UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2020

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-39334

Progenity, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-3950390**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4330 La Jolla Village Drive, Suite 200, San Diego, CA	**92122**
(Address of principal executive offices)	**(Zip Code)**

(855) 293-2639
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	PROG	The Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Small reporting company	☐
Emerging growth company	☒		

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

As of October 31, 2020, the registrant had 46,976,277 shares of common stock, par value $0.001 per share, outstanding.

Progenity, Inc.

INDEX

TRADEMARKS AND CERTAIN TERMS

In this Quarterly Report on Form 10-Q, "Progenity," "we," "us" and "our" refer to Progenity, Inc., and our wholly-owned subsidiaries on a consolidated basis, unless the context otherwise provides.

Progenity® is a registered service mark of Progenity. Any other brand names or trademarks appearing in this Quarterly Report on Form 10-Q are the property of their respective holders.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

PROGENITY, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 60,013	$ 33,042
Accounts receivable, net	13,425	22,189
Inventory	10,383	10,937
Income tax receivable	—	634
Prepaid expenses and other current assets	9,216	7,846
Total current assets	93,037	74,648
Property and equipment, net	16,088	15,891
Other assets	198	198
Goodwill	6,219	6,219
Other intangible assets, net	4,075	4,771
Total assets	$ 119,617	$ 101,727
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 15,666	$ 15,754
Accrued expenses and other current liabilities	71,013	83,615
Current portion of mortgages payable	268	241
Current portion of capital lease obligations	399	727
Total current liabilities	87,346	100,337
Capital lease obligations, net of current portion	97	358
Mortgages payable, net of current portion	2,864	3,081
Note payable to related party, net of unamortized discount of $5,358 and $6,034 as of September 30, 2020 and December 31, 2019, respectively	69,642	68,966
Other long-term liabilities	20,088	12,859
Total liabilities	$ 180,037	$ 185,601
Commitments and contingencies		
Stockholders' deficit:		
Common stock – $0.001 par value. 350,000,000 and 300,000,000 shares authorized as of September 30, 2020 and December 31, 2019, respectively; 50,450,849 and 8,451,415 shares issued as of September 30, 2020 and December 31, 2019, respectively; 46,976,277 and 4,976,843 shares outstanding as of September 30, 2020 and December 31, 2019, respectively	50	9
Series A Preferred Stock – $0.001 par value. 4,120,000 shares authorized, issued and outstanding as of December 31, 2019; no shares authorized, issued and outstanding as of September 30, 2020	—	4
Series B Preferred Stock – $0.001 par value. 126,035,000 shares authorized as of December 31, 2019; 101,867,405 shares issued and outstanding as of December 31, 2019, respectively. No shares authorized, issued and outstanding as of September 30, 2020	—	102
Additional paid-in capital	424,047	283,260
Accumulated deficit	(465,746)	(348,478)
Treasury stock – at cost; 3,474,572 shares of common stock as of September 30, 2020 and December 31, 2019	(18,771)	(18,771)
Total stockholders' deficit	(60,420)	(83,874)
Total liabilities and stockholders' deficit	$ 119,617	$ 101,727

See accompanying notes to unaudited condensed consolidated financial statements.

PROGENITY, INC.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues	$ 25,943	$ 18,772	$ 60,037	$ 123,509
Cost of sales	23,601	24,997	72,006	75,531
Gross profit (loss)	2,342	(6,225)	(11,969)	47,978
Operating expenses:				
Research and development	13,043	17,080	36,517	48,791
Selling and marketing	13,244	15,263	40,416	45,510
General and administrative	20,626	16,273	54,915	44,823
Total operating expenses	46,913	48,616	131,848	139,124
Loss from operations	(44,571)	(54,841)	(143,817)	(91,146)
Interest expense	(2,476)	(2,321)	(7,285)	(6,872)
Interest and other income (expense), net	(18)	29	(3,594)	457
Loss before income taxes	(47,065)	(57,133)	(154,696)	(97,561)
Income tax benefit	—	—	(37,696)	—
Net loss	(47,065)	(57,133)	(117,000)	(97,561)
Dividend paid to preferred stockholders	—	—	(268)	(3,652)
Stock dividend on exchange of Series A-1 to Series B Preferred Stock	—	(27,637)	—	(27,637)
Stock dividend on Series B Preferred Stock	—	(13,137)	—	(13,137)
Net loss attributable to common stockholders	$ (47,065)	$ (97,907)	$ (117,268)	$ (141,987)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.01)	$ (19.85)	$ (5.80)	$ (29.27)
Weighted average number of shares outstanding used in calculating net loss per share attributable to common stockholders, basic and diluted	46,632,043	4,931,204	20,201,325	4,851,603

See accompanying notes to unaudited condensed consolidated financial statements.

PROGENITY, INC.
Condensed Consolidated Statements of Stockholders' Deficit
(In thousands, except share data)
(Unaudited)

	Common Stock		Series A and A-1 Preferred Stock		Series B Preferred Stock		Additional Paid-In	Accumulated	Treasury Stock		Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Shares	Amount	Deficit
Balance at December 31, 2019	**8,451,415**	**$ 9**	**4,120,000**	**$ 4**	**101,867,405**	**$ 102**	**$ 283,260**	**$ (348,478)**	**(3,474,572)**	**$ (18,771)**	**$ (83,874)**
Issuance of common stock upon exercise of options	56,729	—	—	—	—	—	103	—	—	—	103
Issuance of Series B Preferred Stock, net of issuance cost	—	—	—	—	6,033,796	6	14,066	—	—	—	14,072
Stock-based compensation expense	—	—	—	—	—	—	2,057	—	—	—	2,057
Net loss	—	—	—	—	—	—	—	(17,152)	—	—	(17,152)
Balance at March 31, 2020	**8,508,144**	**$ 9**	**4,120,000**	**$ 4**	**107,901,201**	**$ 108**	**$ 299,486**	**$ (365,630)**	**(3,474,572)**	**$ (18,771)**	**$ (84,794)**
Issuance of common stock upon exercise of options	20,880	—	—	—	—	—	45	—	—	—	45
Issuance of common stock upon initial public offering, net	6,666,667	7	—	—	—	—	88,658	—	—	—	88,665
Issuance of Series B Preferred Stock, net	—	—	—	—	4,444,444	4	9,929	—	—	—	9,933
Automatic conversion of preferred stock	33,443,562	33	(4,120,000)	(4)	(112,345,645)	(112)	83	—	—	—	—
Issuance of common stock upon conversion of debt	1,250,000	1	—	—	—	—	18,749	—	—	—	18,750
Issuance of Stock Purchase Warrant	—	—	—	—	—	—	268	(268)	—	—	—
Issuance of common stock upon vesting of restricted stock unit awards	133,353	—	—	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	3,024	—	—	—	3,024
Net loss	—	—	—	—	—	—	—	(52,783)	—	—	(52,783)
Balance at June 30, 2020	**50,022,606**	**$ 50**	**—**	**$ —**	**—**	**$ —**	**$ 420,242**	**$ (418,681)**	**(3,474,572)**	**$ (18,771)**	**$ (17,160)**
Issuance of common stock upon exercise of options	428,243	—	—	—	—	—	431	—	—	—	431
Stock-based compensation expense	—	—	—	—	—	—	3,374	—	—	—	3,374
Net loss	—	—	—	—	—	—	—	(47,065)	—	—	(47,065)
Balance at September 30, 2020	**50,450,849**	**$ 50**	**—**	**$ —**	**—**	**$ —**	**$ 424,047**	**$ (465,746)**	**(3,474,572)**	**$ (18,771)**	**$ (60,420)**

PROGENITY, INC.
Condensed Consolidated Statements of Stockholders' Deficit
(In thousands, except share data)
(Unaudited)

	Common Stock		Series A and A-1 Preferred Stock		Series B Preferred Stock		Additional Paid-In	Accumulated	Treasury Stock		Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Shares	Amount	Deficit
Balance at December 31, 2018	**8,112,581**	**$ 8**	**5,620,000**	**$ 6**	**14,164,306**	**$ 14**	**$ 124,244**	**$ (142,469)**	**(3,474,572)**	**$ (18,771)**	**$ (36,968)**
Adoption of accounting standard	—	—	—	—	—	—	—	23,666	—	—	23,666
Issuance of common stock upon exercise of options	268,549	—	—	—	—	—	322	—	—	—	322
Stock-based compensation expense	—	—	—	—	—	—	555	—	—	—	555
Dividends paid	—	—	—	—	—	—	—	(4,500)	—	—	(4,500)
Net loss	—	—	—	—	—	—	—	(24,019)	—	—	(24,019)
Balance at March 31, 2019	**8,381,130**	**$ 8**	**5,620,000**	**$ 6**	**14,164,306**	**$ 14**	**$ 125,121**	**$ (147,322)**	**(3,474,572)**	**$ (18,771)**	**$ (40,944)**
Issuance of common stock upon exercise of options	15,936	—	—	—	—	—	120	—	—	—	120
Stock-based compensation expense	—	—	—	—	—	—	597	—	—	—	597
Net loss	—	—	—	—	—	—	—	(16,409)	—	—	(16,409)
Balance at June 30, 2019	**8,397,066**	**$ 8**	**5,620,000**	**$ 6**	**14,164,306**	**$ 14**	**$ 125,838**	**$ (163,731)**	**(3,474,572)**	**$ (18,771)**	**$ (56,636)**
Issuance of common stock upon exercise of options	50,860	—	—	—	—	—	88	—	—	—	88
Exchange of Series A-1 Preferred Stock to Series B Preferred Stock of restricted stock unit awards	—	—	(1,500,000)	(2)	35,664,241	36	27,603	(27,637)	—	—	—
Issuance of Series B Preferred Stock, net of issuance cost	—	—	—	—	9,090,910	9	23,974	—	—	—	23,983
Stock dividend on Series B Preferred Stock	—	—	—	—	4,017,512	4	13,133	(13,137)	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	631	—	—	—	631
Net loss	—	—	—	—	—	—	—	(57,133)	—	—	(57,133)
Balance at September 30, 2019	**8,447,926**	**$ 8**	**4,120,000**	**$ 4**	**62,936,969**	**$ 63**	**$ 191,267**	**$ (261,638)**	**(3,474,572)**	**$ (18,771)**	**$ (89,067)**

See accompanying notes to unaudited condensed consolidated financial statements.

