, 2020 Disclosures	73
22		6.	June 2, 2021 Disclosures	73
- 1	V DEI			76
23	V. REL	EVAN	IT LAWS AND ACCOUNTING STANDARDS	70
23 24	V. REL		Vant Accounting Standards	
24 25				76
242526		Rele	vant Accounting Standards	76 76
24 25		Relevented 1.	vant Accounting Standards	76 76 81

1		B.	Releva	ant Government Health Care Program Regulations	.84
2		C.	Disclo Regul	sure Obligations Under the Securities Act and SEC ation S-K	.85
3			1.	Section 11 Disclosure Requirements	.85
4			2.	Disclosure Requirements Under Regulation S-K Item 303	.86
5			3.	Disclosure Requirements Under Regulation S-K Item 105	.88
6 7	VI.	THE STAT	M TEMEN	ATERIALLY MISLEADING REGISTRATION	.88
8		A.	The R	Pegistration Statement Failed To Disclose That Progenity	
9			Had I	mproperly Billed Government Payors For Preparent Tests Likely Received A Material Amount of Overpayments gh "Early 2020"	88
10					
11			1.	Omission of Disclosures Required By Regulation S-K	.89
12			2.	Improper Revenue Recognition And Lack of Disclosure Under ASC 606	.90
13			3.	Failure to Disclose or Accrue Loss Contingencies As Required By ASC 450	.96
14			4.	Additional False and Misleading Statements	100
15 16			5.	Progenity's Misleading Statements And Omissions Would Be Highly Material To A Reasonable Investor	103
17 18		B.	The R 2020	egistration Statement Failed To Disclose That In February Progenity Discontinued The Illegal Marketing Practice On Its Business Depended	
19			1.	Omission of Disclosures Required By Regulation S-K	
20			2.	False And Misleading Statements	
$\begin{bmatrix} 21 \end{bmatrix}$			3.	Progenity's Misleading Statements And Omissions Would	
$\begin{bmatrix} 21 \\ 22 \end{bmatrix}$				Be Highly Material To A Reasonable Investor	111
23		C.	The I Know	Registration Statement Failed To Disclose Progenity's n Trend Of Decreasing Test Volumes	112
24			1.	Omission of Disclosures Required By Regulation S-K	112
25			2.	False And Misleading Statements	113
26			3.	Progenity's Misleading Statements And Omissions Would Be Highly Material To A Reasonable Investor	116
27 28		D.	The I Know	Registration Statement Failed To Disclose Progenity's n Trend Of Decreasing Average Selling Prices	
-					

1		1. Omission of Disclosures Required By Regulation S-K
2		2. False And Misleading Statements
3		3. Progenity's Misleading Statements And Omissions Would Be Highly Material To A Reasonable Investor
5		E. The Registration Statement Failed To Disclose Progenity's Known Trend Of Decreasing Revenues
6		1. Omission of Disclosures Required By Regulation S-K
7		2. Progenity's Omissions Would Be Highly Material To A Reasonable Investor
8	VII.	CLASS ACTION ALLEGATIONS
9	VIII.	INAPPLICABILITY OF THE STATUTORY SAFE HARBOR122
10	IX.	CLAIMS
11	X.	PRAYER FOR RELIEF
12 13	XI.	JURY TRIAL DEMANDED
14		
15		Exhibits
16	1 -	SEC Staff Accounting Bulletin No. 99 (Aug. 12, 1999)
17	2 -	Letter from Progenity to Florida Agency for Health Care Administration (Dec. 5, 2018)
18 19	3 -	Email from Florida Bureau of Medicaid Policy to Progenity (Jan. 24, 2019)
20	4 -	Letter from Progenity to Michigan Department of Community Health (Dec. 5, 2018)
21 22	5 -	Letter from Michigan Department of Health and Human Services to Progenity (Jan. 11, 2019)
23	6 -	Michigan Department of Health and Human Services claims data
2425	7 -	Redline comparison of Third Amended Complaint to Second Amended Complaint
26		-
27		
28		
- 1		

Lead Plaintiffs Lin Shen, Lingjun Lin, and Fusheng Lin ("Plaintiffs"), by and through their attorneys, allege the following upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief is based upon, among other things, their counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Progenity, Inc. ("Progenity" or the "Company"), with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Progenity; (c) review and analysis of analyst reports regarding the Company; (d) interviews with former Progenity employees; (e) review and analysis of information produced in response to freedom of information requests; and (f) review of other publicly available information concerning Progenity, including transcripts of Progenity's investor calls. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a securities class action on behalf of all individuals and entities that purchased or acquired Progenity common stock pursuant and/or traceable to the Company's false and misleading registration statement and prospectus, as amended (collectively, the "Registration Statement"), issued in connection with Progenity's June 2020 initial public offering (the "IPO"), seeking to pursue remedies under Sections 11 and 15 of the Securities Act of 1933 (the "Securities Act") against

As used herein, the term "Registration Statement" refers to, collectively, the Registration Statement that was filed by the Company on May 27, 2020, all amendments thereto, and the Prospectus filed on Form 424B4 on June 22, 2020, which was incorporated into and formed a part of the Registration Statement that became effective on June 18, 2020.

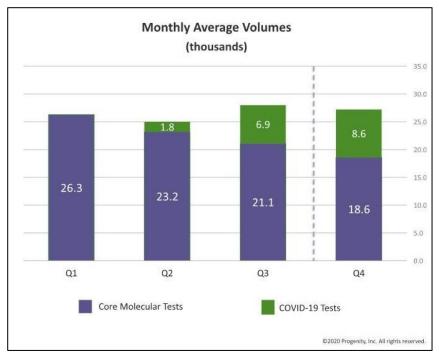
- 2. Progenity was a biotechnology company based in San Diego, California. At the time of the IPO it developed and sold molecular testing products and precision medicine applications. The Company provided in vitro molecular tests designed to assist parents in making informed decisions related to family planning, pregnancy, and complex disease diagnosis. Progenity derived substantially all of its revenue from billing payors (government health care programs and private health insurance companies) for genetic tests provided to patients through their doctors.
- 3. The most important products to Progenity's business at the time of the IPO were the Innatal and Preparent tests, from which Progenity derived a substantial portion of its revenue. The Innatal test was a noninvasive prenatal test offered to women early in pregnancy to screen for risk of fetal chromosomal conditions, such as Down syndrome, trisomy 13, and trisomy 18, and sex chromosome disorders. The Preparent test was an expanded carrier screen that was performed on women or couples before conception or early in a pregnancy to identify if they carry certain mutations that cause genetic diseases. Progenity's competitors offered similar tests, often with superior quality and at lower prices.
- 4. Progenity was a troubled company heading into its IPO. It lost over one hundred million dollars per year, and needed to secure additional investor funds in order to survive. In addition to its precarious financial situation, Progenity had material problems which were not disclosed to investors.
- 5. Progenity improperly billed government payors for Preparent tests beginning in 2019, but stopped this improper billing prior to the IPO in or before "early 2020." From 2019 on Progenity knew of and took some steps to implement a mandatory billing code change for its Preparent tests. Despite Progenity's access to clear billing rules from government payors regarding the use of this new billing code, Progenity nonetheless improperly billed government payors for Preparent

- tests. Progenity identified and stopped its improper billing in or before "early 2020," in advance of the IPO. At the time of the IPO, information existing and knowable to Progenity, including its own billing and reimbursement data, revealed a high probability that it had received a material amount of overpayments from government health care programs for Preparent tests due to its prior improper billing, which would almost certainly have to be refunded under applicable laws and regulations.
- 6. Shortly before the IPO, in March 2020 Progenity agreed in principle to a \$49 million settlement with various government regulators relating in part to nearly identical improper billing practices for its other main product, Innatal tests. Progenity had been in communication with the government about these matters since April 2018. No later than April 2020 Progenity expected to enter into a corporate integrity agreement as a condition of its anticipated settlement. Standard healthcare industry corporate integrity agreement terms include an independent third-party billing review, which would be almost certain to uncover Progenity's previously identified improper billing of government payors for Preparent tests.
- 7. Progenity's agreement in principle on a \$49 million governmental settlement also related to Progenity's illegal marketing practice of telling patients they would only be personally responsible for minimal charges, while billing third-party payors astronomical amounts for Progenity's tests. This practice violated various federal laws relating to the payment of kickbacks in connection with medical care reimbursed by government payors. *See* Department of Health and Human Services Office of Inspector General, Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B, 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994). This practice caused patients and doctors to order Progenity tests regardless of their true overall costs, and saddled governmental and commercial third-party payors with astronomical bills from Progenity, thus reducing the limited funds available for other reasonable and necessary medical treatments.

- 8. Progenity's illegal marketing practice was the centerpiece of its sales and marketing strategy for its genetic tests. According to former Progenity employees, this illegal marketing practice was the only benefit to using Progenity, and competitors had lower prices and offered a more thorough testing platform with higher detection rates. However, due to increasing government scrutiny, Progenity discontinued this practice as of February 2020. This change effectively eliminated Progenity's ability to compete in the highly competitive genetic testing business. Progenity's main selling point, eliminated shortly before the IPO, had been its promise that patients would make minimal payments, regardless of what Progenity billed to government health care programs or commercial insurers. This abrupt change angered Progenity's customers, demoralized its sales team, and lost substantial business for Progenity.
- 9. Based in substantial part on Progenity's decisions to eliminate its improper Preparent billing and its key illegal marketing strategy, at the time of the IPO Progenity suffered from material negative trends in its key performance metrics of test volumes, test average selling prices ("ASP"), and revenues, which trends were reasonably likely to continue beyond the IPO.
- 10. On or about June 19-23, 2020, Defendants conducted Progenity's IPO. In the IPO, Defendants sold over 6.6 million shares of Progenity common stock at a price of \$15 per share, generating over \$100 million in gross proceeds.
- 11. The Registration Statement for the IPO contained untrue statements of material fact, omitted material facts necessary to make the statements contained therein not misleading, and failed to make the necessary disclosures required under the rules and regulations governing its preparation (specifically including Item 303 and Item 105 of SEC Regulation S-K).
- 12. The Registration Statement failed to disclose that (i) Progenity had improperly billed government payors for Preparent tests beginning in 2019 and ending in or before "early 2020," (ii) there was a high probability that Progenity had

received, and would have to refund, a material amount of overpayments from government payors for Preparent tests, (iii) in February 2020 Progenity ended the illegal marketing practice on which the competitiveness of its business depended, and (iv) Progenity was presently suffering from known negative trends in test volumes, ASP, and revenues. The Registration Statement portrayed Progenity's core testing business as poised for success, which was highly misleading to IPO investors given these material undisclosed facts.

- 13. The truth was revealed to Progenity investors in a series of partial disclosures and materializations of undisclosed risks, beginning on or before August 13, 2020 through on or after June 3, 2021.
- 14. Shortly after the IPO, in August 2020, Progenity admitted that it had received \$10.3 million in overpayments from government payors through early 2020 as a result of improper billing practices for its Preparent tests.
- 15. In the months following the IPO, Progenity reported weak, and deteriorating, results caused in substantial part by its decisions to eliminate its improper billing and key illegal marketing strategy, and by the resulting negative trends in test volumes, ASP and revenues. The following chart, prepared and published by Progenity, depicts Progenity's test volumes leading up to and after the IPO, and illustrates the inexorable decline in Progenity's core testing business:



COVID tests generated far less revenue than Progenity's core Preparent and Innatal tests, and so the meager revenue from the increase in COVID testing did not come close to offsetting the substantial revenue lost by the persistent declines in core test volumes.

- 16. Less than one year after the IPO, Progenity announced that it would exit its core genetic testing business. This business was no longer viable without using Progenity's illegal marketing practice of waiving patient payment amounts. Since then, Progenity has exited its historical core genetic testing business, parted ways with its former CEO Defendant Stylli, changed its name to Biora Therapeutics, Inc., and completely changed all of its business activities.
- 17. Although Progenity sold stock for \$15.00 per share in the IPO, its stock closed at only \$2.11 per share on June 3, 2021, a loss of more than 85%.
- 18. On September 1, 2021, with Progenity's business in free-fall and its stock trading at less than \$1.00 per share, Progenity's CEO and Chairman resigned, effective immediately. He had founded the company and led it for a decade.

19. The following chart depicts Progenity's stock price from the IPO to September 2021:



20. As a direct result of Defendants' violations of the Securities Act, Plaintiffs and the Class have suffered significant losses and damages. This action seeks to recover damages for Progenity investors.

II. JURISDICTION AND VENUE

- 21. The claims alleged herein arise under §§11 and 15 of the Securities Act [15 U.S.C. §§77k and 77o].
- 22. This Court has jurisdiction over the subject matter of this action pursuant to §22 of the Securities Act [15 U.S.C. § 77v] and 28 U.S.C. § 1331.
- 23. Venue is proper in this District pursuant to § 22 of the Securities Act [15 U.S.C. § 77v] and 28 U.S.C. § 1391(b) as the Company conducts business in this District and maintains its principal executive offices in this District.
- 24. This Court has personal jurisdiction over each of the Defendants. Progenity is headquartered in this District, and Defendants drafted the offering materials issued in connection with Progenity's IPO in part here, disseminated the

25. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES & RELEVANT NON-PARTIES

A. Lead Plaintiffs

- 26. Lead Plaintiff Lin Shen, as set forth in the previously-filed certification (Dkt. No. 25-4) incorporated by reference herein, purchased or acquired Progenity common stock pursuant or traceable to the Company's Registration Statement issued in connection with the Company's IPO, and was damaged thereby.
- 27. Lead Plaintiff Lingjun Lin, as set forth in the previously-filed certification (Dkt. No. 25-4) incorporated by reference herein, purchased or acquired Progenity common stock pursuant or traceable to the Company's Registration Statement issued in connection with the Company's IPO, and was damaged thereby.
- 28. Lead Plaintiff Fusheng Lin, as set forth in the previously-filed certification (Dkt. No. 25-4) incorporated by reference herein, purchased or acquired Progenity common stock pursuant or traceable to the Company's Registration Statement issued in connection with the Company's IPO, and was damaged thereby.

B. Corporate Defendant

29. Defendant Progenity, Inc. is a biotechnology company. Progenity is incorporated in Delaware, and its principal executive offices are located at 4330 La Jolla Village Drive, Suite 200, San Diego, CA 92122. The Company's common stock trades under the ticker symbol "PROG" on the NASDAQ, which is an efficient market. Progenity, through its officers and directors, published and filed

with the SEC its Registration Statement that, as alleged herein, contained material misrepresentations and omissions that artificially inflated the price of the Company's securities.

C. Individual Defendants

1

2

3

4

5

6

7

8

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

- Defendant Harry Stylli ("Stylli") served as Progenity's Chief Executive 30. Officer ("CEO") and Chairman of Progenity's Board of Directors (the "Board") at the time of the IPO, and continued to serve in those roles until his immediately effective resignation on September 1, 2021. Defendant Stylli co-founded Progenity in 2011 and served as Chairman or Executive Chairman of its Board at all times from the Company's founding until his resignation. At all relevant times, Defendant Stylli has been one of Progenity's largest shareholders. From June 2005 to September 2009, Defendant Stylli was President, Chief Executive Officer, and a member of the board of directors of Sequenom, Inc. ("Sequenom"), a molecular diagnostic testing and genetics analysis company headquartered in San Diego. In September 2009, Sequenom terminated Defendant Stylli's employment in connection with an internal investigation into employee mishandling of test data and results, and at the same time Sequenom terminated the employment of another officer who would later plead guilty to conspiracy to commit securities fraud in connection with the conduct at issue in Sequenom's internal investigation. Defendant Stylli also signed, or authorized the signing of, the Registration Statement issued in connection with the IPO. In Progenity's 2019 fiscal year, Defendant Stylli received \$395,000 in total compensation from Progenity.
- 31. Defendant Eric d'Esparbes ("d'Esparbes") served as Progenity's Chief Financial Officer ("CFO") at the time of the IPO, and continued to serve in that role through September 1, 2021, when he became interim CEO upon Defendant Stylli's resignation. Defendant d'Esparbes joined Progenity as its CFO in May 2019. Prior to joining Progenity, Defendant d'Esparbes had more than 25 years of financial and executive experience in strategic planning and fund-raising functions for both

private and public companies. Defendant d'Esparbes also signed, or authorized the signing of, the Registration Statement issued in connection with the IPO.

- 32. Defendant Jeffrey Alter ("Alter") served as a member of the Board at the time of the IPO. At the time of the IPO, Defendant Alter was a member of the Board's audit and compensation committees. The primary responsibilities of Progenity's audit committee are to oversee Progenity's accounting and financial reporting processes, including the audits of the financial statements, and the internal and external audit processes. The audit committee also oversees the system of internal control established by management. Progenity stated in the Registration Statement that Defendant Alter "has sufficient knowledge in financial and auditing matters to serve on the audit committee." Defendant Alter joined Progenity's Board in January 2019. From April 2004 to June 2018, Defendant Alter served in various chief leadership positions at UnitedHealthcare, a health plan business, including as Chief Executive Officer of its commercial group from November 2014 to June 2018. Defendant Alter also signed, or authorized the signing of, the Registration Statement issued in connection with the IPO. In Progenity's 2019 fiscal year Defendant Alter received \$471,457 in total compensation from Progenity.
- 33. Defendant John Bigalke ("Bigalke") served as a member of the Board at the time of the IPO. At the time of the IPO, Defendant Bigalke was a member of the Board's audit, nominating/corporate governance, and special committees. Progenity stated in the Registration Statement that Defendant Bigalke "qualifies as an 'audit committee financial expert' as that term is defined in the rules and regulations established by the SEC." Progenity stated in the Registration Statement that Defendant Bigalke "has sufficient knowledge in financial and auditing matters to serve on the audit committee." At the time of the IPO, the special committee was responsible for evaluating, overseeing, making decisions, and taking actions for and on behalf of Progenity with respect to the then-pending government investigations and any related proceedings. Defendant Bigalke joined Progenity's Board in January

- 2019. Defendant Bigalke has served as the Chief Executive Officer of Second Half Healthcare Advisors, a healthcare strategy firm, since its founding by him in August 2016. Prior to founding Second Half Healthcare Advisors, he served as Vice Chairman and Senior Partner, Global Health Care Practice at Deloitte USA LLP, an accounting and consulting firm, from April 2012 to August 2016. Defendant Bigalke is a Certified Public Accountant. Defendant Bigalke also signed, or authorized the signing of, the Registration Statement issued in connection with the IPO. In Progenity's 2019 fiscal year Defendant Bigalke received \$489,299 in total compensation from Progenity.
- 34. Defendant Jeffrey Ferrell ("Ferrell") served as a member of the Board at the time of the IPO. At the time of the IPO, Defendant Ferrell was a member of the Board's compensation and nominating/corporate governance committees. Defendant Ferrell joined Progenity's Board in June 2014. Defendant Ferrell has served as the Managing Partner of Athyrium Capital Management, LP, a life sciences focused investment and advisory company, since November 2008. Athyrium Capital Management, LP and its affiliates have been among Progenity's largest investors at all relevant times. Defendant Ferrell also signed, or authorized the signing of, the Registration Statement issued in connection with the IPO.
- 35. Defendant Brian L. Kotzin ("Kotzin") served as a member of the Board at the time of the IPO. At the time of the IPO, Defendant Kotzin was a member of the Board's compensation and science committees. Defendant Kotzin joined Progenity's Board in June 2019. Defendant Kotzin has served as Senior Vice President, Clinical Development at Nektar Therapeutics, a biopharmaceutical company, since April 2017. Prior to Nektar, Defendant Kotzin was at Amgen Inc., where he served as Vice President, Global Clinical Development and Head, Inflammation Therapeutic Area from July 2004 to January 2015. Defendant Kotzin also signed, or authorized the signing of, the Registration Statement issued in

connection with the IPO. In Progenity's 2019 fiscal year Defendant Kotzin received \$290,398 in total compensation from Progenity.

- 36. Defendant Samuel Nussbaum ("Nussbaum") served as a member of the Board at the time of the IPO. At the time of the IPO, Defendant Nussbaum was a member of the Board's nominating/corporate governance, science, and special committees. Defendant Nussbaum joined Progenity's Board in January 2019. Defendant Nussbaum has served as a Strategic Consultant for EBG Advisors, the consulting arm for Epstein Becker and Green, since January 2016. Defendant Nussbaum has also served as a Senior Advisor to Sandbox Industries, a venture fund, since January 2017, and Ontario Teachers' Pension Fund since August 2016. From January 2000 until December 2015, Defendant Nussbaum served as Executive Vice President, Clinical Health Policy, and Chief Medical Officer of Anthem, Inc., a health insurance company. Defendant Nussbaum also signed, or authorized the signing of, the Registration Statement issued in connection with the IPO. In Progenity's 2019 fiscal year Defendant Nussbaum received \$475,207 in total compensation from Progenity.
- 37. Defendant Lynne Powell ("Powell") served as a member of the Board at the time of the IPO. At the time of the IPO, Defendant Powell was a member of the Board's audit, science, and special committees. Progenity stated in the Registration Statement that Defendant Powell "has sufficient knowledge in financial and auditing matters to serve on the audit committee." Defendant Powell joined Progenity's Board in February 2019. Since September 2019 and October 2019, Defendant Powell has served as Chief Executive Officer and as a member of the board of directors, respectively, of Druggability Technologies Holdings Ltd, a specialty pharmaceutical company. Prior to joining Druggability, Defendant Powell served as Senior Vice President and Chief Commercial Officer of BioCryst Pharmaceuticals, Inc., a biotherapeutics company, from January 2015 to July 2019. Defendant Powell also signed, or authorized the signing of, the Registration

Statement issued in connection with the IPO. In Progenity's 2019 fiscal year, Defendant Powell received \$467,874 in total compensation from Progenity.

38. Defendants Stylli, d'Esparbes, Alter, Bigalke, Ferrell, Kotzin, Nussbaum, and Powell are collectively referred to hereinafter as the "Individual Defendants." All of the Individual Defendants signed the Registration Statement for the IPO. Each of the Individual Defendants also reviewed and helped prepare the Registration Statement and, as directors and/or executive officers of the Company, participated in the solicitation and sale of the Company's common stock to investors in the IPO for their own financial benefit and the financial benefit of Progenity.

D. Underwriter Defendants

- 39. Defendant Piper Sandler & Co. ("Piper Sandler") underwrote the Company's IPO. Defendant Piper Sandler also acted as a joint book-running manager and representative of the other underwriters and agreed to purchase 2,466,667 shares in the IPO, exclusive of its option to purchase additional shares. Based on the underwriting discount of \$1.05 per share to be paid from Progenity to the underwriters in the IPO, Defendant Piper Sandler received approximately \$2,590,000 in connection with the IPO.
- 40. Defendant Wells Fargo Securities, LLC ("Wells Fargo") underwrote the Company's IPO. Defendant Wells Fargo also acted as a joint book-running manager and representative of the other underwriters and agreed to purchase 1,933,333 shares in the IPO, exclusive of its option to purchase additional shares. Based on the underwriting discount of \$1.05 per share to be paid from Progenity to the underwriters in the IPO, Defendant Wells Fargo received approximately \$2,030,000 in connection with the IPO.
- 41. Defendant Robert W. Baird & Co. Incorporated ("Baird") underwrote the Company's IPO. Defendant Baird also agreed to purchase 1,000,000 shares in the IPO, exclusive of its option to purchase additional shares. Based on the underwriting discount of \$1.05 per share to be paid from Progenity to the

underwriters in the IPO, Defendant Baird received approximately \$1,050,000 in connection with the IPO.

- 42. Defendant Raymond James ("Raymond James") underwrote the Company's IPO. Defendant Raymond James also agreed to purchase 1,000,000 shares in the IPO, exclusive of its option to purchase additional shares. Based on the underwriting discount of \$1.05 per share to be paid from Progenity to the underwriters in the IPO, Defendant Raymond James received approximately \$1,050,000 in connection with the IPO.
- 43. Defendant BTIG, LLC ("BTIG") underwrote the Company's IPO. Defendant BTIG also agreed to purchase 266,667 shares in the IPO, exclusive of its option to purchase additional shares. Based on the underwriting discount of \$1.05 per share to be paid from Progenity to the underwriters in the IPO, Defendant BTIG received approximately \$280,000 in connection with the IPO.
- 44. Defendants Piper Sandler, Wells Fargo, Baird, Raymond James, and BTIG are referred to hereinafter as the "Underwriter Defendants."
- 45. The Underwriter Defendants served as underwriters for the IPO. Collectively, they sold more than 6.6 million Progenity shares in the IPO at \$15 per share and shared \$7 million in underwriting discounts and commissions. Their failure to conduct adequate due diligence in connection with the IPO and the preparation of the Registration Statement was a substantial factor leading to the harm complained of herein.

E. Non-Party Confidential Witnesses

46. Confidential Witness 1 ("CW1") was employed by Progenity as an Assay Transfer Technologist from March 2018 to October 2020. In this position, she² was responsible for scaling up the work produced by Progenity's research and

² For all confidential witnesses, this Complaint uses female pronouns irrespective of the person's gender in order to maintain the confidentiality of the witness's identity.