PROGENITY, INC.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2020	2019
Operating Activities:		
Net loss	$ (117,000)	$ (97,561)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash revenue reserve	22,848	19,935
Depreciation and amortization	3,762	3,480
Stock-based compensation expense	8,455	1,783
Loss on extinguishment of convertible note	3,401	—
Amortization of debt discount	1,902	1,229
Inventory write-down	80	120
Loss on disposal of property and equipment	67	—
Change in fair value of derivative liability	126	—
Changes in operating assets and liabilities:		
Accounts receivable, net	8,765	695
Inventory	475	(3,675)
Income tax receivable	635	6,173
Prepaid expenses and other current assets	(2,420)	(2,588)
Other assets	—	(62)
Accounts payables	1,441	10,729
Accrued expenses and other liabilities	(29,807)	(537)
Other long-term liabilities	1,583	—
Net cash used in operating activities	(95,687)	(60,279)
Investing Activities:		
Purchases of property and equipment	(3,109)	(2,917)
Purchases of short-term investments	—	(11,214)
Proceeds from sale of short-term investments	—	31,414
Proceeds from sale of equity method investment	—	50
Net cash (used in) provided by investing activities	(3,109)	17,333
Financing Activities:		
Proceeds from issuance of common stock, net	90,344	530
Proceeds from issuance of Series B Preferred Stock, net	21,307	24,967
Proceeds from issuance of convertible note, net	14,895	—
Dividends paid	—	(4,500)
Principal payments on mortgages payable	(190)	(172)
Principal payments on capital lease obligations	(589)	(834)
Net cash provided by financing activities	125,767	19,991
Net increase (decrease) in cash and cash equivalents	26,971	(22,955)
Cash and cash equivalents at beginning of period	33,042	49,005
Cash and cash equivalents at end of period	$ 60,013	$ 26,050

See accompanying notes to unaudited condensed consolidated financial statements.

PROGENITY, INC.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2020	**2019**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,765	$ 5,642
Cash paid for income taxes	58	6
Supplemental schedule of non-cash investing and financing activities:		
Conversion of convertible note	$ 18,750	$ —
Issuance of preferred stock in settlement of interest payable	2,698	—
Equity offering costs incurred but not paid	1,101	984
Issuance of stock options in settlement of accrued bonuses	754	—
Purchases of property and equipment in accounts payable	220	240
Capital lease obligations	—	229
Stock dividend on exchange of Series A-1 to Series B Preferred Stock	—	27,367
Stock dividend on Series B Preferred Stock	—	13,137

See accompanying notes to unaudited condensed consolidated financial statements.

1. Organization and Description of Business

Progenity, Inc. (the "Company" or "Progenity"), a Delaware corporation, commenced operations in 2010 with its corporate office located in San Diego, California. Progenity's primary operations include a licensed Clinical License Improvement Amendment and College of American Pathologists certified laboratory located in Michigan specializing in the molecular testing markets serving women's health providers in the obstetric, gynecological, fertility, and maternal fetal medicine specialty areas in the United States.

The Company has expertise in the national reference laboratory, clinical genetics, laboratory molecular testing, and biotechnology markets. Distribution is managed by a dedicated women's health physician sales force and a field operations team who support all logistical functions in receiving clinical samples to the laboratory for analysis. The Company's core business is focused on the prenatal carrier screening and noninvasive prenatal test market, targeting preconception planning, and routine pregnancy management for genetic disease risk assessment. Through its affiliation with Mattison Pathology, LLP ("Mattison"), a Texas limited liability partnership doing business as Avero Diagnostics ("Avero"), located in Lubbock and Dallas, Texas, the Company's operations have expanded to provide anatomic and molecular pathology testing products in the United States.

On June 10, 2020, the Company amended its certificate of incorporation to reflect a one-for-6.178 reverse stock split of the Company's common stock. The par value and the number of authorized shares of common stock were not adjusted as a result of the reverse stock split. All issued and outstanding shares of common stock and related per share amounts contained in the accompanying condensed consolidated financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented. The reverse stock split resulted in an adjustment to the respective Series A and B preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion.

On June 23, 2020, the Company completed the initial public offering of its common stock (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 Company received approximately $88.7 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by the Company. In connection with the IPO, on June 23, 2020, all outstanding Series A and B preferred stock and the outstanding convertible promissory note converted into shares of common stock and the outstanding warrant to purchase shares of convertible preferred stock became exercisable for shares of common stock.

Liquidity

As of September 30, 2020, the Company had cash and cash equivalents of $60.0 million and an accumulated deficit of $465.7 million. For the nine months ended September 30, 2020, the Company reported a net loss of $117.0 million and cash used in operating activities of $95.7 million. The Company's primary sources of capital have historically been the sale of common stock, private placements of preferred stock and incurrence of debt. As of September 30, 2020, the Company had a $75.0 million term loan outstanding with a private equity firm (see Note 7), and mortgages outstanding of $3.1 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 12 months following the issuance date of the condensed consolidated financial statements for the three and nine months ended September 30, 2020. The Company's ability to continue as a going concern is dependent upon its ability to raise additional funding. Management believes that the Company's liquidity position provides sufficient runway to achieve critical research and development pipeline milestones and show continued progress in the molecular testing activities into mid-2021. Management intends to raise additional capital through equity offerings and/or debt financings, or from other potential sources of liquidity, which may include new collaborations, licensing or other commercial agreements for one or more of the Company's research programs or patent portfolios. Adequate funding, if needed, may not be available to the Company on acceptable terms, or at all. The Company's ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If the Company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce, or eliminate its research and development programs or other operations. If any of these events occur, the Company's ability to achieve its operational goals would be adversely affected.

Uncertainties Related to the COVID-19 Pandemic

The ongoing COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and created significant volatility and disruption of financial markets. The Company has been materially and negatively affected by the COVID-19 pandemic; however, the extent of the impact of the COVID-19 pandemic on the Company's operational and financial performance, including its ability to execute its business strategies and initiatives in the expected time frame, will depend on future developments, including the duration and spread of the pandemic and related restrictions on travel and transports, all of which are uncertain and cannot be predicted. The Company could be further negatively affected by the widespread outbreak of an illness or any other communicable disease, or any other public health crisis that results in economic and trade disruptions, including the disruption of global supply chains. An extended period of global supply chain and economic disruption could materially affect the Company's business, results of operations, access to sources of liquidity and financial condition.

The estimates used for, but not limited to, determining the amount to be collected for accounts receivable, fair value of long-lived assets, and fair value of goodwill could be impacted by the pandemic. While the full impact of COVID-19 is unknown at this time, the Company has made appropriate estimates based on the facts and circumstances available as of the reporting date. These estimates may change as new events occur and additional information is obtained.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. These financial statements should be read in conjunction with the Company's audited financial statements included in the Company's final prospectus filed with the Securities and Exchange Commission on June 22, 2020. The condensed consolidated financial statements include the accounts of Progenity, Inc., its wholly owned subsidiaries, and an affiliated professional partnership with Avero with respect to which the Company currently has a specific management arrangement. The Company has determined that Avero is a variable interest entity and that the Company is the primary beneficiary resulting in the consolidation of Avero as required by the accounting guidance for consolidation (see Note 3). All significant intercompany balances and transactions have been eliminated in consolidation.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of September 30, 2020, the statements of operations and the statements of stockholders' deficit for the three and nine months ended September 30, 2020 and 2019 and the statements of cash flows for the nine months ended September 30, 2020 and 2019 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, that are necessary for the fair statement of the Company's financial position as of September 30, 2020, and the results of its operations and its cash flows for the three and nine months ended September 30, 2020 and 2019. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2020 and 2019 are also unaudited. The results for the three and nine months ended September 30, 2020 are not necessarily indicative of results to be expected for the year ending December 31, 2020, any other interim periods, or any future year or period, particularly in light of the COVID-19 pandemic and its impact on domestic and global economies. The balance sheet as of December 31, 2019 included herein was derived from the audited financial statements as of that date. Certain disclosures have been condensed or omitted from the interim financial statements.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant items subject to such estimates include the estimate of variable consideration in connection with the recognition of revenue, the valuation of Series B preferred stock, the valuation of stock options, the valuation of goodwill and intangible assets, accrual for reimbursement claims and settlements, assessing future tax exposure and the realization of deferred tax assets, the useful lives and the recoverability of property and equipment. The Company bases these estimates on historical and anticipated results, trends, and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities and recorded revenues and expenses that are not readily apparent from other sources. Actual results could differ from those estimates and assumptions.