- 47. Confidential Witness 2 ("CW2") was a Business Development Manager for Progenity in Los Angeles, California from December 2018 to December 2020. CW2 reported to Progenity regional sales director Angie De St. Jeor.
- 48. Confidential Witness 3 ("CW3") was employed by Progenity as a Business Development Manager in Tulsa, Oklahoma from August 2017 to approximately August 2020. CW3 reported to regional manager Jamie McElwrath.
- 49. Confidential Witness 4 ("CW4") worked at Progenity from December 2017 through March 2019, first as a Senior Business Analyst, and from August 2018 on as a Business Intelligence Analyst. CW4 primarily reported to Progenity finance director Daniel Gonzalez and also performed projects at the request of corporate vice president of sales George Gianakopoulos, vice president of finance Eric Fox, and then-CFO Summit Aggarwal (prior to Defendant d'Esparbes taking over the CFO role).
- 50. Confidential Witness 5 ("CW5") was a Revenue Analyst for Progenity in San Diego, California from in or about March 2019 to March 2020. CW5 reported to Nick Christenson. As part of her responsibilities, CW5 helped to produce reports that were presented to Progenity's CFO, vice president of finance, vice president of billing, and vice president of claims. In addition, these reports were disseminated to Progenity's board of directors.
- 51. Confidential Witness 6 ("CW6") was a Senior Business Development Manager in Abilene, Texas from February 2014 to January 2020. CW6 reported to Regional Sales Manager Jamie McElwrath.
- 52. Confidential Witness 7 ("CW7") was a Senior Business Development Manager in Chicago, Illinois from February 2014 to June 2020. CW7 reported to

- 53. Confidential Witness 8 ("CW8") was a Lead Payor Associate in Irving, Texas from August 2015 to September 2018. CW8 officially reported to a mid-level manager, but there was high turnover in this position. This mid-level manager in turn reported to Patrice Robinson, the director of billing and reimbursement, and Robinson in turn reported to CW14, the VP of billing and reimbursement.
- 54. Confidential Witness 9 ("CW9") was a Credentialing Consultant in Ann Arbor, Michigan from March 2013 to October 2018. CW9 reported to Carey Moseley, the national director of health plans, who in turn reported to Dan Visage, the vice president of managed care.
- 55. Confidential Witness 10 ("CW10") was a Billing and Accounts Receivable Supervisor in Irving, Texas from November 2016 to December 2019. CW10 officially reported to a mid-level manager, but there was high turnover in this position. This mid-level manager in turn reported to Patrice Robinson, the director of billing and reimbursement. For much of CW10's tenure at Progenity, there was no mid-level manager in this position, and so CW10 reported directly to Robinson.
- 56. Confidential Witness 11 ("CW11") was a Regional Sales Director in Austin, Texas (though she oversaw sales representatives in mid-central states) from June 2018 to May 2020. CW11 reported to senior area sales director Amy Halstead.
- 57. Confidential Witness 12 ("CW12") was a Medical Science Liaison in Texas and Oklahoma from 2017 to December 2020. CW12 reported to medical science liaison field team manager Laura Bagdy.
- 58. Confidential Witness 13 ("CW13") was a Certified Medical Coder in Irving, Texas from April 2018 to February 2019. CW13 reported to her supervisor Tichelle Lyons, who in turn reported to director of billing and reimbursement Patrice Robinson.

- 59. Confidential Witness 14 ("CW14") was Vice President of Billing and Reimbursement from May 2015 to October 2019. Among CW14's direct reports was Patrice Robinson, director of billing and reimbursement.
- 60. Confidential Witness 15 ("CW15") was a Billing and Reimbursement Specialist from April 2018 to June 2021. CW15 reported to CW10.
- 61. Confidential Witness 16 ("CW16") was Director of Managed Care West (California) from January 2017 to February 2020. CW16 reported to VP of managed care Dan Visage.

IV. STATEMENT OF RELEVANT FACTS

A. Background on Progenity's Business Leading Up To The IPO

62. Based in San Diego, California, Progenity is a biotechnology company. At the time of the IPO it was focused on developing and commercializing molecular testing products and precision medicine applications. The Company provided in vitro molecular tests designed to assist parents in making informed decisions related to family planning, pregnancy, and complex disease diagnosis.

1. Progenity Suffered Large, Persistent Financial Losses And Needed Cash To Survive

- 63. At the time of the IPO, despite having already been in operation for nine years, Progenity had a history of large losses, substantial indebtedness, limited cash on hand, and limited ability to generate revenue. For example, in the Registration Statement, Progenity reported a loss from operations of \$114 million for 2018, \$140 million for 2019, and \$52 million for the first quarter of 2020. Likewise, the Company admitted therein that "[w]e have incurred losses in the past, and we may not be able to achieve or sustain profitability in the future."
- 64. The Registration Statement also explained that the Company's liabilities were greater than its assets, reporting that as of December 31, 2019, Progenity had total current assets of \$75 million, as compared to total current liabilities of \$100 million, and had only \$12 million of cash and cash equivalents on

1

5

6 7

8

9 10

11

1213

14

16

15

17

18

19 20

21

2223

24

25

26

2728

its balance sheet. The Company further admitted that "[o]perating our business will require a significant amount of cash, and our ability to generate sufficient cash depends on many factors, some of which are beyond our control. We expect to need to raise additional capital after this offering, and if we cannot raise additional capital when needed, we may have to curtail or cease operations."

65. These concerns were further addressed by the notes to Progenity's consolidated financial statements included in the Registration Statement, expressing "substantial doubt about the Company's ability to continue as a going concern":

As of December 31, 2019, the Company had cash and cash equivalents of \$33.0 million and an accumulated deficit of \$348.5 million. For the year ended December 31, 2019, the Company also had a net loss of \$148.0 million and cash used in operations of \$106.1 million. The Company's primary sources of capital have been private placements of preferred stock and incurrence of debt. As of December 31, 2019, the Company had a \$75.0 million term loan outstanding with a private equity firm (see Note 7), and mortgages outstanding of \$3.3 million (see Note 8). Management does not believe that the current available cash and cash equivalents will be sufficient to fund the Company's planned expenditures and meet its obligations for at least 12 months following the financial statement issuance date without raising additional funding. As a result, there is substantial doubt about the Company's ability to continue as a going concern for the twelve months following the issuance date of the consolidated financial statements for the year ended December 31, 2019. The Company's ability to continue as a going concern is dependent upon its ability to raise additional funding.

- 66. Therefore, at the time of the IPO, Progenity was in a precarious financial position and had a pressing need for cash.
 - 2. Progenity Depended On Its Core Business From The Preparent and Innatal Testing Products To Generate Revenue
- 67. In 2015, Progenity launched both its "Innatal" Prenatal Screen and its "Preparent" Carrier Test. The Innatal test was a noninvasive prenatal test ("NIPT") offered to women early in pregnancy to screen for risk of fetal chromosomal

conditions, such as Down syndrome, trisomy 13, and trisomy 18, and sex chromosome disorders. The Preparent test was an expanded carrier screen that was performed on women or couples before conception or early in a pregnancy to identify if they carry certain mutations that cause genetic diseases.

- 68. At the time of the IPO, Progenity was heavily dependent on the success of its Preparent and Innatal testing products for the continued survival of the Company. As the Company explained in the Registration Statement, "[s]ubstantially all of our revenue is derived from molecular laboratory tests, principally from the sale of Innatal, Preparent, and pathology molecular testing. The revenue we derive from our Innatal tests and our Preparent tests is roughly equal." Moreover, also in the Registration Statement, the Company explained that, "[w]e currently receive and expect to continue to receive a significant portion of our revenues from the sales of our women's health-related NIPT product, Innatal, and our carrier screening products, including Preparent."
- 69. The Registration Statement further described the Company's "core product portfolio" as consisting of "NIPT [i.e., Innatal]; carrier screening [i.e., Preparent]; and hereditary cancer screening," which it also referred to as its "molecular testing products," and explained "[o]ther than revenues from our molecular testing business, we do not expect to generate revenues from other sources in the immediate future." Similarly, the notes to Progenity's consolidated financial statements state that, "[t]he Company's core business is focused on the prenatal carrier screening and noninvasive prenatal test market."

3. Test Volumes and Average Selling Prices Were Key Performance Indicators for Progenity

70. Because, at the time of the IPO, Progenity's business was heavily dependent on Preparent and Innatal tests for revenue, the volume of such tests processed by Progenity was a key performance indicator for its business.

14 15 16

17 18

19 20

21 22

23 24

25 26

27 28

- 71. According to Progenity's Registration Statement, "[t]he volume of tests that we accession is one of the key performance indicators that we use to evaluate our business. A test is accessioned when we receive the test samples at our laboratory, the relevant information about the desired test is entered into our systems, and the samples are routed into the appropriate process flow."
- As such, the average selling price Progenity received for those tests is 72. also a key performance indicator for its business: "[o]ur gross margin is an important indicator of the operating performance of our business. Higher gross margins reflect the average selling price of our tests, as well as the operating efficiency of our laboratory operations."

Progenity Was Able To Reconcile Its Billed Tests To Its 4. **Recognized Revenue**

- 73. In the Registration Statement, Progenity revealed that it had had "material weaknesses related to a lack of (i) controls designed to reconcile tests performed and recognized as revenue to billed tests and (ii) appropriately designed or effectively operating controls over the proper recording of accounts payable and accrued liabilities."
- However, the Registration Statement assured that Progenity had concluded that the "matters that constituted material weaknesses in our internal control over financial reporting . . . have since been remediated."
- 75. Therefore, at the time of the IPO, Progenity possessed sufficient controls to reconcile tests performed and recognized as revenue to billed tests.

Progenity Depended On Billing Government Health Care 5. Programs And Commercial Health Insurance Providers To

76. The vast majority of Progenity's revenues depended on billing government health care programs and private commercial health insurance companies for Progenity's testing products. As Progenity disclosed in the **Registration Statement:**

We generate revenue from the sales of our molecular tests and receive payments for such tests from four distinct channels: commercial third-party payors, government health benefits programs such as Medicare and Medicaid, laboratory distribution partners, and individual patients. Reimbursements from payors, including commercial third-party payors and government health benefits programs, constituted 97% of our revenue during the year ended December 31, 2019.

- 77. Progenity further disclosed in the Registration Statement that "[o]ur future revenues and profitability will depend heavily upon the availability of coverage and adequate reimbursement from governmental and other third-party payors, both in the United States and in foreign markets, for the use of our products." The Registration Statement also stated that "[t]hird-party reimbursement for our testing represents a significant portion of our revenues, and we expect third-party payors such as third-party commercial payors and government healthcare programs to continue to be our most significant sources of payments in the foreseeable future."
- 78. When billing government health care programs and private insurance companies Progenity was required to use Current Procedural Terminology ("CPT") codes. CPT codes are a set of standardized codes developed and maintained by the American Medical Association that are used to identify and report the services provided when billing payors for medical services. Payors use CPT codes to determine whether they will pay for billed medical services, and the amount of reimbursement that they will pay. Each medical procedure or service furnished to a patient has a specific CPT code. As Progenity states in the Registration Statement:

Laboratory tests are classified for reimbursement purposes under a coding system known as Current Procedure Terminology, or CPT, which we and our physician customers must use to bill payors and to receive payment for our molecular tests. These CPT codes are associated with the particular molecular test that we have provided to the patient. Once the AMA establishes a CPT code, CMS or its contractors may establish payment levels and coverage rules with respect to our molecular tests under Medicare and Medicaid. In

addition, commercial third-party payors independently establish reimbursement rates and coverage rules for our molecular tests under their respective plans.

- 79. Applicable laws and regulations, as well as policies established by government health care programs and private insurers, require providers to submit claims using the correct CPT codes to accurately describe the services provided.
 - 6. Progenity Agreed To A \$49 Million Settlement For Improperly Billing Government Health Care Programs For Innatal Tests And Illegally Waiving Patient Payments
- 80. In April 2018, Progenity received a civil investigative demand from the office of the U.S. Attorney for the Southern District of New York and a Health Insurance Portability and Accountability Act ("HIPAA") subpoena issued by the office of the U.S. Attorney for the Southern District of California. In May 2018, Progenity received a subpoena from the State of New York Medicaid Fraud Control Unit. These investigative demands and subpoenas were part of federal civil and criminal investigations, and state civil investigations, regarding what Progenity referred to in the Registration Statement as "discontinued legacy billing practices for our NIPT [*i.e.*, Innatal] and microdeletion tests and the provision of alleged kickbacks or inducements to physicians and patients."
- 81. According to the Registration Statement, prior to the IPO Progenity "met several times with representatives from the government entities conducting the related investigations, together as a group, to discuss the potential for a global resolution," and the parties had exchanged settlement offers.
- 82. On March 31, 2020, Progenity reached an agreement on the monetary terms of a settlement with the U.S. Department of Justice ("DOJ") and the State of New York (with the State of New York Attorney General representing or facilitating the interests of all States participating in the settlement) with respect to relevant government health benefit programs. According to Progenity's Registration Statement, this agreement would "resolve all of the government's outstanding civil

and criminal investigations, including the investigations by the U.S. Attorney's Office for the Southern District of California and the U.S. Attorney's Office for the Southern District of New York, as well as the investigation by the State AGs."

- 83. The agreement in principle contemplated that Progenity would enter into a civil settlement agreement to pay \$49.0 million in the aggregate in exchange for a release of the civil claims. As part of the settlement, Progenity also expected to enter into a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General, "which would be expected to impose additional compliance, reporting and disclosure obligations." The agreement in principle also contemplated that Progenity would enter into a non-prosecution agreement to resolve all criminal allegations, which Progenity claimed related to "discontinued legacy billing practices for our NIPT tests."
- 84. The NIPT test billing conduct at issue in these investigations related to Progenity's use of incorrect CPT codes when billing government health insurance programs for its Innatal tests. The kickback conduct at issue related to Progenity's key marketing practice of waiving patient payment amounts.
- 85. Shortly following the IPO, Progenity and the various government agencies finalized the settlement and related agreements. In a Stipulation and Order of Settlement and Dismissal, entered into by Progenity, the U.S. Attorney for the Southern District of New York, and various other parties, which was so-ordered on July 23, 2020, Progenity admitted, acknowledged, and accepted responsibility for conduct which the government alleged to violate the False Claims Act, 31 U.S.C. § 3729 et seq., and which conduct included:
- a. CPT codes are part of a numerical coding system that physicians and laboratories must use on claim forms to bill payors for healthcare services and to receive payments. The CPT affects the rate that the payor will reimburse the provider.

- 4 5
- 6
- 7 8
- 9 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17 18
- 19
- 20
- 21 22
- 23
- 24 25
- 26
- 27
- 28

- From March 2014 through April 2016, Progenity submitted false b. claims for payment to government payors to obtain reimbursement for NIPTs by improperly using CPT code 88271, which did not accurately represent the tests performed.
- Until January 2015, there was no CPT code specific to NIPTs. c. On January 2, 2015, a new CPT code, 81420, became active as the correct code that Progenity should have used to bill for its NIPTs. However, Progenity continued to submit false claims to government payors using the incorrect CPT code 88271.
- d. Progenity knew that Medicaid programs for some states excluded reimbursement for some NIPTs, and imposed conditions on reimbursement of other NIPTs. Progenity submitted claims seeking reimbursement for tests provided to Medicaid beneficiaries even when it was aware that the tests were not eligible for coverage under Medicaid.
- a result of incorrectly using CPT code 88721 misrepresenting the type of test performed when submitting claims for payment to government payors for NIPTs, Progenity received payments for non-reimbursable tests, or received substantially higher payments than it was entitled to receive for the genetic testing services provided.
- 86. In the same Stipulation and Order of Settlement and Dismissal, Progenity admitted, acknowledged, and accepted responsibility for conduct which the government alleged to violate the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and which conduct included:
- Progenity offered to reduce or waive coinsurance and deductible a. payments as part of its sales efforts. From January 2012 through April 2018, Progenity routinely reduced or waived Federal healthcare program beneficiaries' coinsurance and deductible payments without making the required individualized determinations of financial need or reasonable collection efforts.

- b. Some of the Progenity tests were costly and required significant patient payments. To market its costly tests, sales representatives informed physicians and their staff, as well as patients, that Progenity would waive coinsurance and deductibles, or limit the patient's payment to a certain maximum out-of-pocket amount regardless of the actual coinsurance or deductible amount. Progenity often referred to this practice as the "Peace of Mind" program. Progenity used the Peace of Mind program to induce physicians to prescribe, and patients to consent to, Progenity tests.
- 87. The misconduct relating to waiver of patient payments to which Progenity admitted in the stipulation was not limited to any particular type of test or product, but rather reflected Progenity's company-wide sales practices.
- 88. In the same Stipulation and Order of Settlement and Dismissal, Progenity agreed that it shall not make any public statement that contradicts or is inconsistent with its admitted conduct, or suggests that its admitted conduct is not wrongful. Any such statement constitutes a violation of the stipulation, and authorizes the government to pursue remedies against Progenity. The agreement allows Progenity to raise defenses in proceedings brought by private parties, but only so long as doing so would not contradict its admitted conduct.
- 89. Prior to the IPO, Progenity's Board established a special committee consisting of Defendants Bigalke (committee chair), Nussbaum, and Powell. The special committee was responsible for evaluating, overseeing, making decisions, and taking actions for and on behalf of Progenity with respect to the then-pending government investigations and any related proceedings.

7. Waiving Patient Payment Amounts Violates Federal Laws and Payor Policies

90. Most government health care programs and private health insurers require beneficiaries to pay a portion of the costs of their medical services, including in the form of coinsurance, co-pays or a deductible. These requirements encourage

beneficiaries to consider the cost of their medical services, and to avoid wasteful, unnecessary, or excessively expensive services. If beneficiaries have no incentive to consider the cost of their medical services, then third party payors are burdened with excessive and unnecessary expenses that substantially reduce their ability to pay for other reasonable and necessary medical services.

- 91. Congress has enacted several laws to combat fraud and abuse in government contracting, and in the health care industry in particular. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) imposes criminal and civil liability with respect to the payment of kickbacks to influence medical services to beneficiaries of federal health care programs. The False Claims Act, 31 U.S.C. § 3729 *et seq.* imposes civil liability with respect to making false statements to the government in connection with claims for payment. The Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a(a)(5) imposes civil liability where a provider transfers value to government health care program beneficiaries to influence their choice of providers.
- 92. The routine waiver of coinsurance or deductible payments for government health care program beneficiaries in order to generate business results in violations of the Anti-Kickback Statute, the False Claims Act, and the Civil Monetary Penalties Law. *See* Department of Health and Human Services Office of Inspector General, Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B, 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994); 42 U.S.C. § 1320a-7b(b); 31 U.S.C. § 3729(a)(1); 42 U.S.C. § 1320a-7a(i)(6). The consequences of these violations can include criminal charges, large monetary penalties, and exclusion from participation in government health care programs. *E.g.*, 42 U.S.C. §§ 1320a-7(b)(7) (regarding exclusion from participation in federal health care programs of entities violating the Anti-Kickback Statute or Civil Monetary Penalties Law).
- 93. Private payor contracts also generally require that providers collect patient payment amounts including copays and deductibles. Routine waiver of

8

9

12

14 15

13

16 17

18 19

21 22

20

23 24

25

26 27

28

patient payment amounts will generally result in breach of private payor contracts, entitling the payor to seek remedies from the provider.

- In its July 2020 stipulation of settlement with various governmental 94. regulators, Progenity agreed that it shall not make any public statement that suggests that its admitted conduct of offering to reduce or waive coinsurance and deductible payments as part of its sales efforts is not wrongful.
 - Progenity Repeatedly Negotiated Payor Refunds, 8. Accounted For Such Refunds Prior To **Determination Of Exact Amounts**
- Progenity's improper billing of the government for Innatal tests was not 95. an isolated incident. Prior to the IPO, Progenity repeatedly improperly billed thirdparty payors, and then later negotiated refunds of the resulting material amounts of overpayments. As Progenity admitted in the Registration Statement:

We have entered into settlement agreements with commercial thirdparty payors in order to settle claims related to past billing and coding practices that have been discontinued, including, without limitation: Connecticut General Life Insurance Company and Cigna Health and Life Insurance Company, or Cigna, United HealthCare Services, Inc. and UnitedHealthcare Insurance Company, or United, and Aetna Health Management, Inc., or Aetna.

Progenity disclosed that it settled with Cigna in December 2018 for \$12 million, with United in September 2019 for \$30 million, and with Aetna in November 2019 for \$15 million.

- 96. Progenity disclosed and accounted for such improper billing and refunds prior to its determination of exact overpayment amounts, or the execution of settlement agreements. Progenity disclosed and accounted for possible future refunds and settlements using estimates based on then-existing information.
- 97. Progenity stated in the Registration Statement that "We have established an accrual for refunds of payments previously made by healthcare insurers based on historical experience and executed settlement agreements with

healthcare insurers. The refunds are accounted for as reductions in revenues in the statement of operations as an element of variable consideration."

98. For example, Progenity's Registration Statement stated regarding governmental investigations into conduct including Progenity's improper billing for Innatal tests:

As of December 31, 2019, we had accrued an aggregate of \$35.8 million associated with a potential settlement with the DOJ and the participating State AGs within accrued expenses and other current liabilities and as a reduction of revenue as reflected on the consolidated balance sheet of the Company as of December 31, 2019 and consolidated statement of operations for the year ended December 31, 2019. In addition, in the guarter ended March 31, 2020, we accrued an additional \$13.2 million with respect to the total amount to be paid under the agreement in principle to the DOJ and the participating State AGs, and additional amounts for related costs as of and for the quarterly period ended March 31, 2020 . . . Until the final documents are approved and signed, there can be no assurance that the amount we have accrued will be sufficient to cover our obligations relating to this matter. Our obligations could also increase, potentially materially, depending on a number of factors including whether or not the agreement in principle is finalized, the terms of the final approved agreements, the parties to the settlement, the cost of complying with the terms of the settlement, including monitoring fees related to any potential corporate integrity agreement, the costs related to the settlement, and other factors.

In part as a result of those accruals, "During the year ended December 31, 2019, the Company updated its estimate of the variable consideration recognized for previously delivered performance obligations which resulted in a reduction of \$16.0 million of revenue for the year ended December 31, 2019." And, "During the three months ended March 31, 2020, the Company updated its estimate of the variable consideration recognized for previously delivered performance obligations which resulted in a reduction of \$12.8 million of revenue for the three months ended March 31, 2020."

28

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

99. Similarly, in the 2018 fiscal year Progenity recognized an "increase in accrued expenses and other current liabilities as a result of accruals for settlement payments due to third-party payors, including accruals for settlement negotiations with UnitedHealthcare and Aetna of \$27.0 million and \$15.0 million, respectively, in December 2018."

9. The 2018 Introduction of the 81443 CPT Code Applicable to Preparent Tests

- 100. Every year the American Medical Association ("AMA") publishes new CPT codes and provides guidance on their implementation. Every year providers and payors implement new CPT codes in their billing and reimbursement processes. The AMA's annual publication of new CPT codes is widely known and followed within the field of health care billing and reimbursement. Information about CPT codes and the medical services they relate to is widely available from the AMA and a number of other online and print sources.
- 101. On September 5, 2018 the American Medical Association announced the release of the 2019 Current Procedural Terminology code set. The newly introduced codes in this set would become effective for reporting as of January 1, 2019, in order to give health care providers and payors sufficient time to implement and transition to the new codes. The AMA also released an "insider's view" commentary with detailed information on the new code changes, and provided a data file available for download which allowed the new CPT codes, their descriptors, and official CPT coding guidelines, to be imported straight into existing claims and billing software. The AMA's publication of this new code set was common knowledge within the field of health care billing and reimbursement.
- 102. The 2019 code set included the new 81443 CPT code, to be effective January 1, 2019, which was intended to report genetic screening for multiple severe inherited conditions with a single test. Prior to the introduction of this code, a single test that screened for multiple such conditions was often simultaneously billed under

multiple codes, relating to each of the specific conditions being tested. For example, this included testing for Cystic Fibrosis (CPT code 81220), Fragile X Syndrome (CPT code 81243) and Ashkenazi Jewish associated disorders (CPT code 81412). Code 81443 was intended to consolidate into a single code the billing that was previously reported under numerous separate codes, when at least 15 of certain specified genes are analyzed by a single test.

10. Reimbursement Rates for the 81443 Code Were Lower Than Reimbursement For Its Predecessor Billing Codes, And Some Payors Did Not Reimburse The 81443 Code At All

- 103. Government payors such as state Medicaid agencies, as well as the federal Centers for Medicare & Medicaid Services, regularly publish fee schedules disclosing which CPT codes are eligible for reimbursement, and for eligible codes the applicable reimbursement rates.
- 104. In October of 2018, the Centers for Medicare & Medicaid Services assigned the 81443 code a rate of \$2,448.56 under the CMS Clinical Laboratory Fee Schedule ("CLFS"). The CLFS effectively sets the maximum reimbursement rate for claims submitted to Medicare under a given CPT code. This amount has remained the rate for the 81443 code under the CLFS at all relevant times. Many insurance companies and government health care programs base their reimbursement rates for laboratory services in substantial part on the CLFS.
- 105. Prior to the effectiveness of the 81443 code, the same testing could receive substantially higher reimbursement under the CLFS than the \$2,448.56 rate for the 81443 code. Such pre-2019 billing of expanded carrier screening tests was often simultaneously billed under numerous different CPT codes to reflect the different individual tests performed. For example, in 2018 testing for Ashkenazi Jewish associated disorders (CPT code 81412) alone had a CLFS rate of \$2,448.56. The sum of the CLFS rates for multiple individual codes often substantially exceeded the \$2,488.56 CLFS rate for the standalone 81443 code.

106. Progenity's Registration Statement acknowledged that its reimbursement levels from payors depended on factors including "reimbursement rates published by CMS," "future CPT code and medical procedure code changes," and "regulatory and payor fee schedule changes for CPT codes with respect to our products."

- 107. Progenity's Registration Statement explained that it "receive[d] the majority of [its] Medicare revenue from payments made under the Clinical Laboratory Fee Schedule or the Physician Fee Schedule."
- 108. As Progenity stated in the Registration Statement, "Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates," and "private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement policies."
 - 109. As Progenity further explained in the Registration Statement:

Medicare reimbursement can affect both Medicaid reimbursement, which is relevant to NIPT and carrier screening, and reimbursement from commercial third-party payors. Specifically, fee-for-service Medicaid programs generally do not reimburse at rates that exceed Medicare's fee-for-service rates, and many commercial third-party payors set their payment rates at a percentage of the amounts that Medicare pays for testing services. Medicare reimbursement rates are typically based on the CLFS [Clinical Laboratory Fee Schedule], set by CMS pursuant to a statutory formula established by Congress.

110. Some state Medicaid programs do not provide any coverage or reimbursement for tests billed under the 81443 code, or impose heightened requirements for such reimbursement that must be satisfied on a case by case basis, thereby significantly limiting reimbursement. As Progenity explained in the Registration Statement:

if Medicare's CLFS rate for our tests are low, the Medicaid reimbursement amounts are sometimes as low, or lower, than the Medicare reimbursement rate. In addition, as noted above, each state's Medicaid program has its own coverage determinations related to our

testing, and many state Medicaid programs do not provide their recipients with coverage for our testing. As a result of all of these factors, our testing is not reimbursed or only reimbursed at a very low amount by many state Medicaid programs. In some cases, a state Medicaid program's reimbursement rate for our testing might be zero dollars.

11. Government Health Care Programs Required Correct Coding and Use of the 81443 Code As Of January 1, 2019

- 111. After the 81443 code became effective on January 1, 2019, it was generally required to be used when billing government healthcare programs for expanded carrier screening tests including Progenity's Preparent test. After the 81443 code became effective, it was generally improper to bill government health care programs for expanded carrier screening tests using one or more CPT codes relating to screening for individual genetic conditions.
- 112. For example, when billing Medicare or Medicaid, providers are required to follow the rules set forth by the CMS National Correct Coding Initiative ("NCCI"). See, e.g., 42 U.S.C. § 1396b(r)(1)(B)(iv). The NCCI promotes national correct coding methodologies and reduces improper coding which may result in inappropriate payments of Medicare claims and Medicaid claims.
- 113. The version of the Medicaid NCCI Policy Manual effective as of January 1, 2019 contained various requirements and prohibitions relating to coding practices, including, as relevant here:
 - a. Physicians³ must report services correctly.
- b. Procedures shall be reported with the most comprehensive CPT code that describes the services performed. Physicians must not unbundle the services described by a HCPCS/CPT code.⁴

³ The NCCI manual generically uses the word "physician" to refer to health care providers billing Medicaid, including, *inter alia*, laboratories. This use of "physician" does not restrict the policy to medical doctors.

- 1 2
- A physician shall not report multiple HCPCS/CPT codes when a single comprehensive HCPCS/CPT code describes these services.
- 3

d. A physician shall not fragment a procedure into component parts.

- 4 5
- A physician shall not unbundle services that are integral to a e. more comprehensive procedure.

6

f. Physicians must avoid downcoding. If a HCPCS/CPT code exists that describes the services performed, the physician must report this code rather than

7 8

report a less comprehensive code with other codes describing the services not

9

- included in the less comprehensive code.
- 114. The version of the Medicaid NCCI Policy Manual effective as of January 1, 2019 also contains instructions specific to laboratory services, including:

11 12

10

a. NCCI policy prohibits separate payment for duplicate testing or

13

testing for the same analyte by more than one methodology.

14 15

b. If a laboratory procedure produces multiple reportable test results, only a single HCPCS/CPT code shall be reported for the procedure.

16 17

All genomic sequencing procedures, molecular multianalyte assays (e.g., CPT codes 81410-81471), many multianalyte assays with algorithmic

18

analyses (e.g., CPT codes 81493-81599, 0004M-XXXXM), and many Proprietary

19

Laboratory Analyses (PLA) (e.g., CPT codes 0001U - XXXXU) are DNA or RNA

20

analytic methods that simultaneously assay multiple genes or genetic regions. A physician shall not additionally separately report testing for the same gene or genetic

21 22

region by a different methodology (e.g., CPT codes 81105-81408, 81479, 88364-

23

88377). CMS payment policy does not allow separate payment for multiple methods

24

to test for the same analyte.

25 26

HCPCS, or Healthcare Common Procedure Coding System, is another medical billing code system, similar to CPT coding.

B. Undisclosed Adverse Facts Existing At The Time Of Progenity's June 2020 IPO

115. At the time of the IPO Progenity suffered from several material problems, which existed and were knowable at the time of the IPO, but which the Registration Statement failed to disclose: (i) Progenity improperly billed government payors for Preparent tests beginning in 2019 and ending in or before "early 2020," (ii) there was a high probability that Progenity had received, and would have to refund, a material amount of overpayments from government payors for Preparent tests, (iii) in February 2020 Progenity ended the illegal marketing practice on which the competitiveness of its business depended, and (iv) Progenity was presently suffering from known negative trends in test volumes, ASP, and revenues, due in substantial part to discontinuing its improper billing and its illegal marketing practice, all of which trends were reasonably likely to continue beyond the IPO. The Registration Statement portrayed Progenity's core testing business as poised for success, which was highly misleading to IPO investors given these material undisclosed facts.

1. Progenity Had Improperly Billed Government Payors For Preparent Tests And Likely Received A Material Amount of Overpayments Through "Early 2020"

116. Progenity improperly billed government payors for Preparent tests beginning in 2019, but identified and stopped this practice in or before early 2020, prior to the IPO. At the time of the IPO information existing and knowable to Progenity revealed a high probability that it had received a material amount of overpayments from government health care programs for Preparent tests, which Progenity would almost certainly have to refund. Progenity admitted to this improper billing in its post-IPO SEC filings, and disclosed that it had received, and was obligated to repay, approximately \$10.3 million in overpayments.

Prior to the IPO Progenity Had Access To Information Regarding CPT Codes and Payor Billing and Reimbursement Policies

117. Information about CPT codes and the medical services they relate to is widely available from the AMA and a number of online and print sources. Progenity had access to and routinely used such information. According to credentialing consultant CW9, Progenity ordered CPT code books every year for its billing department personnel. According to certified medical coder CW13, her team of medical coders would receive spreadsheets reflecting a patient's name, account number, and what testing they had done, which needed to be coded. Her team was also given a "cheat sheet" of billing codes. CW13 would use the cheat sheet, which was her main source of coding information, to choose which codes to use for a given patient spreadsheet. CW13 also used a code book, or would Google a code, to supplement information from the cheat sheet when necessary.

118. Government payors such as state Medicaid agencies, as well as the federal Centers for Medicare & Medicaid Services, regularly publish fee schedules disclosing which CPT codes are eligible for reimbursement, and for eligible codes the applicable reimbursement rates. Progenity had access to and routinely used such information. As part of CW9's work as a credentialing consultant for Progenity, she helped to set up Progenity's contracts with insurance payors, and as a regular part of this process she would obtain Medicaid fee schedules.

119. Payors also regularly publish policies specifying billing procedures and reimbursement eligibility.⁵ Progenity had access to and routinely used such information. Billing and reimbursement specialist CW15 stated that she and her colleagues had to look up medical policies for each insurance plan, that specified

⁵ For example, CMS makes current and prior versions of its National Correct Coding Initiative policy manuals available online free of charge. *See* https://www.medicaid.gov/medicaid/program-integrity/national-correct-coding-initiative/medicaid-ncci-reference-documents/index.html.

what should and should not be billed to each plan. According to CW15, she and her colleagues held regular meetings to discuss "how much each payor was bringing in," "what payors were paying," and "what codes needed to be switched." According to CW15, the director of billing and reimbursement Patrice Robinson was usually the most senior participant in these meetings, though sometimes Robinson's superior CW14, the VP of billing and reimbursement, also attended.

- 120. According to lead payor associate CW8, it should not have been challenging to keep up with coding developments, and she and her colleagues kept up with policies at different payors as part of their responsibilities. CW8 said that Progenity had a system to keep up with coding, led by Danielle Foster, who would obtain payor policies to see what was changing and what would remain the same. CW8 noted that a dedicated Progenity employee was responsible for each payor, and a binder was created for each payor with updated policies and procedures, and that her group held weekly meetings to go over such information.
- 121. The Registration Statement itself makes clear that at the time of the IPO, Progenity was already aware of the CPT code that became effective in 2019 for Progenity's Preparent tests, stating in relevant part, "effective January 1, 2019, the AMA approved the use of a CPT code for expanded carrier screening tests, which may . . . cause reimbursement for our Preparent expanded carrier screening tests to decline."

The Introduction of the 81443 Billing Code For Preparent Tests Befuddled Progenity's Billing and Accounting Operations

122. Interviews with former Progenity employees make clear that Progenity was almost immediately aware of the introduction of the 81443 code and its applicability to Preparent tests. These interviews also reveal that, despite the existence of clear rules and policies regarding correct billing and coding practices, the introduction of this code caused substantial confusion within Progenity regarding its billing and accounting for Preparent tests.

123. CW10 was a Billing and Accounts Receivable Supervisor in Irving, Texas from November 2016 to December 2019. Her duties primarily involved following up with insurance companies if they denied claims, and her team also used Progenity's billing software to generate claims to payors.

- 124. CW10 recalled that Progenity had used 12 codes or more (referred to as "stack codes") that were replaced by the single 81443 code. CW10 said that the replaced codes included ones relating to Cystic Fibrosis and Fragile X Syndrome. CW10 remembers the specific 81443 code number because getting Progenity's billing involving this code the way that insurance companies wanted it was her "biggest headache."
- 125. According to CW10, Progenity billed the old "stack" codes at rates totaling approximately \$14,000 to \$17,000 depending on the tests involved. According to CW10, Progenity billed the new 81443 code at a rate of approximately \$18,500.⁶
- 126. CW10 believes she was told to change these CPT codes at the end of 2018 or early 2019. CW10 recalled that she and her colleagues discussed that they should use the new code because the insurance companies did not like stack billing.
- 127. CW10 recalled a period in which Progenity transitioned to using the 81443 code in its billing. According to CW10, some payors objected to Progenity submitting claims using the old codes and did not pay these claims. In response, CW10 and her colleagues re-billed such claims with the new 81443 code. CW10 described this re-billing as a manual process, for which she had to put together a project team, which corrected thousands of claims over a period of approximately six weeks.

⁶ CW15 also recalled problems with billing for a panel code comprised of multiple tests, including cystic fibrosis, which panel code Progenity billed for approximately \$18,500.

128. CW10 said that after large payors complained to Progenity about its use of the old coding, she and her colleagues knew they had to make the change with all payors. After CW10's project team corrected its claims to use the 81443 code, CW10 believed this code was used by Progenity going forward for all payors.

- 129. CW10 recalled difficulty getting reimbursed by Medicaid plans for Preparent tests. Said CW10 regarding the 81443 billing code, "They were not paying that. We were going in circles, trying to get paid on that and other codes. I can tell you, 81443, yeah, more than likely that was one where other payors were paying us and Medicaid wasn't."
- 130. CW14 was Vice President of Billing and Reimbursement from May 2015 to October 2019. CW14 was CW10's indirect superior. For much of her tenure at Progenity CW10 reported to director of billing and reimbursement Patrice Robinson, who in turn reported to CW14.
- 131. CW14 stated that the 81443 billing code began to be discussed at Progenity prior to her October 2019 departure from Progenity, but that she was "very unclear as to the right way to bill" with respect to that code. CW14 stated that during her tenure at Progenity the 81443 code wasn't really adopted yet, and she did not think that Progenity was billing using the 81443 code while she was at the Company. CW14 stated that when the AMA announced the new 81443 code this was not a significant event, and that some private and governmental payors did not adopt or recognize the new code, which gave rise to inconsistencies between coding for different payors.
- 132. That CW10 had spent six weeks with a team of employees re-billing thousands of denied claims to correctly apply the 81443 code, at a time when her superior, the vice president of billing and reimbursement, did not believe Progenity was using the 81443 code, reflects profound confusion within Progenity as to correct billing practices for its Preparent tests. This confusion also manifested itself in Progenity's accounting and financial reporting.

133. CW5 was a Revenue Analyst for Progenity in San Diego, California from in or about March 2019 to March 2020. As part of her responsibilities, CW5 helped to produce monthly revenue reports that were presented to Progenity's CFO, vice president of finance, vice president of billing, and vice president of claims. In addition, these reports were disseminated to Progenity's board of directors. These monthly revenue reports reported revenue per CPT code, reflecting "the volume of revenue that was applied to the different lab testing we did." CW5 also helped to produce reports showing revenue broken down by payor, on a month-over-month and year-over-year basis. CW5 also produced reports evaluating anticipated revenues in comparison to actually received reimbursements.

134. CW5 recalled issues with revenue reports relating to a panel of codes that was condensed into one code effective as of January 2019 due to "a requirement by CMS." CW5 recalled that Progenity's transition process to the new code was already occurring when she began working at the Company. CW5's recollection strongly appears to relate to the transition to the 81443 billing code for Preparent tests.⁷

135. CW5 stated that "we weren't able to accurately report out revenue for that panel" because Progenity was receiving a number of denials from payors where Progenity had been anticipating receiving payments based on historical reimbursement. According to CW5, Progenity was not being reimbursed

During the 2019-2020 period of CW5's employment, there was no other transition under way from a panel of codes to a single CPT code relating to Progenity's main products, other than the transition to the 81443 code applicable to Preparent tests. For example, the CPT code applicable to Innatal tests, 81420, had been introduced in January 2015, and in use by Progenity since April 2016. CW5 did not recall the new code number that gave rise to the revenue reporting issues she discussed, except that it began with an 8. CW5 thought this was "maybe the GCS test." GCS is a common abbreviation for genetic carrier screening, and Progenity's Registration Statement refers to Preparent as offering "a broad menu of genetic carrier screening tests."

consistently by payors with respect to the new code. CW5 recalled that "there were challenges with payors paying and not paying."

- 136. CW5 recalled that some payors stopped paying Progenity's claims that used the old codes, and these payors said they needed to be billed under the new single code. CW5 thought that most payors were processing claims under the new code during her tenure at Progenity, which she believed included government payors. CW5 referred to this new code as "a CMS-required code."
- 137. According to CW5, some payors were not reimbursing claims made by Progenity under the new code. According to CW5, after receiving claim denials Progenity started negotiating with payors, some of which asked Progenity to bill under the old code because they had not switched to the new code yet.
- 138. Based on these former employee accounts, it is clear that Progenity was aware of the 81443 billing code and its applicability to Preparent tests as of early 2019, and that Progenity was, at least initially, deeply confused as to which payors should be billed using the 81443 code.

In or About the Later Part of 2019 Progenity Began An Audit Relating In Part To Billing And Insurance Payments

- 139. CW5 stated that during her last months at Progenity during 2020, in addition to revenue reporting her work primarily focused on an internal audit carried out with a third-party organization. CW5 believed this audit began "maybe later in 2019." According to CW5 this audit was geared toward "making sure everything was correctly documented," "reporting integrity" and "business practices."
- 140. CW5 worked directly with her superior Nick Christenson on this audit. CW5's responsibilities in connection with this audit included pulling data for random samples of accounts. This included reaching out to the lab department to get information from order forms. This also required CW5 to access billing data, and information relating to insurance payments. CW5's involvement in this audit was limited to obtaining requested data.

141. Statements made by Defendant Stylli after the IPO confirm that Progenity began an audit of its billing practices in or about 2019, which revealed Progenity's improper Preparent billing. Speaking on a September 10, 2020 investor conference call, Defendant Stylli discussed Progenity's improper Preparent billing, describing it as "an issue that occurred about 18 months ago. We had a particular legal view back then, and as part of our new compliance processes we were undertaking internal audits and decided to you know ... [unintelligible] our billing and coding functions we decided to invite an external party to carry out a further independent audit of the billing and coding functions." In response to a follow up question regarding Progenity's improper billing, Defendant Stylli further stated, "the procedures that we've taken with the company over the last couple years and especially in the last 12 months makes it very difficult that we would make those kind of errors again." [emphasis added].

Prior to the IPO Progenity Identified and Ceased Its Improper Preparent Billing for Government Payors

- 142. Progenity's confusion regarding the 81443 billing code was resolved, and Progenity stopped its improper billing for Preparent tests, several months before the June 2020 IPO, in or before early 2020.
- 143. Progenity's later disclosures admit that it only received Preparent overpayments through "early 2020." This admission shows that Progenity identified and ceased its improper Preparent billing of government payors no later than "early 2020."
- 144. There is a time lag between billing and receipt of reimbursement that, according to Progenity's Registration Statement, typically lasted "a number of months" for Progenity. As disclosed in the Registration Statement, "Tests billed to healthcare insurers and directly to patients can take up to six months to collect," and "we customarily receive payment a number of months after completion of a molecular test." Therefore, Progenity necessarily ceased improperly billing

government payors for Preparent tests substantially in advance of the time it ceased receiving related overpayments in "early 2020."

Prior to the IPO Government Health Care Programs Told Progenity That It Had To Use The New Billing Codes, And That The 81443 Code Was Not "Covered"

- 145. Information received by Plaintiff in response to freedom of information requests submitted to government health care programs shows that Progenity was told it was required to use the new 81443 billing code, and that in some cases this would result in reduced or eliminated payments to Progenity. The information received by Plaintiff likewise shows that Progenity in fact used the 81443 code beginning in March 2019, and that at least one state health care program (and likely many others) did not provide *any* reimbursement for claims billed with that code.
- 146. Progenity VP of Strategic Accounts, Daniel R. Visage, sent nearly identical letters (both dated December 5, 2018) on behalf of Progenity to the Florida Agency for Health Care Administration (*see* Exhibit 2) and the Michigan Department of Community Health (*see* Exhibit 4). Based on information and belief, Mr. Visage sent similar letters to other state health care programs. The letters stated, in relevant part, that:

We frequently review our testing and coding procedures to ensure compliance and alignment with our partnering providers' medical policies. During this periodic review, we have identified specific CPT codes we bill for, specifically carrier screening and oncology CPT codes, are changing in 2019.

The new 2019 CPT codes being added that affect us are:

* * *

 81443, Genetic testing for severe inherited conditions genomic sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA,

GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, 1 PAH) 2 3 Our plan is to continue billing for our testing using the 2018 CPT code conventions until there is clarity on these changes from your 4 organization, to determine your timing for implementation of the new 5 codes, including updating the reimbursement fee schedules and coverage. 6 7 In essence, Progenity told these state health care programs that it intended to bill 8 incorrectly for Preparent tests, unless the state health care programs told Progenity 9 not to do so. 10 147. By letter dated January 11, 2019 the Michigan Department of Health and Human Services responded to Progenity (see Exhibit 5), stating in relevant part: 11 12 Michigan Medicaid will release the Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) 13 Code Update bulletin in January. This document serves as the official 14 MDHHS notification of all newly covered codes. The corresponding updated laboratory fee schedule is typically released during the first 15 quarter of the calendar year. Newly covered codes and fee schedules 16 will be retroactively effective beginning January 1, 2019 and claims with dates of service on or after January 1, 2019 should reflect 2019 17 changes. 18 Michigan Medicaid will be covering all new BRAC 1 and 2 and 19 SMN1 and 2 codes. Genetic testing for severe inherited conditions 20 panel, including a minimum of sequencing of at least 15 genes (CPT 81443) will not be covered as this test does not align with Medicaid's 21 laboratory's standards of coverage. 22 web **Providers** should refer the **MDHHS** site to 23 www.nnichigan.gov/medicaidproviders >> Billing & Reimbursement 24 >> Provider Specific Information and the Medicaid Rate and Reference located within CHAMPS for procedure code coverage, 25 rates, and limitations. 26 (emphasis added). Michigan thereby informed Progenity that the newly effective 27 CPT codes, including 81443, must be used for dates of service on or after January 1, 28

2019. Michigan similarly informed Progenity that services represented by the 81443 code "will not be covered," *i.e.*, that Progenity would receive no reimbursement for providing them, because "this test does not align with Medicaid's laboratory's standards of coverage."

148. On January 24, 2019 the Florida Bureau of Medicaid Policy emailed Progenity, with the subject "2019 CPT Code Changes" (*see* **Exhibit 3**), stating in relevant part:

The Agency's Florida Medicaid Laboratory Service Coverage Policy outlines the Agency's laboratory services billing policy. The policy states that Florida Medicaid reimburses for services as specified in the policy and in accordance with the American Medical Association's Current Procedural Terminology (CPT).

The policy also states that *providers must report the most current* and appropriate billing code(s), modifier(s), and billing unit(s) for the service rendered, as incorporated by reference in Rule 59G-4.002, F.A.C..

(emphasis added). Florida thereby likewise informed Progenity that it was required to use the new 2019 CPT codes, including 81443.

- 149. Therefore, from at least January 2019, Progenity was on notice that government health care programs would require use of the new 81443 billing code, and that in some cases this would reduce or eliminate reimbursements to Progenity for its Preparent tests.
- 150. This is further confirmed by claims data received by Plaintiff in response to a freedom of information request seeking "Copies of documents or information sufficient to show, for the period July 1, 2018 to September 30, 2020, on a monthly basis, broken down by CPT billing code, (i) the number of claims made by Progenity Inc. to Michigan Medicaid and/or the Michigan Department of

Health and Human Services." The Michigan Department of Health and Human Services provided claims data in response (see Exhibit 6).⁸

- 151. That claims data shows that, shortly after Florida and Michigan informed Progenity in January 2019 that Progenity had to use the 81443 billing code, Progenity in fact began using the 81443 billing code for claims to Michigan Medicaid. Progenity used that code in March 2019, and made dozens of claims using the 81443 code in each of April and May 2019. Then, Progenity abruptly stopped using the code in June 2019 (with one isolated use in October 2019).
- 152. Progenity only resumed regularly using the 81443 code in claims to Michigan in May 2020, when Progenity was in the midst of settlement discussions with the DOJ and various state agencies relating to Progenity's improper Innatal test billing codes and Progenity's payment of illegal kickbacks.
- 153. The Michigan claims data also shows that, consistent with what Michigan had told Progenity in its January 11, 2019 letter, Michigan never reimbursed Progenity for any claims billed with the 81443 billing code. While numerous other billing codes appear on the "\$ amount details by code" worksheet within the claims data produced by Michigan, along with associated "Approved Amount[s]" of dollars, that claims data does not reflect any "Approved Amount[s]" for any claims billed with the 81443 code (see Exhibit 6).
- 154. Therefore, from at least March 2019, Progenity used of the new 81443 billing code for claims to Michigan, and was on notice that Michigan was not reimbursing those claims.

⁸ Specifically, Michigan produced a spreadsheet file titled "Progenity_-_1.0-13-2021". That spreadsheet file contained four worksheet tabs, "# claims billed", "codes billed by month", "\$ amount paid per month", and "\$ amount details by code". **Exhibit 6** reproduces the entirety of the relevant worksheet tabs, "codes billed by month" and "\$ amount details by code". For ease of reference, **Exhibit 6** also reproduces the worksheet tab "codes billed by month" filtered to only reflect rows listing "81443" in the "Procedure Code" column.