Operating Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker or decision-making group in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business as one operating segment. All revenues are attributable to U.S.-based operations and all assets are held in the United States.

Revenue Recognition

Revenue is recognized in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). In accordance with ASC 606, the Company follows a five-step process to recognize revenues: 1) identify the contract with the customer, 2) identify the performance obligations, 3) determine the transaction price, 4) allocate the transaction price to the performance obligations and 5) recognize revenues when the performance obligations are satisfied.

Revenue is primarily derived from providing molecular testing products, which are reimbursed through arrangements with third-party payors, laboratory distribution partners, and amounts from individual patients. Third-party payors include commercial payors, such as health insurance companies, health maintenance organizations and government health benefit programs, such as Medicare and Medicaid. The Company's contracts generally contain a single performance obligation, which is the delivery of the test results, and the Company satisfies its performance obligation at a point in time upon the delivery of the results, which then triggers the billing for the product. The amount of revenue recognized reflects the amount of consideration the Company expects to be entitled to (the "transaction price") and considers the effects of variable consideration. Revenue is recognized when control of the promised product is transferred to customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those products.

The Company applies the following practical expedients and exemptions:

- Incremental costs incurred to obtain a contract are expensed as incurred because the related amortization period would have been one year or less. The costs are included in selling and marketing expenses.
- No adjustments to amounts of promised consideration are made for the effects of a significant financing component because the Company expects, at contract inception, that the period between the transfer of a promised good or service and customer payment for that good or service will be one year or less.

Payor Concentration

The Company relies upon reimbursements from third-party government payors and private-payor insurance companies to collect accounts receivable. The Company's significant third-party payors and their related accounts receivable balances and revenues as a percentage of total accounts receivable balances and revenues are as follows:

	Percentage of Accounts Receivable	
	September 30, 2020	December 31, 2019
Blue Shield of Texas	21.4%	0.1%
Government Health Benefits Programs	20.5%	16.7%
Aetna	6.4%	6.0%
United Healthcare	5.7%	31.5%

	Percentage of Revenue			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Blue Shield of Texas	26.5%	47.2%	35.4%	19.4%
Government Health Benefits Programs(1)	21.9%	(29.4)%	(5.6)%	9.3%
Aetna	7.9%	10.7%	10.7%	8.1%
United Healthcare	5.5%	28.8%	4.9%	30.9%

(1) The negative amounts presented in the percentage of revenues include accruals for reimbursement claims and settlements included in the estimates of variable consideration recorded during the three and nine months ended September 30, 2020 and 2019. Revenue recognized consider the effects of variable consideration, and include adjustments for estimates of disallowed cases, discounts, and refunds. The variable consideration includes reductions in revenues for the accrual for reimbursement claims and settlements, as described in Notes 4 and 9.

Accounts Receivable

Accounts receivable is recorded at the transaction price and considers the effects of variable consideration. The total consideration the Company expects to collect is an estimate and may be fixed or variable. Variable consideration includes reimbursement from third-party payors, laboratory distribution partners, and amounts from individual patients, and is adjusted for disallowed cases, discounts, and refunds using the expected value approach. The Company monitors these estimates at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required.

Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities. The Company considers all series of preferred stock to be participating securities as the holders of such stock are entitled to receive non-cumulative dividends on an as-converted basis in the event that a dividend is paid on common stock. Under the two-class method, the net loss attributable to common stockholders is not allocated to the preferred stock as the holders of preferred stock do not have a contractual obligation to share in the Company's losses. Under the two-class method, net income is attributed to common stockholders and participating securities based on their participation rights. Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Net loss attributable to common stockholders is calculated by adjusting net loss with dividends to preferred stockholders, if any. As the Company has reported net losses for all periods presented, all potentially dilutive securities are antidilutive and, accordingly, basic net loss per share equals diluted net loss per share.

Comprehensive Loss

The Company did not have any other comprehensive income or loss for any of the periods presented, and therefore comprehensive loss was the same as the Company's net loss.

Recent Accounting Pronouncements Adopted

In June 2018, the FASB issued Accounting Standards Update ("ASU") No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*. The standard simplifies the accounting for share-based payments granted to nonemployees for goods and services and aligns most of the guidance on such payments to the nonemployees with the requirements for share-based payments granted to employees. The Company adopted the new accounting standard in fiscal year 2020 using the retrospective transition method for each period presented, which did not have a material impact on the condensed consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* which removes certain exceptions to the general principles of Topic 740, *Accounting for Income Taxes* ("ASC 740") and is intended to improve consistency and simplify GAAP in several other areas of ASC 740 by clarifying and amending existing guidance. The Company early adopted ASU No. 2019-12 for the quarter ended March 31, 2020, which did not have a material impact on the condensed consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which supersedes FASB ASC Topic 840, *Leases (Topic 840)*, and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method for finance leases or on a straight-line basis over the term of the lease for operating leases. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases. In November 2019, the FASB issued ASU No. 2019-10, *Leases (Topic 842): Effective Dates*. The new standard is effective for the Company for annual reporting periods beginning after December 15, 2020. The Company plans to adopt the new lease standard effective January 1, 2021, using the effective date method with the cumulative effect of the change reflected in retained earnings as of January 1, 2021, if any. The Company plans to elect the package of practical expedients available in the new lease standard, allowing it not to reassess: (a) whether expired or existing contracts contain leases under the new definition of a lease; (b) lease classification for expired or existing leases; and (c) whether previously capitalized initial direct costs would qualify for capitalization under the new lease standard.

The Company continues to monitor FASB activity to assess certain interpretative issues and the associated implementation of the new standard and is in the process of reviewing its lease arrangements, including property, equipment and vehicle leases. The Company is not yet able to estimate the anticipated impact to its consolidated financial statements from the implementation of the new standard as it continues to interpret the principles of the new standard.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses*, which requires the measurement of expected credit losses for financial instruments carried at amortized cost, such as accounts receivable, held at the reporting date based on historical experience, current conditions and reasonable forecasts. The main objective of this standard is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financing Instruments–Credit Losses*, which included an amendment of the effective date. The standard is effective for the Company for annual reporting periods beginning after December 15, 2022. The Company does not expect the adoption of this standard to have a significant impact on its consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment.* The new standard will simplify the measurement of goodwill by eliminating step two of the two-step impairment test. Step two measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. The new guidance requires an entity to compare the fair value of a reporting unit with its carrying amount and recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value. Additionally, an entity should consider income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. The standard is effective for the Company for annual reporting periods beginning after December 15, 2021. The Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

3. Variable Interest Entity

In June 2015, the Company entered into a series of agreements with Avero. The Company entered into a purchase agreement to acquire certain assets from Mattison used in the operations of Avero. The purchase agreement was accounted for under the acquisition method in accordance with the provisions of ASC Topic 805, *Business Combinations.* The Company entered into a nominee agreement which provides it with the right, but not the obligation, to purchase, or to designate a person(s) to purchase, the stock of Avero at any time for a nominal amount.

The Company also entered into a management services arrangement that authorizes the Company to perform the management services in the manner that it deems reasonably appropriate to meet the day-to-day business needs of Avero. The Company's management services include funding ongoing operational needs, directing activities related to contract negotiation, billing, human resources, and legal and administrative matters and processes, among others. In exchange for the management services provided, the Company is entitled to receive an annual management fee equal to the amount of the net operating income of Avero. The term of the agreement with Avero is 10 years, subject to automatic renewals. The agreement can be terminated by either party with a 90-day notice before the end of the term.

Through the management services arrangement with Avero, the Company has (1) the power to direct the activities of Avero that most significantly impact its economic performance, and (2) the obligation to absorb losses of Avero or the right to receive benefits

from Avero that could potentially be significant to Avero. Based on these determinations, the Company has determined that Avero is a variable interest entity and that the Company is the primary beneficiary. The Company does not own any equity interest in Avero; however, as these agreements provide the Company the controlling financial interest in Avero, the Company consolidates Avero's balances and activities within its consolidated financial statements.

In December 2018, Avero entered into a settlement agreement with Cigna (the "Cigna settlement obligation") whereby Avero agreed to pay an aggregate amount of $12.0 million with an upfront payment of $6.0 million and the remaining $6.0 million to be paid over 24 months, beginning in February 2019. The Company guaranteed the $12.0 million Cigna settlement obligation. The Company provided financial support to Avero in the amount of $0.8 million and $2.3 million during the three and nine months ended September 30, 2020, respectively, and $0.8 million and $2.3 million during the three and nine months ended September 30, 2019, respectively, related to the Cigna settlement obligation (see Note 9). The Company did not provide any additional financial support to Avero during the three and nine months ended September 30, 2020 and 2019, other than the Cigna settlement obligation and agreed upon management services.

The following table presents the assets and liabilities of Avero that are included in the Company's condensed consolidated balance sheets as of September 30, 2020 and December 31, 2019, in thousands. The creditors of Avero have no recourse to the general credit of the Company, with the exception of $1.8 million and $1.9 million in mortgage payable guaranteed by the Company as of September 30, 2020 and December 31, 2019, respectively (see Note 8), and $0.8 million and $3.0 million in remaining Cigna settlement obligation guaranteed by the Company as of September 30, 2020 and December 31, 2019, respectively. The assets and liabilities exclude intercompany balances that eliminate in consolidation:

	September 30, 2020	December 31, 2019
Assets of Avero that can only be used to settle obligations of Avero		
Cash and cash equivalents	$ 1,038	$ 1,837
Accounts receivable, net	4,733	4,269
Inventory	2,143	2,572
Prepaid expenses and other current assets	1,093	1,181
Property and equipment, net	5,486	5,586
Other assets	30	30
Goodwill	6,219	6,219
Other intangible assets, net	4,075	4,771
Total assets of Avero that can only be used to settle obligations of Avero	$ 24,817	$ 26,465
Liabilities of Avero		
Accounts payable	$ 3,166	$ 2,450
Accrued expenses and other accrued liabilities	3,609	5,630
Current portion of capital lease obligations	49	59
Current portion of mortgage payable	197	173
Capital lease obligations, net of current portion	16	50
Mortgage payable, net of current portion	1,570	1,733
Other long-term liabilities	571	467
Total liabilities of Avero	$ 9,178	$ 10,562

4. Revenues

Revenue is derived from contracts with healthcare insurers, government payors, laboratory partners and patients in connection with sales of prenatal genetic, anatomic or molecular pathology tests. The Company enters into contracts with healthcare insurers related to tests provided to patients who have health insurance coverage. Insurance carriers are considered third-party payors on behalf of the patients, and the patients who receive genetic, anatomic or molecular pathology test products are considered the customers. Tests may be billed to insurance carriers, patients, or a combination of insurance carriers and patients. The Company also sells tests to laboratory partners, which are also considered to be customers. The Company's test volumes began to decrease in the second half of March 2020 as a result of the COVID-19 pandemic spreading in the United States and resulting limitations and reordering of priorities across the U.S. healthcare system. The Company expects test volumes to continue to be adversely affected by COVID-19 and cannot predict when volumes will return to normal.

In accordance with ASC 606, a performance obligation represents a promise in a contract to transfer a distinct good or service to a customer and the consideration should be allocated to each distinct performance obligation and recognized as revenue when or as the

performance obligation is satisfied. The Company has evaluated its contracts with healthcare insurers, government payors, laboratory partners and patients and identified a single performance obligation in those contracts, the delivery of a test result. The Company satisfies its performance obligation at a point in time upon the delivery of the test result, at which point the Company can bill for its products. The amount of revenue recognized reflects the transaction price and considers the effects of variable consideration, which is discussed below.

Once the Company satisfies its performance obligations upon delivery of a test result and bills for the product, the timing of the collection of payments may vary based on the payment practices of the third-party payor. The Company bills patients directly for co-pays and deductibles that they are responsible for and also bills patients directly in cases where the customer does not have insurance.

The Company has 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. For example, during 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 the Company and its ordering healthcare providers must use to bill and receive reimbursement for 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 Company settled the obligations to the relevant government programs in early October 2020.

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 nine months to collect and the Company may be paid less than the full amount billed or not paid at all. For insurance carriers and government payors, management utilizes the expected value method using a portfolio of relevant historical data for payors with similar reimbursement characteristics. 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. The Company monitors these estimates at each reporting period based on actual cash collections and the status of settlement agreements with third-party payors, in order to assess whether a revision to the estimate is required. Both the initial estimate and any subsequent revision to the estimate contain uncertainty and require the use of judgment in the estimation of the transaction price and application of the constraint for variable consideration. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect revenue and earnings in the period such variances become known. The consideration expected from laboratory partners is generally a fixed amount.

The Company periodically updates its estimate of the variable consideration recognized for previously delivered performance obligations. These updates resulted in an additional $3.3 million and a reduction of $19.4 million of revenue reported for the three and nine months ended September 30, 2020, respectively, and a reduction of $17.8 million and an additional $1.0 million of revenue reported for the three and nine months ended September 30, 2019, respectively. These amounts included (i) adjustments for actual collections versus estimated variable consideration as of the beginning of the reporting period and (ii) cash collections and the related recognition of revenue in the current period for tests delivered in prior periods due to the release of the constraint on variable consideration, offset by (iii) reductions in revenue for the accrual for reimbursement claims and settlements described in Note 9.

Disaggregation of Revenues

The following table shows a further disaggregation of revenues by payor type (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Commercial third-party payors	$ 18,555	$ 23,058	$ 58,148	$ 108,851
Government health benefit programs(1)	5,692	(5,513)	(3,374)	11,432
Patient/laboratory distribution partners	1,696	1,227	5,263	3,226
Total revenues	$ 25,943	$ 18,772	$ 60,037	$ 123,509

(1) The revenue amounts include accruals for reimbursement claims and settlements included in the estimates of variable consideration recorded during the three and nine months ended September 30, 2020 and 2019. Revenue recognized reflect the effects of variable consideration, and include adjustments for estimates of disallowed cases, discounts, and refunds. The variable consideration includes reductions in revenues for the accrual for reimbursement claims and settlements.

5. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Prepaid expenses	$ 8,188	$ 6,476
Other current assets	1,028	1,370
Total	$ 9,216	$ 7,846

Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Computers and software	$ 13,790	$ 13,913
Building and leasehold improvements	9,458	9,491
Laboratory equipment	7,254	5,580
Furniture, fixtures, and office equipment	1,686	1,633
Construction in progress	1,891	1,493
Land	1,091	1,091
Total property and equipment	35,170	33,201
Less accumulated depreciation and amortization	(19,082)	(17,310)
Property and equipment, net	$ 16,088	$ 15,891

Capital leases included in property and equipment, net consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Capital leases	$ 2,467	$ 3,692
Less accumulated depreciation and amortization	(1,835)	(2,239)
Capital leases included in property and equipment, net	$ 632	$ 1,453

Depreciation expense was $1.0 million and $3.1 million for the three and nine months ended September 30, 2020, respectively, and $0.9 million and $2.8 million for the three and nine months ended September 30, 2019, respectively.

Intangible Assets, Net

Intangible assets, net consisted of the following (in thousands):

September 30, 2020	Cost	Accumulated amortization	Net
Payor relationships	$ 7,230	$ (3,856)	$ 3,374
Trade names	1,410	(752)	658
Noncompete agreements	384	(341)	43
Intangible assets, net	$ 9,024	$ (4,949)	$ 4,075

December 31, 2019	Cost	Accumulated amortization	Net
Payor relationships	$ 7,230	$ (3,314)	$ 3,916
Trade names	1,410	(646)	764
Noncompete agreements	384	(293)	91
Intangible assets, net	$ 9,024	$ (4,253)	$ 4,771

Amortization expense of intangible assets was $0.2 million and $0.7 million for the three and nine months ended September 30, 2020, respectively, and $0.2 million and $0.7 million for the three and nine months ended September 30, 2019, respectively.

The future amortization of intangible assets at September 30, 2020 was (in thousands):

Year ending December 31,	
Remainder of 2020	$ 232
2021	891
2022	864
2023	864
2024	864
Thereafter	360
Total future minimum lease payments	$ 4,075

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Accrual for reimbursement claims and settlements, current	$ 47,937	$ 60,386
Commission and bonus	8,283	6,357
Vacation and payroll benefits	7,339	5,506
Accrued professional services	3,092	5,322
Contract liabilities	544	—
Other	3,818	6,044
Total	$ 71,013	$ 83,615

Other Long-term Liabilities

Other long-term liabilities consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Accrual for reimbursement claims and settlements, net of current portion	$ 18,066	$ 12,205
Other	2,022	654
Total	$ 20,088	$ 12,859

6. Fair Value Measurements

The Company's financial assets and liabilities carried at fair value are comprised of investment assets that include money market funds. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date.

The authoritative guidance establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity. The three-level hierarchy for the inputs to valuation techniques is summarized as follows:

Level 1 - Quoted prices in active markets for identical assets and liabilities that the Company has the ability to access.

Level 2 - Observable market-based inputs or unobservable inputs that are corroborated by market data, such as quoted prices, interest rates, and yield curves.

Level 3 - Inputs that are unobservable data points that are not corroborated by market data.

This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. The following table presents information about the Company's assets and liabilities that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value (in thousands):

	Quoted Prices for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
September 30, 2020			
Money market funds(1)	$ 39,737	$ —	$ —
December 31, 2019			
Money market funds(1)	$ 24,432	$ —	$ —

(1) Included in cash and cash equivalents in the accompanying condensed consolidated balance sheets.