5 6

7

- 8 9
- 10 11
- 12
- 13 14
- 15 16
- 17
- 18 19
- 20
- 21 22
- 23 24
- 25
- 26 27
- 28

Prior to the IPO, Progenity Could Estimate The Preparent Overpayments It Had Received From Government Payors

- 155. Having identified and ceased its improper billing of government payors for Preparent tests, Progenity had ample information that would have allowed it to reasonably estimate the amount, or at least the magnitude, of the resulting overpayments.
- 156. At all times Progenity had access to information showing which CPT codes it used to bill which payors for Preparent tests, and the rates at which it billed these tests. For example, this information is contained in the claims submitted to payors by Progenity. At all times Progenity had access to information showing the amounts of reimbursement it received for each bill submitted to payors. For example, for each claim payors receive they later communicate to the provider whether reimbursement is approved or denied, and if approved the amount of reimbursement.
- 157. That Progenity had access to real-time data regarding its billing and reimbursement by CPT code is confirmed by CW4, who worked at Progenity from December 2017 through March 2019, first as a Senior Business Analyst, and from August 2018 on as a Business Intelligence Analyst. CW4 built reports, including in Progenity's Tableau software platform, for Progenity executives including Daniel Gonzalez and Eric Fox. According to CW4, her work included generating reports showing the amount paid over the amount charged for tests, and CPT codes that were getting successfully paid and that were not. CW4 also generated reports regarding denied claims showing CPT codes, denial codes, the test involved, the time, and the state. CW4 stated that information regarding CPT codes, denials, and payments received by month, was part of monthly consolidated reports relating to insurance companies.
- 158. Progenity's Registration Statement stated that it had previously identified a material weakness in control over financial reporting, relating to a lack

of "controls designed to reconcile tests performed and recognized as revenue to billed tests," but that this had "since been remediated." Therefore, at the time of the IPO, Progenity was able to reconcile tests performed and recognized as revenue to the tests that it billed to payors. This information allowed Progenity to compare its billing, reimbursements, and related revenue accruals.

159. From information such as this, once Progenity identified and ceased its improper billing of government payors for Preparent tests, Progenity could have reasonably estimated the amount, or at least the magnitude, of the Preparent overpayments it received from government payors.

Information Available to Progenity Prior to the IPO Showed A Near Certainty That It Would Have To Refund Preparent Overpayments

- 160. Government health care programs generally operate on a system known in the industry as "pay and chase," in which claims for reimbursement for the provision of services to beneficiaries are generally paid up front, and may later be subject to post-payment review and efforts to recoup amounts determined by the government to be overpayments. Given the high volume of claims submitted to government health care programs and their limited resources, it would not be feasible for them to perform detailed pre-payment review of all claims. As such, claims submitted by providers to government health care programs are subject to minimal verification upon submission, and providers are often able to obtain initial overpayments through inappropriate billing practices.
- 161. However, providers are not entitled to retain such overpayments. Providers must report and return any overpayments received from government payors under the Medicare and Medicaid programs within 60 days of identification. 42 C.F.R. § 401.305(b)(1). An overpayment is "identified" for these purposes "when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment." 42 C.F.R. § 401.305(a)(2). "A person should have determined

2

3

4

5

that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment." *Id*.

6 7 10

8 9

11 12

14

15

13

16 17

18 19

20 21

22

23 24

25 26

27 28

162. As discussed above, in or before early 2020 Progenity identified and ceased its improper billing of government payors for Preparent tests. Based on information available to Progenity at the time of the IPO, in the exercise of reasonable diligence Progenity should have quantified the amount of the overpayments it received as a result of this improper billing. At the very least, information existing and knowable to Progenity at the time of the IPO showed that Progenity would at some point in the future be able to quantify the amount of the overpayments, and so Progenity would eventually have an obligation to refund the overpayments, and would not be allowed to retain them indefinitely. See 42 C.F.R. § 401.305.

In addition, at the time of the IPO Progenity had been under investigation by government agencies since April 2018 for its failure to bill using a new CPT code for Innatal tests that resulted in Progenity receiving substantial overpayments from government payors. By the end of March 2020, Progenity had reached an agreement in principle to resolve these and other allegations for \$49 million. Therefore Progenity had information prior to the IPO which showed that government payors would seek to recoup amounts of overpayments resulting from improper billing by failing to effectively transition to a new CPT code.

164. Furthermore, beginning on April 21, 2020, Progenity's draft registration statement filings with the SEC stated that in connection with an expected settlement of the governmental investigations into Progenity's kickbacks and improper NIPT billing, Progenity "expect[ed] to enter into a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General, which would be expected to impose additional compliance, reporting and disclosure obligations, and related costs in the future."

165. At the time of the IPO, most corporate integrity agreements ("CIAs") relating to improper billing of governmental health care programs required a claims review by an independent review organization ("IRO") that is designed to identify and correct any other instances of improper billing by the subject company. The website of the U.S. Department of Health and Human Services (which administers Medicare and Medicaid) Office of Inspector General has a page dedicated to FAQs regarding corporate integrity agreements, which states, "Most CIAs require that a claims review be conducted by an IRO." That webpage further states:

More recent CIAs include claims review procedures that require the review of a randomly selected sample of 100 paid claims. These claims review procedures do not include an error rate threshold. Instead, the provider is required to repay any overpayments identified in the sample of 100 paid claims and evaluate whether the CMS overpayment rule (42 U.S.C. § 1320a-7k(d) and 42 C.F.R. §§ 401.301-305) requires that additional sampling be performed or that an extrapolated overpayment be repaid based on the results of the initial sample. As before, providers must repay any extrapolated overpayment amount at the point estimate.

- 166. By the time of the IPO, facts existed and were knowable to Defendants which showed that Progenity's improper billing of government health care programs for Preparent tests was highly likely to be uncovered as a result of an independent claims review process mandated by Progenity's expected corporate integrity agreement, and that Progenity would eventually have to refund these overpayments.
- 167. Therefore, information existing and knowable at the time of the IPO showed that, for multiple reasons, Progenity would at some point in time be obligated to refund to government payors the overpayments Progenity had received as a result of its improper Preparent billing.

2. In February 2020 Progenity Discontinued The Illegal Marketing Practice On Which Its Business Depended

168. Progenity's marketing of its genetic tests depended on its key illegal sales practice of waiving patient payment amounts while sending third-party payors

astronomical bills. Facing increasing government scrutiny, Progenity abruptly ended this illegal practice in February 2020, which effectively eliminated Progenity's ability to compete in the highly competitive genetic testing market. Less than one year after the IPO, Progenity completely exited its failed genetic testing business, which at the time of the IPO was Progenity's core business and produced substantially all of Progenity's revenue.

Progenity Admitted To Using Its Key Illegal Marketing Practice Through April 2018

- 169. Progenity has admitted that from January 2012 through April 2018 it routinely reduced or waived coinsurance and deductible payments as part of its sales efforts. Progenity further admitted that to market its costly tests, sales representatives informed physicians, their staff, and patients, that Progenity would waive or limit coinsurance and deductibles, regardless of the actual coinsurance or deductible amount. Progenity often referred to this practice as the "Peace of Mind" program.
- 170. In its July 2020 stipulation of settlement with various governmental regulators, Progenity agreed that it shall not make any public statement that suggests that its admitted conduct of offering to reduce or waive coinsurance and deductible payments as part of its sales efforts is not wrongful.
- 171. Progenity Vice president of billing and reimbursement CW14 stated that Progenity's practice of routinely waiving patient payment amounts while billing thousands of dollars to third-party payors was "bad," "flagrant," and "like robbery." Said CW 14, "I couldn't even send a bill to a patient." CW14 stated that it was a problem that Progenity used this practice "as a sales tactic to gain volume." CW14 unsuccessfully tried to get Progenity to stop using marketing language that indicated Progenity would waive patient payment amounts. Said CW14, "Decisions were based on revenue, not compliance."

172. CW7 worked for Progenity as a Senior Business Development Manager in Chicago from February 2014 to June 2020. CW7 recalled that when she began in 2014 "everything was \$25." In or around 2015 this price changed to \$99, and CW7 and her colleagues were told to have patients call in to Progenity get the \$99 price. CW7 does not think that Progenity sent bills for \$99. In or around 2017 or 2018 this policy changed again, and CW7 and her colleagues could no longer promise a test would cost \$99. CW7's understanding was that this change was made because promising an out of pocket maximum was illegal. Under the new policy, CW7 was instructed to tell doctors' offices that patients should ask Progenity for the "prompt pay discount." At some point prior to about 2018, CW7's messaging to providers changed to tell them that if a patient was charged over \$200, they should call and Progenity would reduce it. In or around 2018, CW7 and her colleagues would say "average cost will be under \$200," but without promising a specific dollar amount.

173. Over time Progenity adapted its key illegal marketing practice to become more subtle and less obviously illegal, but the substance and illegality of this practice remained the same.

Progenity's Illegal Marketing Practice Was Its Main Selling Point

174. At all relevant times Progenity has had competitors that offered similar tests, often with higher quality and lower prices. Progenity differentiated itself and gained business by offering to waive the vast majority of patient payment amounts. The illegal waiver of patient payment amounts was the cornerstone of Progenity's marketing efforts for the testing business that generated substantially all of Progenity's revenues.

175. According to Business Development Manager CW2, the only benefit to using Progenity for patients was that they could contact Progenity to obtain discounts and work out any billing issues. CW2 said that competitors had lower prices and offered a more thorough testing platform with higher detection rates.

1
 2
 3

176. As Director of Managed Care – West, CW16's responsibilities involved contracting with health plans. CW16 began looking for new jobs in the third quarter of 2019, and according to CW16:

One of the reasons I left was we were a commodity. Non-invasive prenatal testing was being done by lots of labs that offered pennies on the dollar for the same tests that we were offering for a lot more. Nobody was going to contract with me because our prices were much higher. I left because I couldn't get my bonus, because I couldn't get contracts.

As evidenced by CW16's comments, payors had no reason to select Progenity over its competitors, in contrast to patients, who could benefit from Progenity's key illegal marketing practice.

177. Medical Science Liaison CW12 is a clinically trained genetics counselor. According to CW12 Progenity did not have the best quality test, but rather what they could put together for the cheapest price. CW12 stated that it seemed like the clinical decisions Progenity was making were not sound.

178. Senior Business Development Manager CW6 stated that doctors disliked that their patients would receive high EOBs relating to Progenity tests. However, CW6 and her colleagues would let doctors know not to be alarmed at such EOBs, and that the patient would not necessarily have to pay the EOB. According to CW6, this was a "huge" concern at Progenity, and managers addressed it in sales team calls.

179. Business Intelligence Analyst CW4 stated that healthcare providers were all very worried that Progenity would seek payment from their patients. In response, in the fall of 2018 at the request of sales VP George Gianakopoulos, CW4

⁹ An explanation of benefits (commonly referred to as an "EOB" form) is a statement sent by a health insurance company to covered individuals explaining what medical services were paid for on their behalf by the insurer, and reflecting patient payment amounts such as coinsurance or deductibles.

built a Tableau dashboard that showed what percentage of a provider's patients Progenity sought payment from. CW4 stated that this was only about 2 out of 1,000 patients. The sales team was given access to this dashboard and could use it to obtain information for their sales territory. According to CW4 this dashboard was very successful because if a patient called a provider to complain about a Progenity bill, and the provider in turn complained to Progenity, Progenity could tell the provider that this was their only patient that this would happen to.

Progenity Continued Its Key Illegal Marketing Practice Until February 2020

180. While Progenity has admitted to routinely waiving patient payment amounts to increase sales through April 2018, Progenity in fact continued these practices up until February 2020, albeit in a more disguised and subtle form, when it finally made the decision to discontinue its illegal sales practices. Leading up to February 2020, Progenity had been in settlement negotiations with multiple government regulators to resolve claims including those relating to this illegal marketing practice, and was close to reaching a settlement agreement in principle. These settlement negotiations led to Progenity's decision to abruptly end its key illegal marketing practice.

181. According to Business Development Manager CW2, from the time she joined Progenity in December 2018 up until Progenity's February 2020 national sales meeting, ¹⁰ CW2 and her colleagues would tell health care providers that the average bill to a patient is \$185, and if they had any issue they could contact Progenity to work it out, effectively meaning that if a patient complained they would get a discount. CW2 said that the message from the training by the billing team when she joined Progenity in December 2018 was that fees could be adjusted.

¹⁰ CW2 initially reported that a change in billing policy was effective on or about March 1, 2020 but later clarified that she believed it was effective immediately at Progenity's February 2020 national sales meeting.

- 182. Regional sales director CW11 worked at Progenity from June 2018 to May 2020, and stated that she and her colleagues would let doctors know a maximum dollar amount that a patient would pay out of pocket for a Progenity test. According to CW11, due to concerns that this approach was illegal, at some point this messaging changed to telling doctors that the average a patient would pay was about \$290.
- 183. In or around 2018, CW7 was part of a sales pilot program at Progenity, in which there was to be no talk of dollar amounts, but CW7 and her colleagues would hand customers a sheet that stated the average out-of-pocket cost to patients. Under this pilot program, representatives were allowed to say that if patients were unhappy they could call Progenity regarding the "peace of mind program." According to CW7 the pilot program merely introduced a change in verbiage without a significant difference, and the bottom line was that if a patient called in Progenity would still adjust down their out of pocket charges. According to CW7 these changes in verbiage implemented in the pilot program were later implemented with the full sales staff, which she believed happened at Progenity's February 2019 annual sales meeting.
- 184. As discussed above, in the fall of 2018 CW4 built a Tableau dashboard to allow Progenity to assure doctors that it wasn't seeking to collect from the vast majority of their patients.

Progenity Abruptly Ended Its Key Illegal Marketing Practice in February 2020 In Response to Increasing Government Scrutiny

185. CW7 attended Progenity's national sales meeting in the last week of February 2020 (which was also attended by Defendant Stylli and other Progenity executives). According to CW7, after this meeting "everything changed overnight." CW7 stated that effective immediately following this meeting, patients were required to pay their full charges, and Progenity was not reducing the charges on

request. According to CW7, at the national sales meeting "everyone was kind of up-in-arms" following the announcement of this change in policy.

186. CW7 believes that it was VP of sales George Gianakopoulos and one other person who announced this change to Progenity's policies at the February 2020 national sales meeting. During the meeting CW7 pulled aside Gianakopoulos and asked him why the change to Progenity's policies was being made so suddenly, instead of offering a grace period for customers to adapt to the new policy. According to CW7, Gianakopoulos replied that if Progenity gave customers a grace period "we'd lose our company," and that Progenity was being sued by the federal government.

187. CW2 also attended the February 2020 national sales meeting (and confirmed that Defendant Stylli was present). According to CW2, at this meeting Progenity instructed CW2 and other sales personnel to stop telling clients that they could contact Progenity to obtain discounts and work out billing issues, which CW2 believed was related to ongoing government investigations and settlements involving Progenity. CW2 believes this policy change was effective immediately, with no grace period, and that it applied to all new billing going forward, even if a patient's blood had been drawn prior to the announcement but the test not yet billed.

Progenity Lost Customers Due to Its Decision To End Its Key Illegal Marketing Practice

188. According to CW2, patients and physicians were angry about the sudden change in policy implemented after the February 2020 national sales meeting. CW2 said that this policy change substantially lowered morale among the sales force because Progenity's biggest selling point with customers had been the ability to have Progenity's billing department work with patients to lower out of pocket payments. This billing policy change resulted in lost business for CW2, and substantial lost business for other Progenity sales representatives in territories across

the country, as customers decided to use Progenity's competitors who offered tests at lower prices.

189. According to CW2 the impact of lost business due to this policy occurred nation-wide, "it was everybody." CW2's colleagues in Los Angeles and San Diego lost many customer accounts. At least two California sales representatives told CW2 that they had lost two or more of their large health care providers. CW2 recalled similar conversations with sales personnel in Texas, Arizona, Washington, and Nevada. All of these sales personnel were having issues with accounts not wanting to do business with Progenity due to the change in policy. According to CW2, "Everybody was pissed. Angry that everything we'd been told to sell on was being taken away. Really, the only benefit to using Progenity over competitors was making sure the patient wasn't going to overpay . . . If you've gotten business based on that, you kind of realize that business might go somewhere else now – and people did."

190. Following the February 2020 national sales meeting CW7 noted a decline in test volumes due to the new billing policy. CW7 personally lost her biggest account, which was one of the biggest accounts in the Midwest. CW7 thought this account was upset that many of their patients were upset about the new policy. CW7 described the difficulty of being a Progenity representative during this period, because doctors and patients were upset that patients had received bills for thousands of dollars out of pocket, after having recently given birth. CW7 described her experience as "You're trying to make everything ok and you can't . . . I think, after the national sales meeting, they weren't doing anything about balances. Patients were receiving a bill; that was it."

Progenity Had to Slash Test Prices to Try to Compete Without Its Key Illegal Marketing Practice

191. CW2 stated that also at the February 2020 national sales meeting, Progenity announced that it was lowering the "cash price" (i.e., the cost to a patient

who is not billed via a third-party payor) for tests. The Preparent test cash price was lowered from \$595 to \$250, and the Innatal cash price was lowered from \$595 to \$225. CW2 believed this change was due to the fact that the cash prices of Progenity's competitors were much lower, and she thought Progenity reduced its cash prices to try to be competitive.

192. According to CW7, Progenity informed attendees at the February 2020 national sales meeting that it was billing insurance a lot less than it had previously done.

3. Progenity Suffered From Declining Test Volumes At The Time of the IPO

- 193. At the time of the IPO, Progenity knew of a trend of decreasing test volumes that was having and was reasonably likely to have a material unfavorable impact on net sales, revenues, and income from continuing operations.
- 194. This trend was due in substantial part to the end of Progenity's illegal marketing practice, and so was reasonably likely to have material unfavorable impact beyond the IPO.
- 195. At the time of the IPO, Progenity was on track for a sharp decline in quarterly test volume. In 2019, Progenity averaged over 82,000 tests per quarter, or over 27,000 tests per month. Progenity reported 79,000 tests in the first quarter of 2020, or a monthly average of over 26,000. However, Progenity completed only 24,000 tests in April 2020 and 23,000 tests in May 2020, the last two full months before the IPO.
- 196. Worse still, Progenity's meager second quarter test numbers were inflated by the addition of less valuable COVID tests, which generated far less revenue than the Preparent and Innatal tests that formed the core of Progenity's business. During the second quarter of 2020 Progenity's test volume included on average 1,800 COVID tests per month.

8

9 10

12 13

14

15

11

16 17

18

19 20

22 23

21

25

24

26 27

28

197. Progenity's IPO Prospectus was dated June 19, 2020. At this point, Progenity had had multiple weeks during which to evaluate test volumes for April and May of 2020.

198. Progenity tracked test volumes by test type in real time. Progenity knew in real time the number of each type of test it was processing, because processing tests was Progenity's primary revenue generating activity.

199. Progenity included interim information on test volumes in the Registration Statement (albeit in a limited and misleading fashion). For example, the Registration Statement stated that "we are currently observing a slowdown in volume growth as a result of the COVID-19 pandemic," and that "[o]ur initial assessment of the impact of the COVID-19 pandemic is that our NIPT [i.e., Innatal] test volumes have proved more resilient than our carrier screening [i.e., Preparent] test volumes."

200. The onset of the COVID pandemic in the United States took place at the same time as Progenity's decision to discontinue its illegal marketing practice. The initial COVID lockdowns were implemented shortly following Progenity's decision to discontinue its illegal marketing practice effective after the February 2020 national sales meeting. Although Progenity's core test volumes were adversely affected in part by COVID lockdowns, Progenity's core test volumes did not recover to their pre-pandemic levels following the easing of COVID lockdown restrictions, and in fact continued to fall further. This shows that the decline in test volumes was due in substantial part to non-pandemic related factors, namely Progenity's decision to discontinue its illegal marketing practice.

201. That Progenity was aware of its declining testing volume in real time is confirmed by former Progenity employees. CW1 was employed by Progenity as an Assay Transfer Technologist from March 2018 to October 2020. According to CW1, in the spring of 2020 as the COVID crisis began in the United States, Progenity's testing volume became very low and employees working in the lab had almost no samples coming in. The lab's trends were explained to her by Progenity lab director Chris Riley. According to CW1, the low testing rates in Progenity's lab commenced with the pandemic and continued through her departure in October 2020, at which time testing volume was still not back to its pre-pandemic normal levels. According to CW1, Progenity's executive management was always aware of these trends, and Progenity's lab directors, Tim Webster, and vice president of accessioning, Alex Espinosa, held monthly and quarterly meetings to review incoming test volumes, as well as less formal weekly discussions.

202. CW2 was a Business Development Manager for Progenity in Los Angeles, California from December 2018 to December 2020. In her role as a Business Development Manager, CW2 received sales data for her Los Angeles East sales territory almost daily from at least two different Progenity platforms: Salesforce and Tableau. This data included test volume broken out by test type and by physician. Salesforce and Tableau were company-wide platforms through which sales representatives had access to information about their own sales territories. After a customer sent a test to Progenity, this information would typically appear in Tableau within four to seven days. Within CW2's territory sales volume went down significantly during the initial COVID lockdown.

203. That Progenity had access to real-time data regarding test volumes is further confirmed by CW4. CW4 generated reports showing the amount paid over the amount charged for tests, and CPT codes that were getting successfully paid and that were not. CW4 also generated reports regarding denied claims showing CPT codes, denial codes, the test involved, the time, and the state.

204. That Progenity had access to real-time data regarding its business is also confirmed by CW5. CW5 was a Revenue Analyst for Progenity in San Diego,

¹¹ Progenity's affiliate Avero Diagnostics operated a separate lab in Texas, where according to CW1, Progenity's COVID tests were processed.

California from in or about March 2019 to March 2020. As part of her responsibilities, CW5 helped to produce a monthly revenue "report-out." These reports provided information about Progenity's revenue broken out by CPT code, showing the amount of monthly revenue attributable to each of Progenity's tests. These reports were presented to Progenity's CFO, vice president of finance, vice president of billing, and vice president of claims. In addition, these reports were disseminated to Progenity's board of directors.

4. Progenity Suffered From Declining Test Average Selling Prices At The Time of the IPO

205. At the time of the IPO, Progenity knew of a trend of decreasing test average selling prices that was having and was reasonably likely to have a material unfavorable impact on net sales, revenues, and income from continuing operations.

206. This trend was due in substantial part to (i) Progenity ceasing its improper billing of government payors for Preparent tests, and (ii) price reductions that Progenity implemented in connection with the end of Progenity's illegal marketing practice. Therefore, this trend was reasonably likely to have material unfavorable impact beyond the IPO.

207. ASP is Progenity's revenue from testing divided by the number of such tests.

208. Progenity had ASP of approximately \$438 in 2019. Progenity's ASP decreased to approximately \$380 in the first quarter of 2020, as adjusted to remove the effect of Progenity's settlement accrual in that quarter. In the second quarter of 2020, during which Progenity sold \$100 million of stock in the IPO, Progenity's ASP fell even further to approximately \$368, as adjusted to remove the effect of Progenity's refund accrual in that quarter.

¹² 2019 revenue of \$144.0 million, divided by 329,000 tests equals \$437.69.

- 209. This second quarter decrease was ongoing at the time of the IPO. The IPO Prospectus was dated June 19, 2020, at a point when the second quarter was already nearly completed, thus giving Progenity substantial visibility into its declining ASP.
- 210. Progenity knew in real time the ASPs for each of its test types, because Progenity had only a few commercially available tests and reimbursement for these tests provided almost all of Progenity's revenue.
- 211. As discussed above, Progenity tracked test volumes by test type in real time, and so was capable of determining related trends in ASP in real time. As CW5 explained, reports were given to the Company's officers and executives showing the amount of monthly revenue attributable to Progenity's different types of testing.
- 212. CW2 stated that in her Los Angeles East sales territory the cash price for Progenity's Preparent test had been \$595, but that after approximately March 1, 2020 this price was reduced to \$250 per test. According to CW2, at the same time Progenity also reduced the cash price for the Innatal test from \$595 to \$225 (before increasing to \$250 in May or June of 2020). These changes in price were announced at Progenity's national sales meeting in the last week of February 2020, which was attended by Defendant Stylli.
- 213. According to CW7, Progenity informed attendees at the February 2020 national sales meeting that it was billing insurance a lot less than it had previously done.

5. Progenity Suffered From Declining Revenues At The Time of the IPO

214. At the time of the IPO, Progenity knew of a trend of decreasing revenues that was having and was reasonably likely to have a material unfavorable impact on revenues, as well as the related metrics of net sales and income from continuing operations.

- 215. This trend was due in substantial part to (i) Progenity ceasing its improper billing of government payors for Preparent tests, and (ii) the end of Progenity's illegal marketing practice. Therefore, this trend was reasonably likely to have material unfavorable impact beyond the IPO.
- 216. At the time of the IPO Progenity was experiencing a significant decline in revenue. Progenity reported an 8% sequential quarterly decline in revenue from the first quarter of 2020 to the second quarter (when controlling for refund and settlement accruals). Progenity's second quarter 2020 results were even worse in comparison to the same quarter of the prior year. Even when controlling for the effect of the second quarter 2020 accrual for refund reserves, Progenity's second quarter 2020 results represented a more than 50% decline in revenue from second quarter 2019 revenue of \$57.2 million.
- 217. This second quarter decrease was ongoing at the time of the IPO. The IPO Prospectus was dated June 19, 2020, at a point when the second quarter was already nearly completed, thus giving Progenity substantial visibility into its declining revenue.
- 218. Progenity monitored its revenue in real time. This is confirmed by CW4 who explained that Progenity utilized monthly reports regarding its insurance company payors showing how much they were paying Progenity month over month. CW4 also generated reports showing the amount paid over the amount charged for tests, and CPT codes that were getting successfully paid and that were not. Moreover, this is further supported by CW5, who helped to produce monthly revenue reports that provided information about Progenity's revenue broken out by CPT code, showing the amount of monthly revenue attributable to each of Progenity's tests. The reports produced by CW5 were presented to Progenity's CFO, vice president of finance, vice president of billing, and vice president of claims, and were disseminated to Progenity's board of directors. The reports described by CW4 and CW5 gave Progenity up to date insights into its revenue.