The Company's policy is to recognize transfers between levels at the end of the reporting period. There were no significant transfers between Level 1 and Level 2 during the three and nine months ended September 30, 2020 and 2019.

Fair Value of Financial Instruments

The carrying value of the Company's accounts receivable, income tax receivable, accounts payable, and accrued expenses and other current liabilities are considered to be representative of their respective fair values because of their short-term nature.

The carrying value of the Company's mortgages payable approximates their estimated fair value because the instruments bear interest at rates and have terms that are comparable to those available to the Company for similar loan instruments at September 30, 2020 and December 31, 2019.

The carrying value of the Company's note payable to a related party does not approximate its fair value because the instrument bears interest at a rate that is not comparable to those available to the Company for a similar loan instrument at September 30, 2020 and December 31, 2019. The carrying value and the fair value of the Company's term loan (the "2017 Term Loan") was $75.0 million and $80.0 million, respectively, at September 30, 2020, and $75.0 million and $79.8 million, respectively, at December 31, 2019. The carrying value of the 2017 Term Loan is presented on the accompanying condensed consolidated balance sheets net of discount on the note and debt issuance cost.

7. Related Party Transactions

On October 27, 2017, the Company entered into a Credit and Security Agreement and a Series B Convertible Preferred Stock Purchase Agreement with a private equity firm (the "2017 Transaction"). The 2017 Transaction provided for the 2017 Term Loan, the issuance of Series B Preferred Stock (the "Series B Preferred Stock"), and the issuance of a warrant to purchase Series B Preferred Stock (the "Series B Preferred Stock Purchase Warrant"). The 2017 Term Loan accrues interest at a rate per annum equal to 9.5% and is due October 27, 2022.

The 2017 Term Loan contains customary covenants, including a requirement to maintain a minimum unrestricted cash balance at all times of at least $5.0 million. The Company is in compliance with the 2017 Term Loan covenants. The 2017 Term Loan is secured by all tangible and intangible property and assets of the Company, with the exception of its intellectual property.

The total proceeds of $124.2 million from the 2017 Transaction were allocated to the 2017 Term Loan, Series B Preferred Stock, and the Series B Preferred Stock Purchase Warrant based on the relative fair value of the term loan, equity, and warrant issued. As a result, the Company allocated proceeds of $65.7 million to the 2017 Term Loan. As the proceeds allocated to the 2017 Term Loan are lower than the stated loan amount of $75.0 million, the resulting $9.3 million discount is amortized as interest expense using the effective interest method over the term of the loan.

As of both September 30, 2020 and December 31, 2019, the outstanding unpaid principal under the 2017 Term Loan was $75.0 million. The unamortized discount on the 2017 Term Loan was $5.4 million and $6.0 million as of September 30, 2020 and December 31, 2019, respectively. During the three months ended September 30, 2020 and 2019, the Company recognized interest expense on the 2017 Term Loan of $2.4 million and $2.2 million, inclusive of $0.6 million and $0.4 million of discount amortization for the three months ended September 30, 2020 and 2019, respectively. During the nine months ended September 30, 2020 and 2019, the Company recognized interest expense on the 2017 Term Loan of $7.1 million and $6.6 million, inclusive of $1.7 million and $1.2 million of discount amortization for the nine months ended September 30, 2020 and 2019, respectively.

In connection with the IPO, on June 18, 2020, the Series B Preferred Stock Purchase Warrant became exercisable for 400,160 shares of common stock.

On March 31, 2020, the Company entered into the First Amendment to the Credit Agreement (the “Credit Agreement Amendment”), with the collateral agent and lender party thereto, providing for the payment of interest due and payable as of March 31, 2020 in shares of Series B Preferred Stock, and further providing for the payment of interest due and payable as of June 30, 2020 in shares of the Series B Preferred Stock in the event the IPO has not been consummated by such date. Pursuant to the Credit Agreement Amendment, the Company concurrently entered into a Series B Preferred Stock Subscription Agreement (the “Subscription Agreement”), with the lender, which provided for the issuance of 967,130 shares of Series B Preferred Stock at a subscription price of $2.25 per share, as payment for interest due and payable as of March 31, 2020 and all applicable fees as set forth in the Credit Agreement Amendment.

On May 8, 2020, the Company entered into an unsecured convertible promissory note (the “Note”) with an existing investor pursuant to a note purchase agreement, in an aggregate principal amount of $15.0 million, with an annual interest rate of 8.0% and a maturity date of May 8, 2022. The Note was convertible into (i) common stock upon an initial public offering at the lesser of the conversion price then in effect and a conversion price equal to 80% of the public offering price (or, if not a “qualified IPO” as defined in the Company’s certificate of incorporation, at the election of a majority of the holders), (ii) on the maturity date or at the election of a majority of the holders, Series B preferred stock at an initial conversion price of $13.90 per share subject to certain adjustments, or (iii) at the election of a majority of the holders, shares of another class of equity securities issued by the Company in a future financing at 80% of the price per share of such class of equity securities issued in such offering. Interest under the Note was not generally payable except that if the Note is not converted pursuant to its terms on or prior to the maturity date and there are not sufficient authorized and unissued shares of Series B preferred stock for issuance upon the conversion of the Note on the maturity date, then the Company is required to pay all outstanding principal and any accrued and unpaid interest under the Note in cash. If the holders of the Note have not elected to convert the Note prior to, or in connection with, any sale transaction or a liquidation, dissolution or winding up of the Company, either voluntary or involuntary, then, upon any such sale transaction or liquidation, dissolution or winding up of the Company, the Company would have been required to pay in cash the outstanding principal balance of the Note, together with accrued and unpaid interest thereon, plus a make whole premium of 50% of the aggregate principal amount (less accrued and unpaid interest). The Company evaluated the economic features embedded in the Note and identified features that were required to be bifurcated and accounted for separately as a derivative. Accordingly, a derivative liability of $3.6 million was recorded on the issuance date of the Note and $3.8 million was subsequently reclassified to equity representing the fair value of the derivative liability on the date of extinguishment. The change in the fair value of the derivative liability of $0.2 million is included in interest and other income (expense), net in the accompanying condensed consolidated statements of operations. In June 2020, in connection with completion of the IPO, the Note was converted into 1,250,000 shares of common stock and all obligations under the Note were extinguished. Upon the conversion, the Company recorded a $3.6 million loss on extinguishment of the debt, which represented the difference between the carrying value of the Note and the derivative liability and the fair value of the shares of common stock issued to the Note holder of $3.4 million combined with amortization of the related debt discount of $0.2 million. The loss on extinguishment of debt was included in the interest and other income (expense), net in the accompanying condensed consolidated statements of operations for nine months ended September 30, 2020.

8. Mortgages Payable

In January 2014, the Company executed a mortgage with Comerica Bank for $1.8 million for the purpose of acquiring property located in Ann Arbor, Michigan, which is used for laboratory testing and research purposes. The mortgage matures in 2024 and requires monthly principal and interest payments at a fixed interest rate of 2.94% plus a floating rate at LIBOR. As of September 30, 2020 and December 31, 2019, the outstanding balance of this mortgage was $1.4 million and $1.4 million, respectively. The Company also has a mortgage with American Bank of Commerce (originally executed in February 2008) outstanding on Avero's property located in Lubbock, Texas, which is used primarily for laboratory testing. The mortgage matures in 2029 and requires monthly principal and interest payments at an interest rate of 3.25%. As of September 30, 2020 and December 31, 2019, the outstanding balance of this mortgage was $1.8 million and $1.9 million, respectively.

As of September 30, 2020, the minimum principal payments under the mortgages payable were as follows (in thousands):

Year ending December 31,	Minimum Mortgages Payable Payments Obligations
Remainder of 2020	$ 66
2021	271
2022	281
2023	292
2024	1,338
Thereafter	884
Total future minimum payments	3,132
Less current portion of mortgages payable	(268)
Mortgages payable, net of current portion	$ 2,864

9. Commitments and Contingencies

Operating Leases

The Company has entered into various noncancelable operating lease agreements, primarily for office space, laboratory space, and vehicles, which expire over the next two to four years. Minimum rent payments under operating leases are recognized on a straight-line basis over the term of the lease. Rent expense for operating leases was $1.8 million and $6.0 million, for the three and nine months ended September 30, 2020, respectively, and $2.3 million and $6.6 million, respectively, for the three and nine months ended September 30, 2019.

As of September 30, 2020, net minimum payments under the non-cancelable operating leases were as follows (in thousands):

Year ending December 31,	Minimum Operating Lease Payments
Remainder of 2020	$ 1,933
2021	5,476
2022	3,017
2023	1,036
2024 and thereafter	38
Total future minimum lease payments	$ 11,500

Capital Leases

The Company has entered into various capital lease agreements, primarily for equipment. The outstanding leases have a weighted average imputed interest rate of 5.98% per annum. As of September 30, 2020, the future minimum payments under the capital leases were as follows (in thousands):

Year ending December 31,	Minimum Capital Lease Payments
Remainder of 2020	$ 145
2021	324
2022 and thereafter	47
Total future minimum lease payments	516
Less amounts representing interest	(20)
Present value of minimum capital lease payments	496
Less current portion of capital lease obligations	(399)
Capital lease obligations, net of current portion	$ 97

Contingencies

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 may be 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.

Federal Investigations

In April 2018, the Company received a civil investigative demand from an Assistant U.S. Attorney ("AUSA") for the Southern District of New York ("SDNY") and a Health Insurance Portability and Accountability Act subpoena issued by an AUSA for the Southern District of California ("SDCA"). In May 2018, the Company received a subpoena from the State of New York Medicaid Fraud Control Unit.

On July 21, 2020, July 23, 2020, and October 1, 2020, the Company entered into agreements with certain governmental agencies and the 45 states participating in the settlement ("State AGs") to resolve, with respect to such agencies and State AGs, all of such agencies' and State AGs' outstanding civil, and, where applicable, federal criminal investigations described above. Specifically, the Company has entered into:

- a civil settlement agreement, effective July 23, 2020, with the DOJ through the AUSA for SDNY, and on behalf of the Office of Inspector General of the Department of Health and Human Services (the "OIG"), and with the relator named therein (the "SDNY Civil Settlement Agreement");
- a civil settlement agreement, effective July 23, 2020, with the DOJ through the AUSA for SDCA, and on behalf of the Defense Health Agency, the Tricare Program and the Office of Personnel Management, which administers the Federal Employees Health Benefits Program (the "SDCA Civil Settlement Agreement");
- a non-prosecution agreement, effective July 21, 2020, with the AUSA for SDCA (the "Non-Prosecution Agreement") in resolution of all criminal allegations;
- a corporate integrity agreement, effective July 21, 2020, with the OIG (the "Corporate Integrity Agreement"); and
- civil settlement agreements, effective October 1, 2020, with the State AGs ("the State Settlement Agreements").

The Company refers to the SDNY Civil Settlement Agreement, the SDCA Civil Settlement Agreement, the Non-Prosecution Agreement, the Corporate Integrity Agreement and the State Settlement Agreements collectively as the Agreements.

SDNY Civil Settlement Agreement

Pursuant to the SDNY Civil Settlement Agreement, the Company is required to pay a settlement amount of approximately $19.4 million, which includes approximately $9.7 million designated as restitution to the U.S. federal government. During the three months ended September 30, 2020, the Company paid approximately $9.1 million. The Company paid an additional approximately $4.1 million subsequent to September 30, 2020, for an aggregate of approximately $13.1 million paid to date. The outstanding settlement amount is payable in three installments as follows:

- approximately $1.6 million on or before December 31, 2020;
- approximately $2.0 million on or before December 31, 2021; and
- approximately $2.8 million on or before December 31, 2022.

The remaining amounts payable to the government will be subject to interest at a rate of 1.25% per annum, and any or all amounts may be paid earlier at the option of the Company. Furthermore, the Company has agreed that, if during calendar years 2020 through 2023, and so long as amounts payable to the government remain unpaid, the Company receives any civil settlement, damages awards, or tax refunds, to the extent that the amounts exceed $5.0 million in a calendar year, it will pay 26% of the amount received in such civil settlement, damages award, or tax refunds as an accelerated payment of the scheduled amounts set forth above, up to a maximum total acceleration of $4.2 million. As previously reported, during the three months ended March 31, 2020, the Company recorded a discrete tax benefit of $37.7 million related to the net operating loss carryback provisions available under the Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”) for taxes paid by the Company in years 2013, 2014, 2015 and 2017 (the “CARES Act Tax Benefit”). In June 2020, the Company received a tax benefit payment of approximately $22.7 million for a portion of the CARES Act Tax Benefit, and because this tax refund was received prior to the effective date of the SDNY Civil Settlement Agreement, the payment the initial settlement payment installment included an added payment of approximately $5.9 million. In addition, because the Company received a tax benefit payment of approximately $15.7 million in September 2020, and accelerated payment of approximately $4.1 million was made on October 1, 2020 with a corresponding reduction in the previously agreed upon payment term and subsequent payment amounts.

Additionally, under the SDNY Civil Settlement Agreement, the U.S. federal government and the relator agreed to dismiss all civil claims asserted by the relator under the *qui tam* provisions of the federal False Claims Act.

SDCA Civil Settlement Agreement

The SDCA Civil Settlement Agreement requires the Company to pay a settlement amount of approximately $16.4 million, which includes approximately $10.0 million designated as restitution to the U.S. federal government. During the three months ended September 30, 2020, the Company paid approximately $7.7 million. The Company paid an additional $3.4 million subsequent to September 30, 2020, for an aggregate of $11.1 million paid to date. The outstanding settlement amount is payable in three installments as follows:

- approximately $1.4 million on or before December 31, 2020;
- approximately $1.8 million on or before December 31, 2021; and
- approximately $2.2 million on or before December 31, 2022.

The remaining amounts payable to the government, will be subject to interest at a rate of 1.25% per annum, and any or all amounts may be paid earlier at the option of the Company.

On July 21, 2020, the Company issued a promissory note to the U.S. federal government for the full settlement amount in connection with the SDCA Civil Settlement Agreement (the “Promissory Note”). The Promissory Note contains customary events of default and related acceleration of payment provisions. In addition, the Promissory Note provides, among other terms, that, if during calendar years 2020 through 2023, and so long as amounts payable to the government remain unpaid, the Company receives any civil settlement, damages awards, or tax refunds, to the extent that the amounts exceed $5.0 million in a calendar year, it will pay 22% of the amount received in such civil settlement, damages award, or tax refunds as an accelerated payment of the scheduled amounts set forth above up to a maximum total acceleration of approximately $3.4 million. Because the Company received a tax benefit payment of approximately $22.7 million for a portion of the CARES Act Tax Benefit in June 2020 and because this tax refund was received prior to the effective date of the Promissory Note, the initial payment installment included an added payment of $4.9 million. In

addition, because the Company received a tax benefit payment of approximately $15.7 million in September 2020, an accelerated payment of approximately $3.4 million was made on October 1, 2020, with a corresponding reduction in the previously agreed upon payment term and subsequent payment amounts.

Non-Prosecution Agreement

Effective July 21, 2020, the Company entered into the Non-Prosecution Agreement, pursuant to which the Company agreed with the DOJ to (i) pay the restitution provided for under the SDCA Civil Settlement Agreement, (ii) not commit any felonies, (iii) continue to implement a compliance and ethics program designed to prevent and detect violations of applicable fraud and kickback laws throughout its operations and (iv) fulfill certain other disclosure, reporting and cooperation obligations. The DOJ agreed that it will not prosecute the Company for any conduct described in the Non-Prosecution Agreement provided that the Company performs its obligations under the Non-Prosecution Agreement during the period from July 21, 2020 through July 21, 2021. The Non-Prosecution Agreement provides that the DOJ may unilaterally, upon notice to the Company, extend the term of the agreement in 6-month increments, for a maximum total term of 24 months (that is, two 6-month extensions).

Corporate Integrity Agreement

In connection with the resolution of the investigated matters, and in exchange for the OIG's agreement not to exercise its authority to permissively exclude the Company from participating in federal healthcare programs, effective July 21, 2020, the Company entered into a five-year Corporate Integrity Agreement with the OIG. The Corporate Integrity Agreement requires, among other matters, that the Company maintain a Compliance Officer, a Compliance Committee, board review and oversight of certain federal healthcare compliance matters, compliance programs, and disclosure programs; provide management certifications and compliance training and education; engage an independent review organization to conduct claims and arrangements reviews; and implement a risk assessment and internal review process. The Company's failure to comply with its obligations under the Corporate Integrity Agreement could result in monetary penalties and/or the Company being excluded from participating in federal healthcare programs.

State Settlement Agreements

Effective October 1, 2020, the Company entered into agreements with the State AGs with respect to the investigated matters. The State Settlement Agreements require the Company to pay a settlement amount of approximately $13.2 million to the participating states. The State Settlement Agreements include acceleration provisions similar to the SDNY Civil Settlement Agreement and the SDCA Civil Settlement Agreements described above upon the Company's receipt of civil settlements, damages awards, and tax refunds, with the amount to be accelerated and the timing of accelerated payment subject to such receipts. Because the Company received the June 2020 and September 2020 tax benefits totaling approximately $38.4 million, the initial payment to the participating states included added payments reflecting 17% of that amount, for a total initial payment on October 2, 2020 of approximately $8.7 million. The outstanding settlement amount is payable in four installments as follows:

- approximately $1.1 million on or before December 31, 2020;
- approximately $1.4 million on or before December 31, 2021;
- approximately $1.9 million on or before December 31, 2022; and
- approximately $0.2 million on or before December 31, 2023.

Settlement Accruals

As of December 31, 2019, the Company 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 quarter ended March 31, 2020, the Company 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. As of September 30, 2020, the Company's accrual consists of $20.2 million in accrued expenses and other current liabilities and $12.1 million in other long-term liabilities.

Payor Settlement Agreements

On June 21, 2018, the Company received a letter from Cigna alleging damages related to contract terms. On December 5, 2018, Cigna and the Company entered into a settlement agreement whereby Avero agreed to pay an aggregate amount of $12.0 million with an upfront payment of $6.0 million and the remaining $6.0 million to be paid over 24 months. For the year ended December 31, 2018, the Company recorded a charge of $12.0 million associated with this claim in its consolidated statements of operations as a reduction to revenue. As of September 30, 2020, the remaining settlement accrual related to Cigna is $0.8 million included in accrued expenses and other current liabilities.