1 2 revenue, is our reported volume . . . Revenue for us is a lagging indicator," and 3 4 5 marketing practice. 6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Progenity's June 2020 IPO C.

220. Progenity filed the Registration Statement for its IPO on Form S-1 with the SEC on May 27, 2020, registering common stock of Progenity. The Registration Statement was signed "[p]ursuant to the requirements of the Securities Act of 1933" by Defendants Stylli, d'Esparbes, Alter, Bigalke, Ferrell, Kotzin, Nussbaum, and Powell.

219. Furthermore, as Defendant Stylli admitted in Progenity's November 9,

2020 investor call, "[o]ur leading indicator of demand, and to a large degree,

Progenity knew test volumes to be decreasing at the time of the IPO, and reasonably

likely to continue decreasing due in substantial part to the end of Progenity's illegal

- Subsequent to the filing of the Registration Statement, Progenity filed amendments to the Registration Statement on Form S-1/A on June 4, 2020; June 15, 2020; and June 18, 2020 (filing two amendments on that date). The amendments form part of the Registration Statement and were substantially similar to the Form S-1 filed on May 27, 2020, and were signed by or on behalf of the same Defendants "[p]ursuant to the requirements of the Securities Act of 1933."
- 222. On June 19, 2020, Progenity announced the pricing of its IPO of 6,666,667 shares of its common stock at a public offering price of \$15.00 per share. The Company further announced that the shares were expected to begin trading on The Nasdaq Global Market on June 19, 2020 under the ticker symbol "PROG".
- 223. Together with the Prospectus filed with the SEC on Form 424B4 on June 22, 2020 (the "Prospectus"), which formed part of the Registration Statement, the Registration Statement offered for sale 6,666,667 shares of common stock at \$15.00 per share.
- 224. On June 23, 2020, the Company completed the IPO. In the IPO, the Company issued and sold 6,666,667 shares of its common stock, at a price to the

public of \$15.00 per share. The IPO generated over \$100 million in gross proceeds. The Company received approximately \$88.7 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

D. Investors Learn The Truth And Progenity's Stock Price Plummets

225. Beginning shortly after the IPO, and continuing over the next year, Progenity reported poor results that were the materialization of risks existing at the time of the IPO, but not disclosed in the Registration Statement, in violation of the Securities Act. Progenity likewise revealed to investors in a series of disclosures information that had existed at the time of the IPO but which had been omitted from the Registration Statement in violation of the Securities Act. Over this period, and in substantial part as a result of these revelations, Progenity's stock lost over 85% of its value.

1. August 13-14, 2020 Disclosures

- 226. After the close of stock market trading on August 13, 2020, Progenity filed with the SEC a press release and slide deck reporting on its second quarter 2020 financial results, and hosted an investor call. On August 14, 2020 Progenity filed a Form 10-Q for the second quarter of 2020 with the SEC.
- 227. The second quarter results press release stated that "[t]he second quarter revenues reflected a \$10.3 million accrual for refunds to government payors," and the slide deck similarly indicated that Progenity's second quarter revenue "[i]ncludes \$10.3 million accrual for refund reserve."
- 228. On Progenity's second quarter results investor call, Defendant Stylli further elaborated on this refund reserve:

As part of our work to improve our compliance program, including an internal auditing and monitoring functions, we commissioned the third-party review of our coding and billing processes. In connection with that audit, we identified that we had not appropriately transitioned the implementation of the new billing requirements for larger carrier

34

567

8

1011

12

13 14

1516

17

18 19

20

22

23

21

24

25

26

2728

screening panels, which were introduced in early 2019. As a result over the last 18 months, we received an overpayment of approximately \$10.3 million from government payors during 2019 and early 2020.

229. On Progenity's second quarter results investor call, the first question came from Steven Mah of Piper Sandler who asked, "can you provide some color on the \$10.3 million refund accrual? And my understanding from your comments was that it was a third-party audit. Was that audit part of the corporate integrity agreement? It's part of the settlement?" Defendant Stylli responded:

No. To be clear, that was a self-driven process. as you are aware, we've really invested in briefed [sic] up our compliance and made a lot of changes and this was we've actually performed two audits using third parties to really help us get to a clear understanding of how our operations in billing and coding are performing . . . Steve, it's completely self-reporting and self-driven. So in a way, I'm proud that the process was implemented any words.

230. Progenity further elaborated on this issue in its Form 10-Q for the second quarter of 2020:

[D]uring the three months ended June 30, 2020, the Company accrued \$10.3 million for refunds to government payors related to reimbursement for the Company's Preparent expanded carrier screening tests during 2019 and early 2020. In the United States, the American Medical Association ("AMA") generally assigns specific billing codes for laboratory tests under a coding system known as Current Procedure Terminology ("CPT"), which we and our ordering healthcare providers must use to bill and receive reimbursement for our molecular tests. Effective January 1, 2019, the AMA issued a CPT code for genetic testing for severe inherited conditions that includes sequencing of at least 15 genes, which affects potential reimbursement for the Company's Preparent expanded carrier screening tests. As part of the Company's work to improve its compliance program, including its internal auditing and monitoring function, the Company commissioned a third-party review of its billing processes. In connection with that audit, the Company identified that it had not effectively transitioned to the implementation of the new CPT code in 2019, and as a result the Company received an overpayment of approximately \$10.3 million from government payors during 2019 and early 2020. The final analysis

of the amount of the overpayment is still being completed, but as a result of the analysis to date, during the three months ended June 30, 2020, the Company accrued \$10.3 million for refunds to government payors. The Company's deadline to report and return the overpayment to the government programs is 60 days from the time the overpayment was determined and quantified, thus the Company expects to repay this amount to the relevant government programs by early October 2020.

231. Progenity's second quarter 2020 Form 10-Q further stated:

In connection with the third-party review of the Company's coding and billing processes described in Note 4, which identified that the Company had not effectively transitioned to the implementation of the new CPT code for reimbursement for the Company's Preparent expanded carrier screening tests during 2019 and early 2020, the Company reviewed its reimbursement from commercial payors for these tests over the same time period. The Company may need to engage with payors in order to determine if any amounts could be subject to recovery or recoupment, as it is customarily done with commercial payors. . . If negotiations with payors result in claims or conclusions that overpayments have been made, this could have a material impact on the Company's financial results and position.

- 232. Progenity's second quarter results press release reported that "[t]otal accessioned tests volume was 75,017 in the second quarter of 2020." Progenity's second quarter results slide deck revealed that Progenity's test volumes were only 24,000 for April 2020 and 23,000 for May 2020.¹³
- 233. The second quarter press release also stated that Progenity had "[a]dded COVID-19 testing to our existing test menu" during the second quarter. The second quarter slide deck, under the heading "Volume Showing Signs of Recovery," stated "Demand for SARS CoV-2 tests increasing." And Progenity's August 14, 2020 second quarter Form 10-Q stated that "[t]he Company expects test volumes to

¹³ Progenity later (on March 18, 2021) revealed that during the second quarter of 2020 Progenity's test volume included on average 1,800 COVID tests per month.

continue to be adversely affected by COVID-19 and cannot predict when volumes will return to normal."

234. Progenity's second quarter 2020 slide deck reported first quarter 2020 ASP of \$213.50 as compared to second quarter 2020 ASP of \$230.20, however these figures were accompanied by footnotes reflecting the impact of a \$13.2 million accrual for settlements in the first quarter and a \$10.3 million accrual for refund reserve in the second quarter. Reversing the effects of these accruals, Progenity's ASP in fact decreased from approximately \$380 in the first quarter to approximately \$368 in the second quarter. ¹⁴

235. Defendant d'Esparbes commented on ASPs in Progenity's second quarter 2020 investor call:

We cannot [sic] explain the evolution of our ASP between the periods, while our first and second quarter's ASP was unusually low due to accruals that reduced revenue. Our second quarter ASP also reflects two main contributing factors. The first factor relates to the resilience of our NIPT volume demand during the quarter leading to a higher proportion of NIPT tests in our total volume compared to the first quarter.

The average reimbursement rate for NIPT tends to be slightly lowering [sic] for carrier screening and as a result, our portfolio ASP reflects that temporary shift during the second quarter. On a long-term basis, we believe our NIPT to carrier screening ratio should normalize to 1.2:1, our typical ratio as we've previously disclosed.

The second factor influencing our ASPs are ongoing in-network transition, where lower average rates have not yet been fully compensated by an expected higher percentage of test paid and increased in-network volume numbers.

¹⁴ The sum of first quarter revenue of \$16.8 million and \$13.2 million settlement accrual divided by 79,000 first quarter test volume equals \$379.75. The sum of second quarter revenue of \$17.3 million and \$10.3 million refund accrual divided by 75,000 second quarter test volume equals \$368.00.

236. Later in the call, Baird analyst Catherine Ramsey Schulte pressed for more information regarding the decline in ASPs:

Then maybe, just going back to ASPs in the quarter, how much of that degradation was due to that mix shift away from carrier screening and towards NIPT, is there a way to quantify the impact or magnitude of that mix shift?

Defendant Stylli responded to Schulte, "So, it was not that material. but it's definitely a contributor. Obviously, the accruals that we had in a quarter are the biggest impact on ASP."

- 237. Progenity reported second quarter 2020 revenue of \$17.3 million, or \$27.6 million when controlling for Progenity's \$10.3 million accrual for refund reserves in the second quarter. Progenity's first quarter revenue had been \$16.8 million, or \$30.0 million when controlling for Progenity's \$13.2 million accrual for settlements in the first quarter. This represented a substantial 8% sequential quarterly decline in revenue.
- 238. Progenity's second quarter results press release stated, "[r]evenue was \$17.3 million in the three months ended June 30, 2020, compared to \$57.2 million in the three months ended June 30, 2019," a nearly 70% decline. Even when controlling for the second quarter 2020 accrual for refund reserves, Progenity's second quarter 2020 results represented a more than 50% decline in revenue from the second quarter of 2019.
- 239. Progenity's second quarter 2020 Form 10-Q further commented on the decrease in revenue, stating that the decline was "primarily due to a decrease in test volumes during the three months ended June 30, 2020 compared to the three months ended June 30, 2019, as a result of the COVID-19 shutdown," and in part due to other factors such as "an accrual of \$10.3 million for refunds to government payors," and "rate degradation due to payor policy changes."
- 240. After Progenity revealed the foregoing information after the close of trading on August 13, 2020, on August 14, 2020 Progenity's stock price closed at

\$7.71 per share as compared to \$8.95 per share at the close of trading on August 13, 2020, a decline of \$1.24 per share or 13.8%. The closing price on August 14, 2020 was nearly 50% below the \$15.00 price investors paid for Progenity shares in the IPO less than two months previously.

2. September 10, 2020 Disclosures

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

- 241. On September 10, 2020 Progenity, represented by Defendant Stylli, participated in an analyst-led group meeting at the 2020 Wells Fargo Virtual Healthcare Conference, for which Progenity made available through its website live audio and an archived replay.
- 242. The first question to Defendant Stylli came from Wells Fargo analyst Dan Leonard, who asked, "Maybe what we'll start from the top you just reported Q2 results there was an accrual in the revenue line there that caught some folks by surprise can you maybe just revisit that what drove it and what steps have you taken to address those issues in the future?" Defendant Stylli responded:
 - OK, so this is Harry. I want to, you know, reassure you all that this issue won't arise again, this specific issue won't arise again. It's an issue that occurred about 18 months ago. We had a particular legal view back then, and as part of our new compliance processes we were undertaking internal audits and decided to you know ... [unintelligible] our billing and coding functions we decided to invite an external party to carry out a further independent audit of the billing and coding functions. There was a change in legal view as to how to treat particular coding related matter and we decided at that juncture to deal with it and to deal with it with an accrual. And it's basically a repayment back to the payer which is in this case the government. So we decided to get conservative immediate action to remedy that situation based on our, you know, various internal efforts as well as legal inputs. So the way we see it is our processes, you know, worked. Obviously we'd rather not have to deal with such a matter but they worked, they worked very effectively, they identified the issue. We feel even more confident about our billing and coding on a go forward basis. Like I said this specific thing we've remedied but there's a, what do we call a, tail end financial [unintelligible].

243. Leonard then asked Defendant Stylli, "OK and Harry you started off by saying the issue won't arise again. You know these issues come up with genetic testing companies so what gives you the confidence that it won't arise again?" Defendant Stylli responded:

You know so you can't it's not going to be like 100%. I'm not saying [unintelligible]. But the procedures that we've taken with the company over the last couple years and especially in the last 12 months makes it very difficult that we would make those kind of errors again. Very difficult indeed. And you know there's checks and balances on the way we've organized. It's not just compliance but it's the way we operate, the way we organize, the . . . We've changed the flow of decision making so it goes to committee as opposed to individuals, which was unfortunately the past way we did these matters. So there's a whole series of steps that really have been operationalized, not just oversight checks and balances, where we believe that such an issue is highly unlikely, how about that?

244. After Progenity revealed the foregoing information on September 10, 2020, Progenity's stock price closed at \$8.64 per share as compared to \$9.60 per share at the close of trading on September 9, 2020, a decline of \$0.96 per share or 10.0%.

3. October 29, 2020 Disclosures

- 245. On the morning of October 29, 2020, Progenity filed with the SEC a press release reporting preliminary third quarter 2020 revenue and test volumes.
- 246. Although on October 29, 2020 Progenity reported overall test volume of 84,000 tests representing an increase over prior quarter volume, this overall figure in fact masked a continued decline in Progenity's core Innatal and Preparent test business.¹⁵

¹⁵ Progenity would later reveal (on March 18, 2021) that during the third quarter of 2020 Progenity's test volume included on average 6,900 COVID tests per month, and that Progenity completed only 63,300 core, non-COVID, tests in the third quarter. This represented a continued substantial decline in Progenity's core test business as compared to the first and second quarters of 2020.

- 247. Progenity's October 29, 2020 press release reported that it "expects to report revenue for the third quarter of 2020 in a range of approximately \$25 to \$26 million."
- 248. Based on even the high end of the expected revenue range and the reported test volume, this indicated third quarter ASP of approximately \$310,¹⁶ a dramatic decline from the first and second quarter ASPs of \$380 and \$368 as adjusted for accruals.
- 249. Based on even the high end of the reported revenue range, this represented yet another sequential quarterly revenue decline, as compared to second quarter 2020 revenues of \$27.6 million (controlling for the second quarter refund accrual), a decline of over 6%.
- 250. In the three trading sessions following Progenity's October 29, 2020 disclosures, Progenity's stock price declined by \$3.42 per share or 44.5%.
- 251. On October 29, 2020 Progenity's stock price closed at \$5.96 per share as compared to \$7.69 per share at the close of trading on the prior trading day, a decline of \$1.73 per share or 22.5%. On October 30, 2020 Progenity's stock price closed at \$4.99 per share, a decline of \$0.97 per share or 16.3% as compared to the closing price on the prior trading day. On November 2, 2020 Progenity's stock price closed at \$4.27 per share, a decline of \$0.72 per share or 14.4% as compared to the closing price on the prior trading day.
- 252. The \$4.27 per share closing price on November 2, 2020 was less than one-third of the \$15.00 price investors paid for Progenity shares in the IPO less than five months previously.

¹⁶ Third quarter revenue of \$26 million divided by 84,000 third quarter test volume equals \$309.52.

4. November 9, 2020 Disclosures

- 253. On November 9, 2020, after the close of stock market trading, Progenity provided its final third quarter 2020 results in a press release, slide deck, investor call, and its third quarter Form 10-Q.
- 254. Progenity's third quarter 2020 slide deck confirmed third quarter test volume of 84,000. However, as with Progenity's October 29, 2020 disclosure, this overall figure was substantially inflated by far less valuable COVID tests, which masked a continued decline in Progenity's core Innatal and Preparent test business.
- 255. Progenity's third quarter results disclosed that the growth in its test volume came "primarily from Covid testing." Progenity's third quarter press release confirmed that the test volumes Progenity had reported for the second and third quarters "include[] the company's Innatal, Preparent, Riscover and COVID-19 testing."
- 256. Progenity reported results indicating third quarter 2020 ASP of approximately \$309, a dramatic decline from the first and second quarter ASPs as adjusted for accruals. This additional information confirmed the dramatic decline in Progenity's ASP that was ascertainable from the Company's October 29 press release.
- 257. The information Progenity provided in its final third quarter 2020 results also confirmed the continued substantial decline in Progenity's revenue as reflected in the Company's October 29 press release. The November 9, 2020 slide deck stated that Progenity had earned only \$25.9 million in third quarter 2020 revenue.
- 258. On November 10, 2020, the first trading day after Progenity's November 9, 2020 disclosures, Progenity's stock price closed at \$4.60 per share as compared to \$4.87 per share at the close of trading on the prior trading day, a decline of \$0.27 per share or 5.5%.

5. November 18, 2020 Disclosures

- 259. After the close of stock market trading on November 18, 2020, Progenity filed a current report on SEC Form 8-K, in which it disclosed another Preparent billing dispute.
 - 260. Progenity's Form 8-K stated:

In our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, we disclosed that we were aware of a commercial payor that was reviewing historical payments and could make a claim for recoupment in the future. On November 16, 2020, the Company received a letter from that particular payor informing the Company that the payor is seeking recoupment for historical payments made by such payor in an aggregate amount of approximately \$27.4 million. The historical payments for which such payor is seeking recoupment are claimed to relate primarily to discontinued legacy billing practices for our NIPT and microdeletion tests and secondarily to the implementation of the new CPT code for reimbursement for the Company's Preparent expanded carrier screening tests.

- 261. Progenity later revealed the payor in question to be Anthem, Inc.
- 262. In the three trading sessions following Progenity's November 18, 2020 disclosures, Progenity's stock price declined by \$0.52 per share or 12.5%.
- 263. On November 19, 2020 Progenity's stock price closed at \$4.00 per share as compared to \$4.16 per share at the close of trading on the prior trading day, a decline of \$0.16 per share or 3.9%. On November 20, 2020 Progenity's stock price closed at \$3.92 per share, a decline of \$0.08 per share or 2.0% as compared to the closing price on the prior trading day. On November 23, 2020 Progenity's stock price closed at \$3.64 per share, a decline of \$0.28 per share or 7.1% as compared to the closing price on the prior trading day.

6. June 2, 2021 Disclosures

264. On the morning of June 2, 2021, Progenity issued a press release and filed a current report on SEC Form 8-K, in which it announced that it would

discontinue its core genetic testing business, including the Preparent and Innatal tests that were Progenity's main revenue generating products. Also on the morning of June 2, 2021, Progenity hosted a conference call to discuss its exit from the genetic testing business.

265. The title of Progenity's press release proclaimed that it was "Eliminating Costs of Progenity Genetics Lab and Focusing on Robust, Innovative R&D Pipeline." The press release highlighted that "Closure of genetics lab and other operational improvements expected to result in approximately 70% reduction of annual capital required for operations – from more than \$180 million currently to targeted operating expenses of ~\$50 million in 2022."

266. Progenity's press release stated in relevant part:

Cost Realignment. Progenity will discontinue providing genetic laboratory-developed test services through its Ann Arbor, Michigan CLIA-certified laboratory and cease offering its Preparent® Carrier Test, Innatal® Prenatal Screen, Riscover® Hereditary Cancer Test, and Resura® Prenatal Test. This strategic transformation is expected to be completed over the next approximately 60 days and will include a reduction in force of approximately 374 employees across Progenity and Avero, or approximately 56% of its total workforce. The transformation is also expected to result in annualized cost savings of approximately \$130 million in SG&A. The company's capital requirements after accounting for the costs of the transformation are expected to be approximately \$4-5 million per month before any non-dilutive inflows.

267. Progenity's press release quoted defendant Stylli as saying, "The strategic transformation presented today seeks to significantly reduce our burn rate by eliminating major costs and reducing our cash needs considerably to a normalized rate of \$4-5 million per month (before taking into account non-dilutive sources of capital)." The press release further quoted Defendant Stylli, "We believe that we can deploy capital more efficiently by focusing on the differentiated

3

4 5

6

7 8

10

9

12

11

13 14

15 16

17

18 19

20

21 22

23 24

25

26 27

28

innovation assets in our portfolio that have the greatest potential to drive shareholder value and generate non-dilutive dollars through scalable partnerships."

- 268. Progenity further stated in the press release that "In light of the impact of this strategic transformation, the company is withdrawing previously announced financial guidance for 2021."
- 269. On the June 2, 2021 conference call, Progenity reiterated the information contained in its press release, and provided additional detail in response to analysts' questions.
- 270. Steven Mah of Piper Sandler asked, "Why not sell the genetic testing business to another lab?" Defendant Stylli responded:

There's two parts. One, that process was complicated by our CIA [corporate integrity agreement], which I can go into detail at another time. That restricted the buyer universe, and that considerably. Two, any process would require time. So between those two and time costs considerable amounts of money. So those were two reasons why that option really wasn't a viable option.

271. In response to follow-up questions from Mah regarding a potential acquirer for the lab business, Defendant Stylli further stated:

No, that the CIA would remain -- Yes, the CIA -- they would have inherited the CIA, because the CIA moves with the assets and the operations. And it's very difficult to get the OIG to rescind a CIA. So that would have confounded, so unless you have a lot of experience in operating companies or dealing with the corporate integrity agreements, it would be a deterrent, believe me, we considered all these options.

272. Among the key terms of Progenity's corporate integrity agreement were strict compliance procedures with respect to laws including the Anti-Kickback Statue, which prohibits the routine waiver of patient payment amounts. Because Progenity ended its key illegal marketing practice in February 2020, and because the corporate integrity agreement prevented Progenity or an acquirer from resuming this practice, Progenity's lab business was no longer commercially viable.

- 273. In the two trading sessions following Progenity's June 2, 2021 disclosures, Progenity's stock price declined by \$0.75 per share or 26.2%.
- 274. On June 2, 2021 Progenity's stock price closed at \$2.19 per share as compared to \$2.86 per share at the close of trading on the prior trading day, a decline of \$0.67 per share or 23.4%. On June 3, 2021 Progenity's stock price closed at \$2.11 per share, a decline of \$0.08 per share or 3.7% as compared to the closing price on the prior trading day.
- 275. The \$2.11 per share closing price on June 3, 2021 was less than 15% of the \$15.00 price investors paid for Progenity shares in the IPO less than one year previously.

V. RELEVANT LAWS AND ACCOUNTING STANDARDS

A. Relevant Accounting Standards

276. The Financial Accounting Standards Board maintains the Accounting Standards Codification ("ASC"), which organizes and codifies U.S. Generally Accepted Accounting Principles ("GAAP").

1. Accounting Standards Codification 606 – Revenue from Contracts With Customers

- 277. ASC 606 "specifies the accounting for revenue from contracts with customers," and "establishes principles for reporting useful information to users of financial statements about the nature, amount, timing, and uncertainty of revenue and cash flows arising from the entity's contracts with customers." ASC 606-10-05-1; ASC 606-10-05-2.
- 278. The "core principle" of ASC 606 "is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services." ASC 606-10-05-3.
- 279. Under ASC 606-10-32-1, "When (or as) a performance obligation is satisfied, an entity shall recognize as revenue the amount of the transaction price

, . . .

(which excludes estimates of variable consideration that are constrained in accordance with paragraphs 606-10-32-11 through 32-13) that is allocated to that performance obligation."

280. Under ASC 606-10-32-2:

An entity shall consider the terms of the contract and its customary business practices to determine the transaction price. The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both.

- 281. "For the purpose of determining the transaction price, an entity shall assume that the goods or services will be transferred to the customer as promised in accordance with the existing contract and that the contract will not be cancelled, renewed, or modified." ASC 606-10-32-4.
- 282. "If the consideration promised in a contract includes a variable amount, an entity shall estimate the amount of consideration to which the entity will be entitled in exchange for transferring the promised goods or services to a customer." ASC 606-10-32-5. "An amount of consideration can vary because of discounts, rebates, refunds, credits, price concessions, incentives, performance bonuses, penalties, or other similar items." ASC 606-10-32-6.

283. Under ASC 606-10-32-10:

An entity shall recognize a refund liability if the entity receives consideration from a customer and expects to refund some or all of that consideration to the customer. A refund liability is measured at the amount of consideration received (or receivable) for which the entity does not expect to be entitled (that is, amounts not included in the transaction price). The refund liability (and corresponding change in the transaction price and, therefore, the contract liability) shall be updated at the end of each reporting period for changes in circumstances. To account for a refund liability relating to a sale with

a right of return, an entity shall apply the guidance in paragraphs 606-10-55-22 through 55-29.