On June 25, 2018, the Company received a letter from Aetna's external legal counsel that included various allegations relating to the Company's past practices. In November 2019, the Company and Aetna entered into a settlement agreement for $15.0 million, to be paid in installment payments through December 2020. During the year ended December 31, 2018, the Company recorded a charge of $15.0 million associated with this claim in its consolidated statements of operations as a reduction to revenue. As of September 30, 2020, the Company's accrual consists of $5.0 million included in accrued expenses and other current liabilities.

On October 18, 2018, the Company received a letter from UnitedHealth Group that included various allegations relating to the Company's past practices. On September 30, 2019, the Company entered into a settlement agreement with United HealthCare Services, Inc. and UnitedHealthcare Insurance Company ("United") in which the Company agreed to pay an aggregate amount of $30.0 million. The settlement is to be paid with an upfront payment of $2.0 million, and the remaining balance to be paid every six months starting December 31, 2019, with the first two installment payments of $5.0 million each, and $6.0 million each thereafter. As of September 30, 2020, the remaining settlement accrual related to United is $18.0 million consisting of $12.0 million included in accrued expenses and other current liabilities and $6.0 million included in other long-term liabilities.

Payor Recoveries

As noted above, the regulations governing government reimbursement programs (e.g., Medicaid, Tricare, and Medicare) and commercial payor reimbursement programs are complex and may be subject to interpretation. As a provider of services to patients covered under government reimbursement and commercial payor programs, the Company is routinely subject to post-payment review audits and other forms of reviews and investigations. If a third-party payor successfully challenges that a payment to the Company for prior testing was in breach of contract or otherwise contrary to policy or law, they may recoup such payment. The Company may also decide to negotiate and settle with a third-party payor in order to resolve an allegation of overpayment. In the ordinary course of business, the Company addresses and evaluates a number of such claims from payors. In the past, the Company has negotiated and settled these types of claims with third-party payors. The Company may be required to resolve further disputes in the future. The Company is aware of one commercial payor that is reviewing historical payments and may make a claim for recoupment in the future. While management is unable to predict the exact outcome of any such claims, 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.

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. Any amounts subject to recovery or recoupment will depend on the interpretation of widely variable payor medical and billing policies. The Company will not know if any overpayments exist until it completes this engagement with individual 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. The Company is unable to predict the outcome of this matter and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome related to this matter.

OIG Inquiry

On October 16, 2019, the Company received an inquiry from the Texas Health & Human Services Commission Office of Inspector General (the "TX OIG") alleging that the Company did not hold the required CLIA Laboratory Certificate of Accreditation to perform, bill for, or be reimbursed by the Texas Medicaid Program for certain tests performed by us from January 1, 2015 through December 31, 2018. Although management believes that the Company holds and have held all required CLIA certificates and/or subcontract with third-party laboratories that hold and have held such certificates to perform all of the tests subject to the TX OIG inquiry, there can be no assurance that the TX OIG will agree with this position. The Company submitted a written response to the inquiry on October 23, 2019 and are awaiting a response from the TX OIG on the matter. It is not possible to predict the outcome of these matters and the timing for resolution.

Natera Lawsuit

On June 17, 2020, Natera, Inc. ("Natera") filed suit in the Western District of Texas (W.D. Texas Civil Action No. 6:20-cv-532) asserting the Company's infringement of six Natera patents based on a portion of the Company's NIPT product offering. On June 19, 2020, Natera filed a substantially similar second suit in the Northern District of Texas (N.D. Texas Civil Action No. 3:20-cv-1634). On July 31, 2020, the Company filed a motion to dismiss the Western District of Texas case based improper venue. The parties are now conducting limited discovery related to this motion, after which Natera will file its responsive pleadings. The Northern District of Texas case has been stayed until a decision with respect to the motion to dismiss is made.

On July 2, 2020, the Company filed a Complaint for Declaratory Judgment of Non-Infringement against Natera in the Southern District of California (S.D. California Civil Action No. 3:20-cv-1252). This case has been stayed pending the outcome of the Company's venue motion in the Western District of Texas.

Management believes that the claims in Natera's complaints are without merit and the Company is vigorously defending against them.

IPO Litigation

On June 23, 2020, the Company completed the IPO. Subsequent to the IPO, two lawsuits were filed against the Company, certain of its executive officers and directors, and the underwriters of the IPO. The lawsuits allege that the Company's registration statement and related prospectus for the IPO made false and misleading statements and omissions in violation of the Securities Act of 1933 by failing to disclose that the Company (i) had overbilled government payors by $10.3 million in 2019 and early 2020; (ii) would need to refund this overpayment in the second quarter of 2020; and (iii) were allegedly suffering from accelerating negative trends with respect to testing volumes, revenues, and product pricing during the second quarter of 2020. Both lawsuits seek, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. The Company intends to vigorously defend against these claims. Given the uncertainty of litigation, the preliminary stages of these cases, and the legal standards that must be met for, among other things, success on the merits, the Company is unable to predict the ultimate outcome of these actions, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from these actions. Subject to a reservation of rights, the Company is advancing expenses subject to indemnification by the underwriters of the IPO. More details on each lawsuit are below:

- *Soe Action*. On August 28, 2020, a putative securities class action was filed in the U.S. District Court for the Southern District of California, entitled *Aung Kyaw Soe v. Progenity, Inc., et al.*, No. 3:20-cv-01683-CAB-AHG. The plaintiff, Aung Kyaw Soe, seeks to bring this action on behalf of all purchasers of Progenity common stock pursuant to or traceable to the registration statement issued in connection with the IPO. On September 23, 2020, the court ordered that no defendant has any obligation to answer or otherwise respond to the complaint in this action pending appointment of a lead plaintiff and the lead plaintiff's filing of an amended complaint or designation of the existing complaint as the operative complaint.
- *Brickman Investments Inc. Action*. On September 11, 2020, another putative securities class action was filed in the U.S. District Court for the Southern District of California, entitled *Brickman Investments Inc. v. Progenity, Inc., et al.*, No. 3:20-cv-01795-BEN-LL. The plaintiff, Brickman Investments Inc., seeks to bring this action on behalf of all purchasers of Progenity common stock pursuant to or traceable to the registration statement and related prospectus issued in connection with the IPO. In addition to the remedies described above, the plaintiff seeks rescission or rescissory damages.

Motions for appointment of lead plaintiff and lead counsel, as well as to consolidate the two actions, are pending.

10. Stockholders' Equity

Common Stock

Pursuant to the Company's eighth amended and restated certificate of incorporation, which went into effect immediately prior to the completion of the IPO, the Company is authorized to issue 350 million shares of common stock and 10 million shares of undesignated preferred stock. Each holder of common stock is entitled to one vote per share of common stock held.

On June 18, 2020, the Company completed its 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 Company received approximately $88.7 million in net proceeds, after deducting $7.0 million in underwriting discounts and commissions and $4.3 million in other offering expenses payable by the Company. Other offering costs consisted primarily of legal and accounting fees, which were direct and incremental fees related to the IPO. As of December 31, 2019, $1.1 million of deferred offering costs were included in prepaid expenses and other current assets in the accompanying condensed consolidated balance sheet.

Treasury Stock

In June 2014, the Company authorized an Equity Repurchase Program for Key Employees (the "Repurchase Program"). The Repurchase Program allowed the Company to repurchase for cash a portion of the common stock equity interests of certain employees, provided that (i) no more than 25% of the equity interest of any employee was repurchased under the Repurchase Program, (ii) the purchase price paid for each share of common stock equaled the most recent appraisal valuation of the Company's common stock, and (iii) the aggregate repurchases did not exceed the lesser of (a) equity interest representing, in the aggregate, 0.8 million shares of common stock, (b) a purchase price, in the aggregate, of more than $6.0 million, and (c) the maximum repurchases permitted under the General Corporation Law of the State of Delaware. In addition, it was the Company's practice to require individuals exercising stock options to hold the shares received upon exercising for a reasonable period of time in order for the holder to be exposed to the economic risks and rewards of share ownership prior to participating in the Repurchase Program. A reasonable period of time was defined as a period of at least six months and that covered at least two common stock appraisal valuations. The Repurchase Program has been discontinued.

Convertible Preferred Stock

As of December 31, 2019, the Company had outstanding Series A Preferred Stock and Series B Preferred Stock. The Company recorded the preferred stock at fair value on the dates of issuance net of issuance costs.

On August 27, 2019, the Company issued 9,090,910 shares of Series B Preferred Stock at an issuance price of $2.75 per share for an aggregate consideration of $25.0 million (the "August 2019 Financing") pursuant to a Series B Preferred Stock Purchase Agreement with a private equity firm. In addition, the Company amended the Series B Preferred Stock Purchase Warrant dated October 27, 2017 to increase the Series B Preferred Stock underlying the Series B Preferred Stock Purchase Warrant from 1,416,431 shares to 1,818,182 shares and adjust the exercise price to $2.75 per share. The $25.0 million of proceeds from the August 2019 Financing were allocated among the newly issued Series B Preferred Stock shares and additional shares of Series B Preferred Stock Purchase Warrant based on their relative fair values.