284. Under ASC 606-10-32-11:

An entity shall include in the transaction price some or all of an amount of variable consideration estimated in accordance with paragraph 606-10-32-8 only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

285. Probable means that the future event or events are likely to occur. ASC 606-10-20.

286. Under ASC 606-10-32-12:

In assessing whether it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur once the uncertainty related to the variable consideration is subsequently resolved, an entity shall consider both the likelihood and the magnitude of the revenue reversal. Factors that could increase the likelihood or the magnitude of a revenue reversal include, but are not limited to, any of the following:

- a. The amount of consideration is highly susceptible to factors outside the entity's influence. Those factors may include volatility in a market, the judgment or actions of third parties, weather conditions, and a high risk of obsolescence of the promised good or service.
- b. The uncertainty about the amount of consideration is not expected to be resolved for a long period of time.
- c. The entity's experience (or other evidence) with similar types of contracts is limited, or that experience (or other evidence) has limited predictive value.
- d. The entity has a practice of either offering a broad range of price concessions or changing the payment terms and conditions of similar contracts in similar circumstances.

e. The contract has a large number and broad range of possible consideration amounts.

287. ASC 606-10-32-14 states that:

At the end of each reporting period, an entity shall update the estimated transaction price (including updating its assessment of whether an estimate of variable consideration is constrained) to represent faithfully the circumstances present at the end of the reporting period and the changes in circumstances during the reporting period. The entity shall account for changes in the transaction price in accordance with paragraphs 606-10-32-42 through

32-45.

contracts." Id.

288. The objective of the disclosure requirements of ASC 606 "is for an entity to disclose sufficient information to enable users of financial statements to understand the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers." ASC 606-10-50-1. "To achieve that objective, an entity shall disclose qualitative and quantitative information about" items including "Its contracts with customers" and "The significant judgments, and changes in the judgments, made in applying the guidance" in ASC 606 "to those

- 289. Under ASC 606-10-50-12, "An entity shall disclose information about its performance obligations in contracts with customers, including a description of" any "Obligations for returns, refunds, or similar obligations."
- 290. "An entity shall disclose the judgments, and changes in the judgments, made in applying the guidance in [ASC 606] that significantly affect the determination of the amount and timing of revenue from contracts with customers. In particular" as regards the "transaction price." ASC 606-10-50-17.
- 291. "An entity shall disclose information about the methods, inputs, and assumptions used for" items including "Determining the transaction price, which includes, but is not limited to, estimating variable consideration," and "Measuring obligations for returns, refunds, and other similar obligations." ASC 606-10-50-20.

292. ASC 606-10-55-23 provides:

To account for the transfer of products with a right of return (and for some services that are provided subject to a refund), an entity should recognize all of the following:

a. Revenue for the transferred products in the amount of consideration to which the entity expects to be entitled (therefore, revenue would not be recognized for the products expected to be returned)

b. A refund liability

c. An asset (and corresponding adjustment to cost of sales) for its right to recover products from customers on settling the refund liability.

293. Similarly, ASC 606-10-55-25 provides in relevant part, "For any amounts received (or receivable) for which an entity does not expect to be entitled, the entity should not recognize revenue when it transfers products to customers but should recognize those amounts received (or receivable) as a refund liability."

294. "An entity should update the measurement of the refund liability at the end of each reporting period for changes in expectations about the amount of refunds. An entity should recognize corresponding adjustments as revenue (or reductions of revenue)." ASC 606-10-55-26.

295. The Securities and Exchange Commission has pursued enforcement action against a securities issuer for improper revenue recognition under ASC 606. For example, the SEC found that despite disclosing that it would follow ASC 606, Pareteum Corporation recognized as revenue the full stated contract price for purchase orders immediately upon their execution, "even though these purchase orders were non-binding and the product had not yet been shipped," and without confirming whether ASC 606's criteria for revenue recognition had been satisfied. *In the Matter of Pareteum Corporation*, Securities Act of 1933 Release No. 10975

(Sept. 2, 2021), 2021 WL 4031174. The SEC found this conduct to violate federal securities laws, and imposed a cease and desist order and civil money penalties.

2. Accounting Standards Codification 450 – Contingencies

- 296. ASC 450 "establishes standards of financial accounting and reporting for loss contingencies and gain contingencies, including standards for disclosures." ASC 450-10-05-4.
- 297. ASC 450-20 "provides guidance for the recognition and disclosure of a loss contingency." ASC 450-20-05-1. A loss contingency is "[a]n existing condition, situation, or set of circumstances involving uncertainty as to possible loss to an entity that will ultimately be resolved when one or more future events occur or fail to occur." ASC 450-20-20. Loss contingencies include, for example, "actual or possible claims and assessments." ASC 450-20-05-10(c).
 - 298. ASC 450-20-25-2 provides in relevant part:

An estimated loss from a loss contingency shall be accrued by a charge to income if both of the following conditions are met:

- a. Information available before the financial statements are issued or are available to be issued (as discussed in Section 855-10-25) indicates that it is probable that an asset had been impaired or a liability had been incurred at the date of the financial statements. Date of the financial statements means the end of the most recent accounting period for which financial statements are being presented. It is implicit in this condition that it must be probable that one or more future events will occur confirming the fact of the loss.
- b. The amount of loss can be reasonably estimated.

The purpose of those conditions is to require accrual of losses when they are reasonably estimable and relate to the current or a prior period . . . As discussed in paragraph 450-20-50-5, disclosure is preferable to accrual when a reasonable estimate of loss cannot be made.

- 299. Probable means that the future event or events are likely to occur. ASC 450-20-20.
- 300. ASC 450-20-25-3 clarifies that "The conditions in the preceding paragraph are not intended to be so rigid that they require virtual certainty before a loss is accrued."
- 301. Under ASC 450-20-25-5, the requirement that the amount of loss can be reasonably estimated:

shall not delay accrual of a loss until only a single amount can be reasonably estimated. To the contrary, when the condition in paragraph 450-20-25-2(a) is met and information available indicates that the estimated amount of loss is within a range of amounts, it follows that some amount of loss has occurred and can be reasonably estimated. Thus, when the condition in paragraph 450-20-25-2(a) is met with respect to a particular loss contingency and the reasonable estimate of the loss is a range, the condition in paragraph 450- 20-25-2(b) is met and an amount shall be accrued for the loss.

- 302. Under ASC 450-20-30-1, when accruing a loss based on a reasonably estimable range, at least the minimum amount in that range must be accrued.
 - 303. Under ASC 450-20-50-3:

Disclosure of the contingency shall be made if there is at least a reasonable possibility that a loss or an additional loss may have been incurred and either of the following conditions exists:

- a. An accrual is not made for a loss contingency because any of the conditions in paragraph 450-20-25-2 are not met.
- b. An exposure to loss exists in excess of the amount accrued pursuant to the provisions of paragraph 450-20-30-1.
- 304. A reasonable possibility exists where "The chance of the future event or events occurring is more than remote but less than likely." ASC 450-20-20. Remote means that "The chance of the future event or events occurring is slight." *Id*.
- 305. Pursuant to ASC 450-20-50-4, the disclosure required by ASC 450-20-50-3 "shall include both of the following: [a] The nature of the contingency [b] An

estimate of the possible loss or range of loss or a statement that such an estimate cannot be made."

306. ASC 450-20-50-5 provides:

Disclosure is preferable to accrual when a reasonable estimate of loss cannot be made. For example, disclosure shall be made of any loss contingency that meets the condition in paragraph 450-20-25-2(a) but that is not accrued because the amount of loss cannot be reasonably estimated (the condition in paragraph 450-20-25-2[b]). Disclosure also shall be made of some loss contingencies for which there is a reasonable possibility that a loss may have been incurred even though information may not indicate that it is probable that an asset had been impaired or a liability had been incurred at the date of the financial statements.

307. ASC 450-20-55-14 provides in relevant part that:

With respect to unasserted claims and assessments, an entity must determine the degree of probability that a suit may be filed or a claim or assessment may be asserted and the possibility of an unfavorable outcome. If an unfavorable outcome is probable and the amount of loss can be reasonably estimated, accrual of a loss is required by paragraph 450-20-25-2. For example:

b. An investigation of an entity by a governmental agency, if enforcement proceedings have been or are likely to be instituted, is often followed by private claims for redress, and the probability of their assertion and the possibility of loss should be considered in each case.

308. The Securities and Exchange Commission has pursued enforcement action against securities issuers for failure to appropriately disclose loss contingencies and accrue losses under ASC 450. For example, the SEC alleged that Mylan N.V. violated ASC 450 and federal securities laws in connection with a possible loss relating to a Department of Justice probe into whether Mylan overcharged Medicaid for EpiPen sales. *S.E.C. v. Mylan N.V.*, Case No. 1:19-cv-2904 (D.D.C.). The SEC alleged that Mylan violated ASC 450 by failing to disclose a that a loss relating to the DOJ probe was reasonably possible, and by failing to

accrue an estimate of the loss relating to the DOJ probe when a loss was both probable and reasonably estimable. The SEC and Mylan agreed to a \$30 million penalty and permanent injunction.

3. Accounting Standards Codification 855 – Subsequent Events

- 309. ASC 855-10-25-1 provides, "An entity shall recognize in the financial statements the effects of all subsequent events that provide additional evidence about conditions that existed at the date of the balance sheet, including the estimates inherent in the process of preparing financial statements."
- 310. Under ASC 855-10-25-1A and ASC 855-10-25-2, an entity shall evaluate subsequent events through at least "the date that the financial statements are available to be issued."

B. Relevant Government Health Care Program Regulations

- 311. As Progenity stated in the Registration Statement, "the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010, or collectively, the ACA, enacted in March 2010, requires providers and suppliers to report and return any overpayments received from government payors under the Medicare and Medicaid programs within 60 days of identification." *See* 42 U.S.C § 1320a-7k(d).
- 312. This requirement to return overpayments to government payors is set forth in Centers for Medicare & Medicaid Services regulations, which provide that, insofar as applicable here, an overpayment must be reported and returned by "[t]he date which is 60 days after the date on which the overpayment was identified." at 42 C.F.R. § 401.305(b)(1). Those regulations, at 42 C.F.R. § 401.305(a)(2), further provide that:

A person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. A person should have determined that the person received an overpayment and quantified the amount of the

overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment.

C. Disclosure Obligations Under the Securities Act and SEC Regulation S-K

- 313. "The Securities Act of 1933 . . . was designed to provide investors with full disclosure of material information concerning public offerings of securities in commerce, to protect investors against fraud, and, through the imposition of specified civil liabilities, to promote ethical standards of honesty and fair dealing." Ernst & Ernst v. Hochfelder, 425 U.S. 185, 195 (1976); see also Randall v. Loftsgaarden, 478 U.S. 647, 659 (1986) (The Securities Act aims "to place adequate and true information before the investor"); Pinter v. Dahl, 486 U.S. 622, 638 (1988) ("The primary purpose of the Securities Act is to protect investors by requiring publication of material information thought necessary to allow them to make informed investment decisions concerning public offerings of securities in interstate commerce.").
- 314. To effectuate this purpose, a Company's registration statement must provide a full disclosure of material information. *See Herman & MacLean v. Huddleston*, 459 U.S. 375, 381 (1983). Failure to do so gives rise to private rights of action under the Securities Act. *Id.* at 381-82 (Private rights of action were "designed to assure compliance with the disclosure provisions of the Act by imposing a stringent standard of liability on the parties who play a direct role in a registered offering"); *see also* 15 U.S.C. § 77k(a).

1. Section 11 Disclosure Requirements

315. Section 11 prohibits materially misleading statements or omissions in registration statements filed with the SEC. *See* 15 U.S.C. § 77k. Accordingly, Section 11 gives rise to liability if "any part of [a company's] registration statement, when such part became effective, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

statements therein not misleading." 15 U.S.C. § 77k(a). Section 11 provides for a cause of action by the purchaser of a registered security against certain statutorily enumerated parties, including: "(1) every person who signed the registration statement; (2) every person who was a director . . . at the time of the filing of . . . the registration statement with respect to which his liability is asserted; (3) every person who, with his consent, is named in the registration as being or about to become a director [;]" (4) "any person . . . who has with his consent been named as having prepared or certified any part of the registration statement[;]" and (5) "every underwriter with respect to such security." 15 U.S.C. § 77k(a)(1)-(5).

2. Disclosure Requirements Under Regulation S-K Item 303

- 316. Item 303 of Regulation S-K imposes an affirmative duty on issuers to disclose "known trends or any known demands, commitments, events or uncertainties that will result in or that are reasonably likely to result in the registrant's liquidity increasing or decreasing in a material way." S.E.C. Release No. 6835, 1989 WL 1092885, at *4; see also 17 C.F.R. § 229.303(a). "Disclosure of known trends or uncertainties that the registrant reasonably expects will have a material impact on net sales, revenues, or income from continuing operations is also required." Id.
- 317. Pursuant to Item 303(a), for a fiscal year, a registrant thus has an affirmative duty to:
 - Describe any unusual or infrequent events or transactions or any significant economic changes that materially affected the amount of reported income from continuing operations and, in each case, indicate the extent to which the income was so affected.
 - ii. Describe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. If the registrant knows of events that will cause a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases

or inventory adjustments), the change in the relationship shall be disclosed.

17 C.F.R. § 229.303(a)(3)(i)-(ii); *see also* S.E.C. Release No. 6835, 1989 WL 1092885, at *8 (May 18, 1989) ("Other non-recurring items should be discussed as unusual or infrequent events or transactions that materially affected the amount of reported income from continuing operations.") (citation and quotation omitted).

318. Thus, even a one-time event, if "reasonably expect[ed]" to have a material impact of results, must be disclosed. Examples of such required disclosures include: "[a] reduction in the registrant's product prices; erosion in the r[e]gistrant's market share; changes in insurance coverage; or the likely non-renewal of a material contract." S.E.C. Release No. 6835, 1989 WL 1092885, at *4 (May 18, 1989).

319. Accordingly, as the SEC has repeatedly emphasized, the "specific provisions in Item 303 [as set forth above] require disclosure of forward-looking information." *See* Mgmt's Discussion and Analysis of Fin. Condition and Results of Operation, S.E.C. Release No. 6835, 1989 WL 1092885, at *3 (May 18, 1989). Indeed, the SEC has stated that disclosure requirements under Item 303 are "intended to give the investor an opportunity to look at the company through the eyes of management by providing both a short and long-term analysis of the business of the company" and "a historical and prospective analysis of the registrant's financial condition . . . with particular emphasis on the registrant's prospects for the future." *Id.* at *3, *17. Thus, "material forward-looking information regarding known material trends and uncertainties is required to be disclosed as part of the required discussion of those matters and the analysis of their effects." *See* Comm'n Guidance Regarding Mgmt's Discussion and Analysis of Fin. Condition and Results of Operations, S.E.C. Release No. 8350, 2003 WL 22996757, at *11 (December 19, 2003).

3. Disclosure Requirements Under Regulation S-K Item 105

320. Item 105 of Regulation S-K requires that offering documents "provide under the caption 'Risk Factors' a discussion of the material factors that make an investment in the registrant or offering speculative or risky." 17 C.F.R. § 229.105(a). Item 105 further requires the offering documents to "[c]oncisely explain how each risk affects the registrant or the securities being offered." 17 C.F.R. § 229.105(b). The discussion of risk factors:

must be specific to the particular company and its operations, and should explain how the risk affects the company and/or the securities being offered. Generic or boilerplate discussions do not tell the investors how the risks may affect their investment.

Statement of the Comm'n Regarding Disclosure of Year 2000 Issues and Consequences by Pub. Cos., Inv. Advisers, Inv. Cos., & Mun. Sec. Issuers, 1998 WL 425894, at *14 (July 29, 1998).

VI. THE MATERIALLY MISLEADING REGISTRATION STATEMENT

321. The Registration Statement contained untrue statements of material fact, omitted material facts necessary to make the statements contained therein not misleading, and failed to make necessary disclosures required under the rules and regulations governing its preparation (specifically including Item 303 and Item 105 of SEC Regulation S-K).

A. The Registration Statement Failed To Disclose That Progenity Had Improperly Billed Government Payors For Preparent Tests And Likely Received A Material Amount of Overpayments Through "Early 2020"

322. Nowhere did the Registration Statement disclose that (i) Progenity had improperly billed government payors for Preparent tests beginning in 2019 and ending in or before early 2020, or (ii) there was a high probability that Progenity had received, and would have to refund, a material amount of overpayments from government payors for Preparent tests. However, these material facts existed at the time of the IPO, were necessary to make the statements in the Registration

Statement not misleading, and were required to be included in the Registration Statement.

1. Omission of Disclosures Required By Regulation S-K

- 323. That (i) Progenity had improperly billed government payors for Preparent tests beginning in 2019 and ending in or before early 2020, and (ii) there was a high probability that Progenity had received, and would have to refund, a material amount of overpayments from government payors for Preparent tests, made an investment in Progenity speculative or risky. Item 105 of SEC Regulation S-K required Progenity to include a discussion of these factors in the Registration Statement, and to explain how they affect Progenity or the stock offered in the IPO. Progenity failed to do so.
- 324. Progenity's improper billing of government payors for Preparent tests and likely receipt of a material amount of overpayments made an investment in Progenity speculative or risky because, *inter alia*: (i) Progenity would almost certainly have to refund the overpayments, (ii) Progenity's Preparent tests would generate less revenue in the future due to the correction of the improper billing, (iii) the existence of this improper billing of government payors created a heightened risk that Progenity had similarly improperly billed other payors, and (iv) Progenity had recently announced a settlement relating to improper billing for its other main product. Therefore, Progenity's improper billing of government payors for Preparent tests and likely receipt of a material amount of overpayments presented material risks that Progenity's revenues would decline, it would be forced to belatedly recognize additional refund liabilities, it suffered from widespread billing and compliance failures, and it may be subject to additional regulatory scrutiny.
- 325. That (i) Progenity had improperly billed government health care programs for Preparent tests, and (ii) there was a high probability that Progenity had received, and would have to refund, a material amount of overpayments from government payors for Preparent tests, were known trends or uncertainties that had

and were reasonably likely to have a material unfavorable impact on net sales and revenues and income from continuing operations. Item 303 of SEC Regulation S-K required Progenity to describe these trends and uncertainties in the Registration Statement. Progenity failed to do so.

326. That Progenity had improperly billed government health care programs for Preparent tests was a known trend, and that there was a high probability that Progenity had received, and would have to refund, a material amount of overpayments from government payors gave rise to known uncertainties relating to Progenity's refund liabilities. This trend and these uncertainties had already materially unfavorably affected sales, revenues, and income because Progenity had already stopped its improper billing, thus reducing revenues. This trend and these uncertainties were reasonably likely to continue to materially unfavorably affect sales, revenues, and income for the same reason, and because Progenity would have to reverse previously recognized revenue once it belatedly accounted for its refund obligations.

2. Improper Revenue Recognition And Lack of Disclosure Under ASC 606

327. Progenity violated GAAP and ASC 606 by improperly accounting for revenue from its Preparent tests and failing to make required qualitative disclosures, which rendered numerous statements in the Registration Statement materially false and misleading, including those statements relating to Progenity's first quarter 2020 revenues and liabilities.

328. ASC 855 regarding subsequent events applies to ASC 606 regarding revenue from contracts with customers. Under ASC 855-10-25-1 and ASC 855-10-25-2 Progenity was required to recognize in its financial statements for the period ending March 31, 2020 the effects of all subsequent events through May 27, 2020,¹⁷

¹⁷ The notes to Progenity's first quarter 2020 financial statements in the Registration Statement state that "The Company has evaluated subsequent events from the (footnote continued)

that provided additional evidence about conditions that existed as of March 31, 2020. Progenity's improper billing of government payors for Preparent tests from 2019 through in or before early 2020, and its receipt of related overpayments through early 2020, were conditions that existed as of March 31, 2020.

329. ASC 606 requires an entity, when determining the "transaction price" for purposes of revenue recognition, to consider the terms of its contracts and to assume that services will be delivered in accord with contract terms. ASC 606-10-32-2; ASC 606-10-32-4. Progenity's contracts with government payors, and applicable laws and regulations, required Progenity to bill for its tests using the correct CPT codes. Therefore, due to information existing and knowable as of May 27, 2020, ASC 606 required Progenity to adjust its revenue for the period ending March 31, 2020, based on the reimbursements it would have received if it had accurately and properly billed for its tests. Progenity did not do so, and instead maintained its previously recognized revenues based on expected reimbursements for Preparent tests billed with improper codes.

330. Consideration received by an entity that the entity expects to refund should not be recognized as revenue, and must be accounted for as a refund liability, which must be updated at the end of each reporting period for changes in circumstances and changes in expectations about the amount of refunds. ASC 606-10-32-10; ASC 606-10-55-23; ASC 606-10-55-25; ASC 606-10-55-26. Progenity received Preparent overpayments from government payors only through "early 2020." Some time prior to "early 2020" Progenity identified its improper billing and halted the practice. Therefore, prior to May 27, 2020 Progenity should have expected to eventually refund a portion of payments received from government payors for Preparent tests, and should have recognized a refund liability, and

balance sheet date through May 27, 2020, the date the consolidated financial statements were available to be issued."

reversed corresponding revenues, for the reporting period ended March 31, 2020. Progenity failed to do so until the period ended June 30, 2020.

- 331. No later than May 27, 2020, information existing and knowable to Progenity showed that it was not "probable that a significant reversal in the amount of cumulative revenue recognized will not occur," when the uncertainty regarding the timing and amount of its obligation to refund Preparent overpayments to government payors was subsequently resolved. ASC 606-10-32-11. Information existing and knowable to Progenity showed that a refund of the overpayments was both probable to occur and to be material in amount, in part because such a refund was highly susceptible to factors outside of Progenity's influence including the actions of governmental regulators and third-party claims reviewers, and because Progenity had a practice of offering refunds to payors in similar circumstances. ASC 606-10-32-12. Therefore, for the reporting period ended March 31, 2020, Progenity was required to reverse its previously recognized revenue relating to the overpayments, in order "to represent faithfully the circumstances present at the end of the reporting period and the changes in circumstances during the reporting period." ASC 606-10-32-14. Progenity failed to do so until the period ended June 30, 2020.
- 332. In addition to these quantitative disclosures, ASC 606 required Progenity to provide "qualitative" information regarding its contracts with government payors and its significant judgments in applying ASC 606 to those contracts. ASC 606-10-50-1; ASC 606-10-50-17. Progenity was likewise required to disclose qualitative information including a description of its obligations for refunds, and the methods, inputs, and assumptions used relating to refund obligations. ASC 606-10-50-12; ASC 606-10-50-20. Progenity failed to make these qualitative disclosures with respect to its improper billing of government payors for Preparent tests and its probable receipt of a material amount of overpayments.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

333. In light of the foregoing violations of ASC 606, the Registration Statement repeatedly presented incorrect information relating to Progenity's first quarter 2020 financial statements, including its revenue (which was materially overstated in the Registration Statement) and liabilities (which were materially understated in the Registration Statement). The Registration Statement's qualitative disclosures regarding Progenity's application of ASC 606 were also materially false and misleading due to their failure to disclose that (i) Progenity had improperly billed government payors for Preparent tests beginning in 2019 and ending in or before early 2020, and (ii) there was a high probability that Progenity had received, and would have to refund, a material amount of overpayments from government payors for Preparent tests.

334. For example, the Registration Statement contained the following materially false financial information:

		Three Months Ended March 31,	
	2019	2020	
Revenue	\$ 47,507	\$ 16,828	
Cost of sales	24,421	26,570	
Gross profit (loss)	23,086	(9,742	
Operating expenses:			
Research and development	15,248	11,240	
Selling and marketing	15,567	14,436	
General and administrative	14,278	17,108	
Total operating expenses	45,093	42,784	
Loss from operations	(22,007)	(52,526	
Interest expense	(2,269)	(2,302	
Interest and other income (expense), net	257	(20	
Loss before taxes	(24,019)	(54,848	
Income tax benefit	_	(37,696	
Net loss	\$ (24,019)	\$ (17,152	
Dividend paid to preferred stockholders	(3,652)	_	
Net loss attributable to common stockholders	\$ (27,671)	\$ (17,152	
Net loss per share attributable to common stockholders, basic and diluted	\$ (5.88)	\$ (3.43	
Weighted average number of shares outstanding, basic and diluted	4,705,641	4,993,393	
Pro forma loss per share, basic and diluted		\$ (0.49	

These statements were materially false and misleading when made because no later than May 27, 2020, Progenity identified and ceased its improper billing of government payors for Preparent tests, and so Progenity was required to reduce its revenues for the period ended March 31, 2020 (and possibly for periods in 2019) by

an estimate of the resulting overpayments. This, in turn, caused every financial metric derived in whole or in part from Progenity's reported first quarter 2020 revenue to be similarly false.

335. The Registration Statement also contained the following materially false financial information:

- 1						
7	Accrued expenses and other current liabilities					
	Accrued expenses and other current liabilities consist of the following (in thousands):					
3						
$\backslash \mid$	December 2019					
!	Accrual for reimbursement claims and settlements \$ 60	,386 \$33,	560			
	Commissions and bonus 6	,357 6,	,185			
)		,506 8,	,751			
	Accrued professional services 5	,322 3,	,206			
ıl	Other 6	,044 4,	,708			
`	Total \$ 83	,615 \$ 56,	410			
2			_			
	Other long-term liabilities					
3						
	Other long-term liabilities consist of the following (in thousands):					
1						
١.	December 2019					
5		,205 \$ 49,				
	Other	654	586			
۱ ۱	Total \$ 12	,859 \$ 49,	723			

These statements were materially false and misleading when made because no later than May 27, 2020, Progenity identified and ceased its improper billing of government payors for Preparent tests, and so Progenity was required to recognize a liability for the period ended March 31, 2020 in the amount of an estimate of the resulting overpayments. This, in turn, caused every financial metric derived in whole or in part from Progenity's reported first quarter 2020 accrual for reimbursement claims and settlements to be similarly false.

336. The Registration Statement contained several misleading statements relating to Progenity's procedures for recognizing variable consideration in revenue under ASC 606. For example, the Registration Statement misleadingly stated:

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Effective January 1, 2019, in accordance with ASC 606, the total consideration we expect to collect from insurance carriers, clinics, and patients in exchange for the tests accessioned is recognized in the period in which our tests are performed and reported to customers.

The transaction price is an estimate and may be fixed or variable. Variable consideration includes reimbursement from healthcare insurers, government payors, and patients and is adjusted for estimates of disallowed cases, discounts, and refunds using the expected value approach. Tests billed to healthcare insurers and directly to patients can take up to six months to collect and we may be paid less than the full amount billed or not be paid at all. For insurance carriers and government payors, we utilize the expected value approach using a portfolio of relevant historical data for payors with similar reimbursement experience. The portfolio estimate is developed using historical reimbursement data from payors and patients, as well as known current reimbursement trends not reflected in the historical data. Such variable consideration is included in the transaction price only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainties with respect to the amount are resolved. We monitor these estimates at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required.

These statements were materially false and misleading when made because no later than May 27, 2020, Progenity identified and ceased its improper billing of government payors for Preparent tests, but failed to make qualitative disclosures required under ASC 606 regarding the relevant contracts, significant judgments, and refunds. In addition, the foregoing statements were materially false and misleading because, *inter alia*, with respect to Progenity's revenue recognition for Preparent tests, the Company did not appropriately adjust its variable consideration to reflect refunds owed for overpayments, failed to consider material historical data and reimbursement trends when evaluating variable consideration, and included variable consideration in revenue when it was not probable that a significant reversal in the amount of cumulative revenue recognized would not occur when the uncertainties with respect to the amount were resolved.

3. Failure to Disclose or Accrue Loss Contingencies As Required By ASC 450

337. Progenity violated GAAP and ASC 450 by improperly failing to account for loss contingencies relating to its Preparent billing and make required qualitative disclosures, which rendered numerous statements in the Registration Statement materially false and misleading, including those statements relating to Progenity's first quarter 2020 income.

338. ASC 450 required Progenity to accrue an estimated loss because (i) information available before May 27, 2020,¹⁸ indicated that it was probable that a liability had been incurred as of March 31, 2020 relating to Progenity's obligation to refund Preparent overpayments, and (ii) Progenity could reasonably estimate the loss. ASC 450-20-25-2. Progenity identified and ceased its improper billing of government payors for Preparent tests in or before early 2020. Based on the billing and reimbursement information in Progenity's possession, Progenity could at least reasonably estimate a range of loss relating to Preparent refund obligations, and so was required to accrue at least the minimum amount of such range. ASC 450-20-25-5; ASC 450-20-30-1. Progenity failed to make the required accrual.

339. In the alternative, even if Progenity was not required to accrue a loss, ASC 450 required Progenity to disclose the loss contingency relating to its improper Preparent billing because there was at least a reasonable possibility as of May 27, 2020 that such a loss may have been incurred, *i.e.*, the chance that such a loss may have been incurred was more than remote. ASC 450-20-50-3; ASC 450-20-20. Such disclosure was required to include (i) the nature of the improper Preparent billing

¹⁸ The notes to Progenity's first quarter 2020 financial statements in the Registration Statement state that "The Company has evaluated subsequent events from the balance sheet date through May 27, 2020, the date the consolidated financial statements were available to be issued." ASC 855 regarding subsequent events applies to ASC 450 regarding contingencies. *See* ASC 450-20-25-2.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

loss contingency, and (ii) either an estimate of the possible loss or range of loss or a statement that such an estimate could not be made. ASC 450-20-50-4. Progenity made no such disclosures.

340. As of May 27, 2020 it was probable that government payors would eventually make a claim or assessment relating to Progenity's receipt of Preparent overpayments, because from no later than April 21, 2020 Progenity expected to enter a corporate integrity agreement which was highly likely to reveal Progenity's improper Preparent billing to the government. ASC 450-20-55-14. An unfavorable outcome of such a claim or assessment was highly likely because, as Progenity implicitly admitted by ceasing its improper Preparent billing in or before early 2020, and by Defendant Stylli's later admission that this improper billing was an "error," Progenity's prior Preparent billing to government payors was clearly incorrect. *Id.* The governmental investigation and enforcement proceedings against Progenity with respect to its improper billing of government payors for Innatal tests made it highly likely that these proceedings would be followed by additional governmental claims for redress in relation to Progenity's similar pattern of improper Preparent billing. See ASC 450-20-55-14(b). In addition, information existing and knowable to Progenity showed that it would eventually be required to refund the overpayments regardless of whether the government independently identified the issue and affirmatively demanded repayment. See 42 C.F.R. § 401.305. Therefore, Progenity was required to accrue a charge to income no later than for the period ended March 31, 2020, but failed to do so.

341. In light of the foregoing violations of ASC 450, the Registration Statement repeatedly presented incorrect information relating to Progenity's first quarter 2020 financial statements, including net loss (which was materially understated in the Registration Statement, *i.e.*, the reported loss was smaller than it should have been). The Registration Statement's qualitative disclosures regarding loss contingencies were also materially false and misleading due to their failure to

disclose that (i) Progenity had improperly billed government payors for Preparent tests beginning in 2019 and ending in or before early 2020, and (ii) there was a high probability that Progenity had received, and would have to refund, a material amount of overpayments from government payors for Preparent tests.

342. For example, the Registration Statement contained the following materially false financial information:

		Three Months Ended March 31,	
	2019	2020	
Revenue	\$ 47,507	\$ 16,828	
Cost of sales	24,421	26,570	
Gross profit (loss)	23,086	(9,742)	
Operating expenses:			
Research and development	15,248	11,240	
Selling and marketing	15,567	14,436	
General and administrative	14,278	17,108	
Total operating expenses	45,093	42,784	
Loss from operations	(22,007)	(52,526)	
Interest expense	(2,269)	(2,302)	
Interest and other income (expense), net	257	(20)	
Loss before taxes	(24,019)	(54,848)	
Income tax benefit	_	(37,696)	
Net loss	\$ (24,019)	\$ (17,152)	
Dividend paid to preferred stockholders	(3,652)		
Net loss attributable to common stockholders	\$ (27,671)	\$ (17,152)	
Net loss per share attributable to common stockholders, basic and diluted	\$ (5.88)	\$ (3.43)	
Weighted average number of shares outstanding, basic and diluted	4,705,641	4,993,393	
Pro forma loss per share, basic and diluted		\$ (0.49)	

These statements were materially false and misleading when made because no later than May 27, 2020, Progenity identified and ceased its improper billing of government payors for Preparent tests. Furthermore, no later than April 21, 2020 Progenity expected to enter into a corporate integrity agreement that was highly likely to reveal Progenity's improper Preparent billing to the government. In addition, information existing and knowable to Progenity showed that it would eventually be required to refund the overpayments regardless of whether the government independently identified the issue and affirmatively demanded repayment. See 42 C.F.R. § 401.305. Therefore Progenity was required to accrue a charge to income in the amount of an estimate of the resulting loss for the reporting period ended March 31, 2020. This, in turn, caused every financial metric derived in

whole or in part from Progenity's reported first quarter 2020 net loss to be similarly false.

343. The Registration Statement contained several misleading statements relating to Progenity's contingencies. For example, the Registration Statement misleadingly stated:

The Company, in the ordinary course of its business, can be involved in lawsuits, threats of litigation, and audit and investigative demands from third parties. While management is unable to predict the exact outcome of such matters, it is management's current belief, that any potential liabilities resulting from these contingencies, individually or in the aggregate, could have a material impact on the Company's financial position and results of operations.

The regulations governing government reimbursement programs (e.g., Medicaid, Tricare, and Medicare) and commercial payor reimbursement programs are complex and subject to interpretation. As a provider of services to patients covered under government and commercial payor programs, post payment review audits, and other forms of reviews and investigations are routine. The Company believes it complies in all material respects with the statutes, regulations, and other requirements applicable to its laboratory operations.

These statements were materially false and misleading when made because no later than May 27, 2020, Progenity identified and ceased its improper billing of government payors for Preparent tests. Furthermore, no later than April 21, 2020 Progenity expected to enter into a corporate integrity agreement that was highly likely to reveal Progenity's improper Preparent billing to the government. In addition, information existing and knowable to Progenity showed that it would eventually be required to refund the overpayments regardless of whether the government independently identified the issue and affirmatively demanded repayment. *See* 42 C.F.R. § 401.305. Therefore, Progenity failed to make disclosures required under ASC 450 regarding (i) the nature of the improper Preparent billing loss contingency, and (ii) either an estimate of the possible loss or range of loss or a

statement that such an estimate could not be made. In addition, the foregoing statements were materially false and misleading because, *inter alia*, Progenity's management was able to reasonably estimate a possible range of loss relating to its improper Preparent billing, Progenity's billing of government payors for Preparent tests was clearly incorrect and not subject to interpretation, and information existing and knowable to Progenity showed that it had not complied in all material respects with government payor billing requirements as relates to its Preparent laboratory tests.

4. Additional False and Misleading Statements

344. The Registration Statement itself makes clear that at the time of the IPO, Progenity was already aware of the CPT code that became effective in 2019 for Progenity's Preparent tests, stating in relevant part, "effective January 1, 2019, the AMA approved the use of a CPT code for expanded carrier screening tests, which may . . . cause reimbursement for our Preparent expanded carrier screening tests to decline." This risk factor disclosure was itself misleading because it merely stated in hypothetical terms that the new CPT code "may" cause a decline in Preparent reimbursement, and failed to disclose that reimbursement rates for this new CPT code were lower (or zero for certain payors) as compared to its predecessor codes, and that in or before early 2020 Progenity had ceased improperly billing government payors for Preparent tests and so had already experienced a decline in reimbursements.

345. The Registration Statement misleadingly reassured investors that Progenity used correct CPT codes in its billing, stating in relevant part "[w]e currently submit for reimbursement using CPT codes that we believe are appropriate for our testing, but codes may be rejected or withdrawn and payors may seek refunds of amounts that they claim were inappropriately billed to a specified CPT code." These statements were materially false and misleading when made because they represented that Progenity appropriately billed payors for its tests, and failed to

1

4

6 7

5

9 10

8

11 12

13 14

15 16

17

18 19

20

21 22

23

24 25

26

27 28 disclose that from 2019 until in or before early 2020 Progenity had improperly billed government payors for Preparent tests, and there was a high probability that Progenity had received and would have to refund a material amount of overpayments.

346. The Registration Statement also contained a misleading risk factor which stated in relevant part:

We have implemented compliance policies and procedures intended to train and monitor our sales, billing, marketing and other personnel. Our efforts to implement appropriate monitoring of such personnel are ongoing and we have experienced situations in which employees may have failed to fully adhere to our policies and applicable laws in the past. There can be no assurance that we will not experience similar issues in the future. Failure by our sales, billing, marketing, or other personnel to follow our policies and comply with applicable laws may subject us to administrative, civil, and criminal actions, penalties, damages, fines, individual imprisonment, exclusion from participation in federal healthcare programs, refunding of payments received by us, and curtailment or cessation of our operations. . . In addition, commercial third-party payors may refuse to provide all or any reimbursement for tests administered, seek repayment from us of amounts previously reimbursed, and harm our ability to secure network contracts with third-party payors.

These statements were materially false and misleading when made because they presented as a mere hypothetical risk that compliance failures by Progenity's billing personnel "may" result in the need to refund payments, and failed to disclose that Progenity had already improperly billed government payors for Preparent tests due to billing compliance failures from 2019 until in or before early 2020, and there was a high probability that Progenity had received and would have to refund a material amount of overpayments.

347. The Registration Statement also contained another misleading risk factor which stated in relevant part:

Third-party payors may decide to deny payment or recoup payment for testing that they contend to have been not medically necessary, against

their coverage determinations, or for which they have otherwise overpaid, and we may be required to refund reimbursements already received. . . If a third-party payor successfully challenges that payment for prior testing was in breach of contract or otherwise contrary to policy or law, they may recoup payment, which amounts could be significant and would impact our operating results and financial condition, and it may decrease reimbursement going forward. We may also decide to negotiate and settle with a third-party payor in order to resolve an allegation of overpayment. Any of these outcomes, including recoupment or reimbursements, might also require us to restate our financials from a prior period, any of which could have a material and adverse effect on our business, operating results, and financial condition.

These statements were materially false and misleading when made because they presented as a mere hypothetical risk that Progenity "may" be required to refund third-party payors for improper billing, and failed to disclose that from 2019 until in or before early 2020 Progenity had improperly billed government payors for Preparent tests, and there was a high probability that Progenity had received and would have to refund a material amount of overpayments.

348. The Registration Statement misleadingly stated multiple times that:

On March 31, 2020, we reached an agreement on the monetary terms

with the DOJ and the State of New York (with the State of New York Attorney General representing or facilitating the interests of all States participating in the settlement, which we refer to collectively as the State AGs) with respect to relevant government health benefit programs to resolve all of the government's outstanding civil and criminal

investigations, including the investigations by the U.S. Attorney's Office for the Southern District of California and the U.S. Attorney's Office for the Southern District of New York, as well as the investigation by the State A.G. The terms of this agreement in principle.

investigation by the State AGs. The terms of this agreement in principle contemplate that we will enter into a civil settlement agreement providing that we will pay \$49.0 million in the aggregate . . . for a release of the civil claims and that we will enter into a non-prosecution

These statements were materially false and misleading when made because they failed to disclose that Progenity had improperly billed government payors for

agreement to resolve all criminal allegations.

Preparent tests from 2019 until in or before early 2020, in a pattern almost identical to Progenity's improper billing of government payors for Innatal tests, and that Progenity's improper Preparent billing would not be resolved by the \$49 million settlement.

5. Progenity's Misleading Statements And Omissions Would Be Highly Material To A Reasonable Investor

- 349. That Progenity had improperly billed government health care programs for Preparent tests from 2019 until in or before early 2020, and that there was a high probability that Progenity had received, and would have to refund, a material amount of overpayments from government payors for Preparent tests, were material facts.
- 350. These facts were material because Preparent tests were one of Progenity's two main products, which generated a substantial portion of Progenity's revenues.
- 351. The omission of Progenity's improper Preparent billing and likely receipt of a material amount of overpayments with respect to Preparent tests were additionally material because Progenity had recently disclosed almost identical improper billing and overpayments with respect to Innatal tests, which were Progenity's other main product. The Innatal improper billing conduct substantially contributed to Progenity's agreement to a \$49 million settlement in principle.
- 352. The existence of improper billing for both of Progenity's main products indicated the likelihood of pervasive billing and compliance failures at Progenity, which heightened the risks to its business including the risk of further adverse regulatory actions. These facts would be material to a reasonable investor.
- 353. Progenity's improper billing of government payors for Preparent tests was also material because this presented the strong likelihood that Progenity had similarly improperly billed commercial health insurance companies for Preparent

6

10 11

9

12 13

15

14

17

18

16

19 20

22 23

24 25

26 27

21

28

tests. Progenity generated approximately 97% of its revenues through billing government health care programs and commercial health insurance companies.

- 354. It would also have been material to a reasonable investor that Progenity had discontinued improper billing for Preparent tests in or before "early 2020," and that Progenity's Preparent revenue would be correspondingly reduced going forward.
- 355. Furthermore, the amount of overpayments received, as later determined by Progenity, was material. Progenity's improper Preparent billing of government payors resulted in its accrual of a \$10.3 million refund liability and revenue reduction in the period ended June 30, 2020. This represented 23.7% of Progenity's 2019 gross profits, and 30.5% of Progenity's gross profits for 2019 and the first quarter of 2020. This accrual represented 7.2% of Progenity's 2019 revenue, and 6.4% of Progenity's revenue for 2019 and the first quarter of 2020.
- 356. These facts were all the more material in light of Progenity's precarious financial position and pressing need for cash. Progenity could ill afford reductions in revenue and refund payments at this time, when it needed to continue raising new investor capital to survive.
- 357. Further confirming the materiality of these facts and the resultant effects on Progenity's stock price, in an October 23, 2020 research note, BTIG analyst Sung Ji Nam wrote that Progenity shares were trading "significantly below the June IPO price," identifying "the recent federal/state scrutiny on legacy billing practices (resolved) and related settlement accruals impacting revenues" as "potential drivers" of Progenity's share price decline.
- 358. Based on information existing and knowable to Defendants at the time of the IPO, there was a high probability that Progenity had received a material amount of overpayments from government payors for Preparent tests. Even if the information existing and knowable at the time of the IPO had indicated that Progenity had received a quantitatively small amount of overpayments (which was

2

3

4

5

6

7

8

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

26

27

28

not the case), the existence of such overpayments would nonetheless have been material to investors for the above stated reasons.

359. Securities and Exchange Commission guidance regarding materiality of financial statement items makes clear that, even as relates to quantifiable financial statement information, the materiality inquiry cannot be reduced to a numerical formula, and must take into consideration a wide range of "qualitative" factors. S.E.C. Staff Accounting Bulletin No. 99 (Aug. 12, 1999), 1999 WL 1123073 (filed herewith as **Exhibit 1**) (evaluation of materiality requires consideration of all relevant circumstances, and "[q]ualitative factors may cause misstatements of quantitatively small amounts to be material."). Such qualitative factors include "whether the misstatement masks a change in earnings or other trends," "whether the misstatement concerns a segment or other portion of the registrant's business that has been identified as playing a significant role in the registrant's operations or profitability," or "whether the misstatement affects the registrant's compliance with regulatory requirements." Id. Progenity's failure to disclose its improper Preparent billing and overpayments masked negative trends in revenue and ASP. These omissions concerned one of Progenity's two main products. And these omissions related to regulatory violations by Progenity. Qualitative factors such as these heightened the importance of the undisclosed information relating to Progenity's improper Preparent billing, which would have been material to a reasonable investor.

B. The Registration Statement Failed To Disclose That In February 2020 Progenity Discontinued The Illegal Marketing Practice On Which Its Business Depended

360. Nowhere did the Registration Statement disclose that Progenity had recently ended the illegal marketing practice on which the competitiveness of its business depended. However, this material fact existed at the time of the IPO, was necessary to make the statements in the Registration Statement not misleading, and was required to be included in the Registration Statement.

1. Omission of Disclosures Required By Regulation S-K

- 361. Progenity's February 2020 decision to end its key illegal marketing practice of waiving patient payment amounts made an investment in Progenity speculative or risky. Item 105 of SEC Regulation S-K required Progenity to include a discussion of this factor in the Registration Statement, and to explain how it affects Progenity or the stock offered in the IPO. Progenity failed to do so.
- 362. Progenity's February 2020 decision to end its key illegal marketing practice of waiving patient payment amounts made an investment in Progenity speculative or risky because, *inter alia*: (i) this illegal marketing practice had been Progenity's main selling point for its entire history through February 2020, (ii) Progenity's competitors offered higher quality tests at lower prices, (iii) Progenity's historical results reflected additional testing and revenue which Progenity would not have achieved absent its illegal marketing practice, (iv) the end of this illegal marketing practice had already resulted in Progenity losing certain customers and angering others, and (v) the end of this illegal marketing practice would make it more difficult for Progenity to obtain new customers in the future. Therefore, this change in policy presented a material risk that Progenity would be unable to compete effectively in its core molecular testing business that generated substantially all of Progenity's revenues, and that this business would experience declining test volumes and revenues.
- 363. Progenity's February 2020 decision to end its key illegal marketing practice of waiving patient payment amounts was a known trend, and gave rise to known uncertainties, that had and were reasonably likely to have a material unfavorable impact on net sales and revenues and income from continuing operations. Item 303 of SEC Regulation S-K required Progenity to describe this trend and these uncertainties in the Registration Statement. Progenity failed to do so.
- 364. That Progenity had previously waived patient payment amounts but would no longer do so was a known trend, and this decision gave rise to known

uncertainties relating to whether Progenity's molecular testing business could effectively compete without using its key illegal marketing practice. This trend and these uncertainties had already materially unfavorably affected sales, revenues, and income because they had already resulted in Progenity losing customers and reducing test prices. This trend and these uncertainties were reasonably likely to continue to materially unfavorably affect sales, revenues, and income for the same reasons, and because they had angered other Progenity customers whose business Progenity risked losing, and it would become more difficult for Progenity to attract new customers in the future.

2. False And Misleading Statements

365. The Registration Statement repeatedly stated "Since 2010, our molecular testing business has achieved consistent year-over-year test volume growth through our robust product portfolio and our strong commercial organization." These statements were materially false and misleading when made because the volume growth in Progenity's genetic testing business was driven primarily by Progenity's illegal marketing practices, which Progenity had ended in February 2020 shortly before the IPO.

366. The Registration Statement repeatedly stated "We believe our future success will be driven by continued capture of market share by our molecular testing business and new revenue streams resulting from our diversified product development pipeline, both within and beyond women's health." These statements were materially false and misleading when made because they omitted to disclose that Progenity had recently ended the illegal marketing practice that was key to the success of its molecular testing business, and so it was highly likely that Progenity would lose substantial market share to competitors in the molecular testing business who offered superior quality tests at lower prices.

367. The Registration Statement contained a misleading risk factor, which stated in relevant part:

25

26

27

28

1

We have implemented compliance policies and procedures intended to train and monitor our sales, billing, marketing and other personnel. Our efforts to implement appropriate monitoring of such personnel are ongoing and we have experienced situations in which employees may have failed to fully adhere to our policies and applicable laws in the past. There can be no assurance that we will not experience similar issues in the future. Failure by our sales, billing, marketing, or other personnel to follow our policies and comply with applicable laws may subject us to administrative, civil, and criminal actions, penalties, damages, fines, individual imprisonment, exclusion from participation in federal healthcare programs, refunding of payments received by us, and curtailment or cessation of our operations.

These statements were materially false and misleading when made because they indicated that Progenity's policies were in compliance with applicable laws, and that any violations of those laws resulted only from employees deviating from Progenity's policies, when in fact, for Progenity's entire history up until February 2020, Progenity's key marketing policies violated laws including the Anti-Kickback Statute, the False Claims Act, and the Civil Monetary Penalties Law.

368. The Registration Statement contained another misleading risk factor, which stated in relevant part:

If a third-party payor denies coverage, or if the patient has a large deductible or co-insurance amount, it may be difficult for us to collect from the patient, and we may not be successful in doing so. If we are in-network, we are often contractually prohibited from seeking payment from the patient. If we are out-of-network, we are often unable to collect the full amount of a patient's responsibility, despite our good faith efforts to collect. As a result, we cannot always collect the full amount due for our tests when third-party payors deny coverage, cover only a portion of the invoiced amount or the patient has a large deductible, which may cause payors to raise questions regarding our billing policies and patient collection practices. We believe that our billing policies and our patient collection practices are compliant with applicable laws; however, we have in the past received, and we may in the future receive, inquiries from third-party payors regarding our billing policies and collection practices in these circumstances.

These statements were materially false and misleading when made because they indicated that Progenity made good faith efforts to collect from patients and that its patient collection practices were compliant with applicable laws, when in fact, for Progenity's entire history up until February 2020, Progenity's policy was to waive the vast majority of patient payment amounts and this key marketing policy violated laws including the Anti-Kickback Statute, the False Claims Act, and the Civil Monetary Penalties Law.

369. The Registration statement stated that:

We compete in the molecular testing market based upon several factors, including (i) the strong performance and short turnaround time of our integrated tests, (ii) the quality of our sales and marketing efforts with physicians, (iii) the quality of our end-to-end customer service and support solutions, and (iv) the availability of reimbursement for our tests.

These statements were materially false and misleading when made because they failed to disclose that the primary factor on which Progenity had competed in the molecular testing market was its illegal sales practice of waiving patient payment amounts, which Progenity had discontinued in February 2020.

370. The Registration Statement stated that:

We generally seek to collect co-payments and deductibles directly from patients in cases where we have billed the payor. For these patients, we offer a range of flexible payment plans to assist in the payment of co-payments and deductibles . . . We are subject to applicable state and federal laws regarding who should be billed, how they should be billed, how business should be conducted, and how patient obligations regarding cost sharing should be handled.

These statements were materially false and misleading when made because up until February 2020 Progenity generally did not seek to collect patient payment amounts in cases where Progenity billed third-party payors, but rather routinely waived the vast majority of patient payment amounts, and these practices violated laws

including the Anti-Kickback Statute, the False Claims Act, and the Civil Monetary Penalties Law.

371. In describing competition in the molecular testing market, the Registration Statement stated:

We believe the principal competitive factors in our market include the following:

- test performance, including sensitivity, specificity, failure rates, and turnaround time, as demonstrated in clinical validation;
- value of product offerings, including pricing and impact on healthcare spending;
- coverage and reimbursement arrangements with third-party payors;
- convenience of testing;
- additional value-added services and digital healthcare tools;
- effectiveness of sales and marketing efforts;
- development and introduction of new, innovative products;
- key opinion leader support;
- brand awareness; and
- ease of integration with healthcare provider practices.

We believe that we compete favorably on the basis of the factors above, particularly in test performance, additional value-added services, and digital healthcare tools, value of product offerings, and effectiveness of sales and marketing efforts.

These statements were materially false and misleading when made because they failed to disclose that the primary factor on which Progenity had competed in the molecular testing market was its illegal sales practice of waiving patient payment amounts, which Progenity had discontinued in February 2020.

372. The Registration Statement stated, "While we believe we are not in violation of the AKS [Anti-Kickback Statute], we cannot provide assurance that our relationships with physicians, hospitals, and other customers will not be subject to scrutiny or will survive regulatory challenge." These statements were materially false and misleading when made because they omitted to disclose that Progenity had

recently ended the illegal marketing practice that was key to the success of its molecular testing business and which was in violation of the Anti-Kickback Statute.

373. The Registration Statement stated:

Finally, federal law prohibits any entity from offering or transferring to a Medicare or Medicaid beneficiary any remuneration that the entity knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services, including waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. Any violation of these prohibitions may result in civil monetary penalties up to \$20,000 for each wrongful act. Although we believe that our sales and marketing practices comply in all materials respects with all applicable federal and state laws and regulations, regulatory authorities may disagree.

These statements were materially false and misleading when made because they failed to disclose that up until February 2020 Progenity's key marketing policy centered on illegal waivers of copayments and deductible amounts designed to influence beneficiaries to select Progenity products.

3. Progenity's Misleading Statements And Omissions Would Be Highly Material To A Reasonable Investor

- 374. Progenity's February 2020 decision to end the illegal marketing practice on which the competitiveness of its business depended was a material fact.
- 375. Sales of Progenity's tests were critical to its success. As the Registration Statement disclosed, "[o]ther than revenues from our molecular testing business, we do not expect to generate revenues from other sources in the immediate future."
- 376. A reasonable investor would find highly material the fact that Progenity had lost its main selling point and competitive advantage for these tests by discontinuing its illegal marketing practices shortly before the IPO.
- 377. Progenity's decision to end the illegal marketing practice on which the competitiveness of its business depended was additionally material because it had

> 4 5

6

7 8 9

11

12

10

13 14

16

17

15

18

19 20

22

21

23 24

25 26 27

28

already resulted in lost customers and lost business, and would foreseeably make it more difficult for Progenity to acquire new customers in the future.

- 378. This information was also material because Progenity had been forced to reduce its test prices in order to attempt to compete without its key illegal marketing practice, which would foreseeably reduce Progenity's future revenues.
- 379. These facts were all the more material in light of Progenity's precarious financial position and pressing need for cash. Progenity could ill afford to lose customers and reduce test prices at this time, when it needed to continue raising new investor capital to survive.

The Registration Statement Failed To Disclose Progenity's Known C. **Trend Of Decreasing Test Volumes**

380. Nowhere did the Registration Statement fully disclose the decreasing trends in Progenity's test volumes. However, these material facts existed at the time of the IPO, were necessary to make the statements in the Registration Statement not misleading, and were required to be included in the Registration Statement but were omitted.

1. **Omission of Disclosures Required By Regulation S-K**

- Progenity's decreasing test volumes constituted a known trend that had and was reasonably likely to have a material unfavorable impact on net sales and revenues and income from continuing operations. Item 303 of SEC Regulation S-K required Progenity to describe this trend in the Registration Statement. Progenity failed to do so.
- 382. This known trend had already materially unfavorably affected sales, revenues, and income because as Progenity's test volumes decreased in April and May of 2020, Progenity's revenue (and related metrics) correspondingly decreased. Progenity recognized revenue "in the period in which our tests are performed and reported to customers." This trend was reasonably likely to continue to materially unfavorably affect sales, revenues, and income because the trend of decreasing test

volumes was caused by factors likely to continue into the future, including Progenity's decision to discontinue its key illegal marketing practice.

2. False And Misleading Statements

- 383. Progenity's failure to disclose the negative trends in its test volumes rendered materially false and misleading statements contained in the Registration Statement.
- 384. The Registration Statement misleadingly assured investors that "[s]ince 2010, our molecular testing business has achieved consistent year-over-year test volume growth through our robust product portfolio and our strong commercial organization." These statements were materially false and misleading when made because they indicated that Progenity's test volumes were still growing at the time of the IPO and that these test volumes exceeded those from the same time period in the previous year, and because they failed to disclose that Progenity's test volumes were sharply lower in April and May of 2020 and were likely to remain depressed due to known trends. These statements were additionally misleading for failing to disclose that Progenity's decision to end its key illegal marketing practice in February 2020 had, and would foreseeably have, the effect of depressing test volumes.
- 385. The Registration Statement also misleadingly emphasized in an eyecatching graphic, "CONSISTENT GROWTH," in a heading with large size, all capital letter font, and stated underneath that heading "~1.5 million tests performed." These statements were materially false and misleading when made because they indicated that Progenity's test volumes were still growing at the time of the IPO, and failed to disclose that Progenity's test volumes were sharply lower in April and May of 2020 and were likely to remain depressed due to known trends. These statements were additionally misleading for failing to disclose that Progenity's decision to end its key illegal marketing practice in February 2020 had, and would foreseeably have, the effect of depressing test volumes.

5

8 9

10 11

12

13

14 15

17

16

18 19

20 21

22 23

24 25

26

27

28

- 386. The Registration Statement misleadingly contained three different versions of the same disclosure relating to Progenity's test volume growth, each of which was misleading in its own way.
- 387. First, the Registration Statement outright falsely stated that "the growth rate of our test volume is accelerating":

Since our inception, we have accessioned approximately 1.5 million tests in the United States and the growth rate of our test volume is accelerating. The figure below shows our test volume growth from 2016 through 2019, as well as the first quarter of 2020, in which quarter we observed volumes largely consistent with the fourth quarter of 2019 despite the challenges presented by the COVID-19 pandemic. We believe our business is resilient and we have observed positive signs of recovery so far.

These statements were materially false and misleading when made because they indicated that Progenity's test volumes were growing and that this growth was accelerating at the time of the IPO, and because they failed to disclose that Progenity's test volumes were sharply lower in April and May of 2020 and were likely to remain depressed due to known trends. These statements were additionally misleading for failing to disclose that Progenity's decision to end its key illegal marketing practice in February 2020 had, and would foreseeably have, the effect of depressing test volumes.

388. Second, the Registration Statement admitted to "a slowdown in volume growth" rather than accelerating growth, but nonetheless claimed that Progenity was currently experiencing "volume growth," albeit at a slower rate than previously:

Since our inception, we have accessioned approximately 1.5 million tests in the United States and the growth rate of our test volume was accelerating over a multi-year period, including early 2020. However, we are currently observing a slowdown in volume growth as a result of the COVID-19 pandemic. The figure below shows our test volume growth from 2016 through 2019, as well as the first quarter of 2020, in which quarter we observed volumes largely consistent with the fourth quarter of 2019 despite the challenges presented by the COVID-19

pandemic. We believe our business is resilient and we have observed positive signs of recovery so far.

These statements were materially false and misleading when made because they indicated that Progenity's test volumes were still growing at the time of the IPO, and failed to disclose that Progenity's test volumes were sharply lower in April and May of 2020 and were likely to remain depressed due to known trends. These statements were additionally misleading for failing to disclose that Progenity's decision to end its key illegal marketing practice in February 2020 had, and would foreseeably have, the effect of depressing test volumes.

389. Third, the Registration Statement admitted to temporary volume declines beginning in March, while misleadingly emphasizing the resilience and recovery of Progenity's test volumes:

Beginning in March 2020, we began to observe significant declines in the volumes of our molecular tests as well as the pathology tests conducted by Avero Diagnostics due to the impact of the COVID-19 pandemic and work-from-home policies and other operational limitations mandated by federal, state and local governments as a result of the pandemic. However, we believe our business is resilient and we have observed positive signs of recovery so far. While we are implementing mitigation strategies to address these limitations, such as supporting patients and physicians virtually, there can be no assurance that the rate of decline in our testing volumes will not continue or accelerate in future periods. Our initial assessment of the impact of the COVID-19 pandemic is that our NIPT test volumes have proved more resilient than our carrier screening test volumes; however, the comparative impact may change over time.

These statements were materially false and misleading when made because they misleadingly emphasized resilience and recovery in Progenity's test volumes, and failed to disclose that Progenity's test volumes were sharply lower in April and May of 2020 and were likely to remain depressed due to known trends. These statements were additionally misleading for failing to disclose that Progenity's decision to end

3

4 5

7 8

6

9 10

11

13

14

12

15

16

17 18

19

20 21

22

23

24 25

26

27

28

its key illegal marketing practice in February 2020 had, and would foreseeably have, the effect of depressing test volumes.

390. Although the Registration Statement contained a risk factor relating to fluctuations in test volumes and other performance metrics, this risk factor disclosure was itself materially misleading:

Our operating results, including our revenues, gross profitability, and cash flows, have varied in the past and may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. . . . We also may face competitive pricing or reimbursement rate pressures, and we may not be able to maintain our sales volume and/or reimbursement rates in the future, which would adversely affect our business, operating results, and financial condition.

These statements were materially false and misleading when made because they presented as a mere hypothetical risk that Progenity "may" experience a decrease in test volumes, pricing or revenue, and failed to disclose that Progenity was at the time of the IPO experiencing significant declines for each of these metrics. These statements were additionally misleading for failing to disclose that Progenity's decision to end its key illegal marketing practice in February 2020 had, and would foreseeably have, the effect of depressing test volumes, pricing and revenue.

391. Based on these and other misleading omissions and disclosures in the Registration Statement, at the time of the IPO investors reasonably (though it would later turn out, incorrectly) understood that Progenity's test volumes were growing at the time of the IPO, and were positioned for continued growth in the near future.

Progenity's Misleading Statements And Omissions Would Be Highly Material To A Reasonable Investor **3.**

The negative trends in Progenity's test volumes were material facts. Progenity had identified test volumes to investors as a "key performance indicator" for its business, and Progenity was dependent on its Preparent and Innatal tests to generate a significant portion of the Company's revenues.

393. The negative trends in Progenity's test volumes at the time of the IPO were additionally material because they would have provided investors with critical information regarding Progenity's test volume performance subsequent to its decision to end its key illegal marketing practice in February 2020.

- 394. These facts were all the more material in light of Progenity's precarious financial position and pressing need for cash.
- 395. Further confirming the materiality of these facts and the resultant effects on Progenity's stock price, in an October 23, 2020 research note, BTIG analyst Sung Ji Nam wrote that Progenity shares were trading "significantly below the June IPO price," identifying "COVID-19-related headwinds on the core business" as a "potential driver[]" of the share price decline. The note went on to detail an "Upside Scenario" for Progenity's stock including "[f]aster than expected recovery in test volume growth adversely impacted by COVID-19," and a "Downside Scenario" with "[s]lower than expected recovery in test volume growth."

D. The Registration Statement Failed To Disclose Progenity's Known Trend Of Decreasing Average Selling Prices

396. Nowhere did the Registration Statement fully disclose the decreasing trends in Progenity's ASP. However, these material facts existed at the time of the IPO, were necessary to make the statements in the Registration Statement not misleading, and were required to be included in the Registration Statement but were omitted.

1. Omission of Disclosures Required By Regulation S-K

397. Progenity's decreasing ASP constituted a known trend that had and was reasonably likely to have a material unfavorable impact on net sales and revenues and income from continuing operations. Item 303 of SEC Regulation S-K required Progenity to describe this trend in the Registration Statement. Progenity failed to do so.

398. This known trend had already materially unfavorably affected sales, revenues, and income because as Progenity's ASP decreased throughout the second quarter of 2020, Progenity's revenue (and related metrics) correspondingly decreased. This trend was reasonably likely to continue to materially unfavorably affect sales, revenues, and income because the trend of decreasing ASP was caused by factors likely to continue into the future, including (i) Progenity's decision in or before early 2020 to stop improperly billing for Preparent tests, (ii) Progenity's February 2020 decision to cut test prices and likely need to further lower test prices in the future in order to compete without using Progenity's key illegal marketing practice, and (iii) the decline in Progenity's core test volumes (in response to ending the illegal sales practice) and rise in COVID test volumes which had far lower ASP.

2. False And Misleading Statements

- 399. Progenity's failure to disclose the negative trends in its ASP rendered materially false and misleading statements contained in the Registration Statement.
- 400. The Registration Statement stated that "[i]n response to the COVID-19 pandemic, the Avero Diagnostics laboratory is providing molecular testing for diagnosing COVID-19." However, these statements were materially false and misleading when made because they failed to disclose that Progenity's COVID tests had much lower ASP than its other tests, that Progenity's core test volumes were in decline in part due to its decision to discontinue its illegal marketing practice, and that Progenity's revenues and business would be harmed as a result of Progenity's core tests becoming a smaller portion of its product mix relative to COVID tests.
- 401. The Registration Statement stated that "effective January 1, 2019, the AMA approved the use of a CPT code for expanded carrier screening tests, which may similarly cause reimbursement for our Preparent expanded carrier screening tests to decline." These statements were materially false and misleading when made because they presented as a mere hypothetical risk that this CPT code "may" cause Preparent reimbursement to decline, while omitting to disclose that Progenity had

1
 2
 3

2 || 3 ||

5

6

4

7 8

10

9

12

11

13 14

16

15

17 18

19 20

2223

21

2425

2627

28

improperly billed government health care programs for Preparent tests, and that Progenity ceased this improper billing in or before early 2020, which caused the ASP for Preparent tests (and therefore Progenity's overall ASP) to decline.

3. Progenity's Misleading Statements And Omissions Would Be Highly Material To A Reasonable Investor

- 402. The negative trends in Progenity's ASP were material facts. Progenity told investors that ASPs were an important contributor to its gross margin, and that gross margin was an "important indicator of the operating performance of our business."
- 403. Progenity was dependent on its tests to generate substantially all of the Company's revenues, and test ASP was a key determinant of revenues from tests.
- 404. The negative trends in Progenity's ASP at the time of the IPO were additionally material because they would have provided investors with critical information regarding Progenity's ASP performance subsequent to its decision to end its key illegal marketing practice in February 2020.
- 405. These facts were all the more material in light of Progenity's precarious financial position and pressing need for cash.

E. The Registration Statement Failed To Disclose Progenity's Known Trend Of Decreasing Revenues

406. Nowhere did the Registration Statement fully disclose the decreasing trends in Progenity's revenue. However, these material facts existed at the time of the IPO and were required to be included in the Registration Statement but were omitted.

1. Omission of Disclosures Required By Regulation S-K

407. Progenity's decreasing revenues constituted a known trend that had and was reasonably likely to have a material unfavorable impact on net sales and revenues and income from continuing operations. Item 303 of SEC Regulation S-K required Progenity to describe this trend in the Registration Statement. Progenity failed to do so.

408. This known trend of decreasing revenues had already directly affected

revenues, and so also affected the related metrics of sales and income. This trend

was reasonably likely to continue to materially unfavorably affect sales, revenues,

and income because it was caused by factors likely to continue into the future,

including (i) Progenity's decision in or before early 2020 to stop improperly billing

for Preparent tests, (ii) Progenity's February 2020 decision to discontinue its key

illegal marketing practice, (iii) Progenity's resulting February 2020 decision to cut

test prices and likely need to further lower test prices in the future, and (iv) the

decline in Progenity's core test volumes (in response to ending the illegal sales

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

practice).

2. Progenity's Omissions Would Be Highly Material To A Reasonable Investor

409. The negative trends in Progenity's revenue were material facts. Revenues are a highly important financial metric to investors.

410. The negative trends in Progenity's revenues at the time of the IPO were additionally material because they would have provided investors with critical information regarding Progenity's revenue performance subsequent to its decision to end its key illegal marketing practice in February 2020.

- 411. These facts were all the more material to investors in light of Progenity's precarious financial position and pressing need for cash.
- 412. The materiality of these facts and its resultant effects on Progenity's stock price are confirmed by a November 10, 2020 research note by CGS-CIMB analysts Andrew Cooper and Lawrence Keusch, who wrote that Progenity's "\$25-26M of pre-announced revenue" for the third quarter was "disappointing," that "since its IPO" Progenity had "an unfortunate financial performance," and that "Progenity needs to show that the base business can perform as advertised."

VII. CLASS ACTION ALLEGATIONS

413. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of the "Class," consisting of all individuals and entities that purchased or acquired Progenity common stock pursuant and/or traceable to the Company's false and misleading IPO Registration Statement, seeking to pursue remedies under Sections 11 and 15 of the Securities Act. Excluded from the Class are Defendants, the officers and directors of the Company (at all relevant times), members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

- 414. The members of the Class are so numerous that joinder is impracticable. Progenity common stock is actively traded on the NASDAQ and millions of shares were sold in the IPO. While the exact number of Class members is unknown to plaintiffs at this time and can only be ascertained through discovery, plaintiffs believe there are hundreds, if not thousands, of members in the Class. Record owners and other Class members may be identified from records procured from or maintained by the Company or its transfer agent and may be notified of the pendency of this action using a form of notice similar to that customarily used in securities class actions.
- 415. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members, including:
 - (a) whether defendants violated the Securities Act, as alleged herein;
- (b) whether the Registration Statement misrepresented and/or omitted material information in violation of the Securities Act;
- (c) whether the Individual Defendants have a viable "due diligence" defense to the strict liability imposed by Sections 11 of the Securities Act;

- (d) whether Defendants can establish negative causation as a defense to or as a reduction of the strict liability otherwise imposed by Sections 11 of the Securities Act;
- (e) whether the Individual Defendants are control persons of Progenity for purposes of Section 15 of the Securities Act; and
- (f) whether and to what extent Class members have sustained damages, as well as the proper measure of damages.
- 416. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.
- 417. Plaintiffs will fairly and adequately protect the interests of Class members and have retained counsel competent and experienced in securities class actions.
- 418. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Because the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it exceedingly difficult, if not impossible and impracticable, for Class members to individually redress the wrongs alleged. There will be no difficulty in managing this action as a class action.

VIII. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR

419. Defendants are liable for any false and misleading forward-looking statements issued in connection with the IPO. The safe harbor provision of § 27A of the Securities Act, 15 U.S.C. § 77z-2(b)(2)(D), specifically excludes those statements "made in connection with an initial public offering," which includes all of the false and misleading statements made in connection with the IPO alleged herein.

IX. CLAIMS

FIRST CLAIM Violations of Section 11 of the Securities Act <u>Against All Defendants</u>

- 420. Plaintiffs repeat, incorporate, and reallege each and every allegation set forth above as if fully set forth herein.
- 421. This claim is brought under §11 of the Securities Act [15 U.S.C. §77k], on behalf of the Class, against all Defendants.
- 422. This claim does not allege, and does not intend to allege, fraud or fraudulent intent, which is not a required element of §11, and any implication of fraud or fraudulent intent is hereby expressly disclaimed. This claim is based solely on strict liability and negligence.
- 423. The Registration Statement for the IPO contained inaccurate and misleading statements of material fact, omitted facts necessary to render statements therein non-misleading, and omitted to state material facts required to be stated therein.
- 424. Progenity is the registrant for the IPO. Defendants were responsible for the contents and dissemination of the Registration Statement. The Individual Defendants signed or authorized the signing of the Registration Statement on their behalves. The Underwriter Defendants marketed and underwrote the IPO and sold the Progenity stock issued in the IPO to Plaintiffs and the Class.
- 425. As the issuer of the shares, Progenity is strictly liable to Plaintiffs and the Class for the Registration Statement's material misstatements and omissions. Signatories of the Registration Statement, and possibly other defendants, may also be strictly liable to Plaintiffs and the Class for such material misstatements and omissions. None of the Defendants made a reasonable investigation or possessed reasonable grounds to believe that the statements in the Registration Statement were complete, accurate or non-misleading.

- 426. Defendants had a duty to make a reasonable and diligent investigation of the truthfulness and accuracy of the statements contained in the Registration Statement. Each had a duty to ensure that such statements were true and accurate and that there were no omissions of material fact that would make the statements in the Registration Statement inaccurate. Because Defendants failed to make a reasonable and diligent investigation of the truthfulness and accuracy of the statements contained in the Registration Statement, the Registration Statement contained misrepresentations and/or omissions of material fact. As such, Defendants are strictly liable to Plaintiffs and the Class.
- 427. By reason of the conduct alleged herein, Defendants violated §11 of the Securities Act. Plaintiffs and the Class members purchased common stock pursuant and/or traceable to the Registration Statement and have sustained damages as a result. The value of the stock has declined substantially subsequent and due to Defendants' violations. At the time of their purchases, Plaintiffs and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein.
- 428. Because of the foregoing, Plaintiffs and the members of the Class are entitled to damages under Section 11 of the Securities Act.

SECOND CLAIM Violations of Section 15 of the Securities Act Against the Individual Defendants

- 429. Plaintiffs repeat, incorporate, and reallege each and every allegation set forth above as if fully set forth herein.
- 430. This claim is brought under §15 of the Securities Act [15 U.S.C. §770], against the Individual Defendants.
- 431. This claim does not allege, and does not intend to allege, fraud or fraudulent intent, which is not a required element of §15, and any implication of

- 3
- 4 5
- 6 7
- 8 9
- 10 11
- 12 13
- 14 15
- 16 17
- 18 19
- 20
- 21
- 22 23
- 24

- 26 27
- 28

- fraud or fraudulent intent is hereby expressly disclaimed. This claim is based solely on strict liability and negligence.
- 432. As detailed herein, each of Defendants committed primary violations of the Securities Act by committing conduct in contravention of §11 of the Securities Act.
- 433. By reason of the conduct alleged herein, the Individual Defendants violated §15 of the Securities Act, and Plaintiffs and the Class have suffered harm as a result.
- The Individual Defendants, due to their control, ownership, offices, directorship, and specific acts were, at the time of the wrongs alleged herein and as set forth herein, controlling persons of Progenity within the meaning of Section 15 of the Securities Act. The Individual Defendants had the power, influence, and knowledge—and exercised the same—to cause Progenity to engage in the acts described herein.
- 435. The Individual Defendants, at all relevant times, participated in the operation and management of Progenity, and conducted and participated, directly and indirectly, in the conduct of Progenity's business affairs. The Individual Defendants were under a duty to disseminate accurate and truthful information with respect to Progenity's financial condition and prospects. Because of their positions of control and authority as officers and directors of Progenity, the Individual Defendants were able to, and did, control the contents of the Registration Statement (including the IPO Prospectus), which contained materially untrue and/or misleading statements and/or omitted to state material facts required to be stated therein.
- 436. Because of their conduct, the Individual Defendants are liable under Section 15 of the Securities Act to Plaintiffs and the members of the Class who purchased or acquired shares pursuant to the Registration Statement. As a direct and proximate result of the Individual Defendants' wrongdoing, Plaintiffs and the other

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

members of the Class suffered damages in connection with their purchase and acquisition of shares pursuant to the Registration Statement. X. PRAYER FOR RELIEF WHEREFORE, Plaintiffs, individually and on behalf of the proposed Class, respectfully pray for judgment against Defendants as follows: Α. Determining that this action is a proper class action and certifying Plaintiffs as class representatives under Rule 23 of the Federal Rules of Civil Procedure; В. Awarding Plaintiffs and the Class compensatory damages against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, together with interest thereon; C. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including, but not limited to, attorneys' fees and costs incurred by consulting and testifying expert witnesses; D. Awarding extraordinary, equitable, and/or injunctive relief as permitted by law; and E. Granting such other, further and/or different relief as the Court deems just and proper. XI. **JURY TRIAL DEMANDED** Plaintiffs hereby demand a trial by jury.

DATED: February 3, 2023 **GLANCY PRONGAY & MURRAY LLP** By: s/ Garth A. Spencer ROBERT V. PRONGAY (#270796) rprongay@glancylaw.com **CASEY E. SADLER (#274241)** csadler@glancylaw.com GARTH A. SPENCER (#335424) gspencer@glancylaw.com 1925 Century Park East, Suite 2100 Los Angeles, California 90067 Telephone: (310) 201-9150 Facsimile: (310) 201-9160 Attorneys for Lead Plaintiffs

PROOF OF SERVICE BY ELECTRONIC POSTING

I, the undersigned say:

I am not a party to the above case and am over eighteen years old. On February 3, 2023, I served true and correct copies of the foregoing document, by posting the document electronically to the ECF website of the United States District Court for the Southern District of California, for receipt electronically by the parties listed on the Court's Service List.

I affirm under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on February 3, 2023, at Wilmington, North Carolina.

s/ Garth A. Spencer
Garth A. Spencer