In connection with the August 2019 Financing, the Board of Directors and stockholders approved a 1.28-for-1 stock split for the Company's Series B Preferred Stock and Series B Preferred Stock Purchase Warrant issued and outstanding prior to the August 2019 Financing, which was effected on August 27, 2019 pursuant to an amendment to the amended and restated certificate of incorporation. The conversion price of the Series B Preferred Stock and exercise price of the outstanding Series B Preferred Stock Purchase Warrant was lowered from $3.53 to $2.75 per share. As a result, the Company issued 4,017,512 additional shares of Series B Preferred Stock as a stock dividend to the preferred stockholders, which was recorded as a $13.1 million increase to accumulated deficit in the consolidated statements of stockholders' deficit during the year ended December 31, 2019.

On August 27, 2019, the Company entered into an Exchange Agreement with holders of Series A-1 Preferred Stock (the "Exchange Agreement") pursuant to which the outstanding 1,500,000 shares of Series A-1 Preferred Stock were exchanged for 35,664,240 shares of Series B Preferred Stock. The exchange ratio was 1.2 to 1 on as-if converted to 4,810,651 shares of common stock that the Series A-1 Preferred Stock can be converted to, based on the conversion rate of 3.2 to 1. The Company determined that such exchange constituted a modification to the Series A-1 Preferred Stock. Accordingly, the increase comparing the fair value of the Series B Preferred Stock with the fair value of the Series A-1 Preferred Stock represented a dividend to the preferred stockholders of approximately $27.6 million, which was recorded as an increase to accumulated deficit in the consolidated statements of stockholders' deficit during the year ended December 31, 2019.

On November 12, 2019, the Company entered into a Series B Preferred Stock Purchase Agreement (the "November Series B Preferred Stock Purchase Agreement") with a private equity firm and received $25.0 million (the "November 2019 Financing") in exchange for the issuance of 11,111,111 shares of Series B Preferred Stock at $2.25 per share. In connection with the November 2019 Financing, the Board of Directors and stockholders approved a 1.22-for-1 stock split for the Company's Series B Preferred Stock and Series B Preferred Stock Purchase Warrant issued and outstanding prior to the November 2019 Financing. The conversion price of the Series B Preferred Stock and exercise price of the outstanding Series B Preferred Stock Purchase Warrant was lowered from $2.75 to $2.25 per share. As a result, the Company issued 13,985,993 additional shares of Series B Preferred Stock and adjusted the Series B Preferred Stock Purchase Warrant to purchase up to 2,222,222 shares of Series B Preferred Stock. The issuance of additional shares represented a stock dividend to the preferred stockholders, which was recorded as a $36.4 million increase to accumulated deficit in the consolidated statements of stockholders' deficit during the year ended December 31, 2019. In connection with the November 2019 Financing, the Company amended the certificate of incorporation. Following the amendment, there are no authorized or outstanding shares of Series A-1 Preferred Stock.

On November 22, 2019, the Company completed an additional equity financing pursuant to the November Series B Preferred Stock Purchase Agreement with certain existing, accredited investors for an aggregate of $6.1 million in exchange for the issuance of an aggregate of 2,722,222 shares of Series B Preferred Stock at $2.25 per share.

On December 19, 2019, the Company completed an additional equity financing pursuant to the November Series B Preferred Stock Purchase Agreement with the same private equity firm as the November 2019 Financing for $25.0 million in exchange for the issuance of 11,111,111 shares of Series B Preferred Stock at $2.25 per share.

In February 2020, the Company issued and sold an aggregate of 5,066,666 shares of Series B Preferred Stock at a purchase price of $2.25 per share to existing investors in exchange for aggregate consideration of approximately $11.4 million.

On March 31, 2020, in connection with the Credit Agreement Amendment, which provided for the payment of interest due and payable as of March 31, 2020 and June 30, 2020 (only in the event the IPO had not been consummated by such date) in shares of Series B Preferred Stock, the Company issued an aggregate of 967,130 shares of Series B Preferred Stock at a subscription price of $2.25 per share to existing investors as payment for interest due and payable as of March 31, 2020 and all applicable fees.

On April 3, 2020, the Company issued and sold an aggregate of 4,444,444 shares of its Series B Preferred Stock at a purchase price of $2.25 per share to existing investors in exchange for aggregate consideration of approximately $10.0 million in cash.

The fair value of the preferred stock was estimated using a hybrid between a probability-weighted expected return method (“PWERM”) and option pricing model (“OPM”), estimating the probability weighted value across multiple scenarios, while using an OPM to estimate the allocation of value within one or more of these scenarios. Under a PWERM, the value of the Company’s various classes of stock was estimated based upon an analysis of future values for the Company assuming various future outcomes, including two IPO scenarios and one scenario contemplating the continued operation of the Company as a privately held enterprise. Guideline public company multiples were used to value the Company under its various scenarios. Share value for each class of stock was based upon the probability-weighted present value of expected future share values, considering each of these possible future outcomes, as well as the rights of each share class.

The significant unobservable inputs into the valuation model used to estimate the fair value of the preferred stock include the timing of potential events (primarily the IPO) and their probability of occurring, the selection of guideline public company multiples, a discount for the lack of marketability of the common stock, and the discount rate used to calculate the present value of the estimated equity value allocated to each share class.

Preferred stock outstanding as of December 31, 2019 consisted of the following (in thousands, except share and per share data):

December 31, 2019	Shares Authorized	Shares Issued and Outstanding	Per Share Price at Issuance	Aggregate Liquidation Preference
Series A	4,120,000	4,120,000	$ 0.48543	$ 2,000
Series B	126,035,000	101,867,405	2.25000	229,202
Total preferred stock	130,155,000	105,987,405		$ 231,202

In connection with the IPO, on June 18, 2020, all outstanding Series A Preferred Stock and Series B Preferred Stock converted into 33,443,562 shares of common stock, including the issuance of 2,045,522 shares of common stock pursuant to an adjustment in the conversion rate of all of the shares of Series B Preferred Stock outstanding immediately prior to the IPO. Upon conversion of the convertible preferred stock, the Company reclassified their carrying value to common stock and additional paid-in capital.

Common Stock Reserved for Future Issuance

The Company reserved shares of common stock, on an as-if-converted basis, for future issuance as follows:

	September 30, 2020	December 31, 2019
Series A Preferred Stock	—	13,213,254
Series B Preferred Stock	—	16,488,731
Series B Preferred Stock Purchase Warrant	—	359,699
Common stock warrant	400,160	—
Restricted stock units outstanding	1,194,077	322,608
Outstanding options to purchase common stock	3,531,577	2,561,866
Available for future issuance under equity incentive plan	4,109,953	1,717,817
Total	9,235,767	34,663,975

11. Stock-Based Compensation

In February 2018, the Company adopted the 2018 Equity Incentive Plan (the "2018 Plan"), with 0.7 million shares available for future grant. Upon adoption of the 2018 Plan, no new stock options or awards are issuable under the Second Amended and Restated 2012 Stock Plan (the "2012 Plan") or the 2015 Consultant Stock Plan (the "2015 Plan"). The 2018 Plan is the successor to and continuation of the 2012 Plan, as amended, and the 2015 Plan, and is administered with either stock options or restricted stock units. The 2018 Plan also provides for other types of equity to issue awards, which at this time the Company does not plan to utilize. The 2018 Plan was amended in March 2019 with 1.1 million shares available for future grant.

In December 2019, the Company adopted the Second Amended and Restated 2018 Equity Incentive Plan, which increased the number of shares available for future grant to 2.7 million shares. On March 4, 2020, the Board of Directors adopted the Third Amended and Restated 2018 Equity Incentive Plan (the "2018 Third Amended Plan"), which increased the number of shares available for future grant to a total of 7.6 million shares and was approved by stockholders on March 5, 2020. The Board of Directors administers the plans.

In January 2020, the Board of Directors approved the modification of the exercise price of certain outstanding stock options under the existing incentive plans. As a result of this modification, an additional stock-based compensation expense of $0.9 million is being recognized over the remaining vesting period for the unvested stock options.

Activity under the 2012 Plan, the 2015 Plan, and the 2018 Third Amended Plan for the nine months ended September 30, 2020, is set forth below (in thousands, except share and per share data):

	Stock Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance at December 31, 2019	2,561,866	$ 9.01		
Options granted	1,757,170	10.23		
Options exercised	(505,852)	1.14		
Options forfeited/cancelled	(281,607)	11.31		
Balance at September 30, 2020	3,531,577	$ 9.01	7.67	$ 3,965
Vested and expected to vest at September 30, 2020	3,531,577	$ 9.01	7.64	$ 3,965
Vested and exercisable at September 30, 2020	1,674,215	$ 7.98	5.81	$ 3,744

As of September 30, 2020, the number of shares available for grant under the 2018 Third Amended Plan was 4,109,953.

The Company uses the Black-Scholes option pricing model to estimate the fair value of each option grant on the date of grant or any other measurement date. The following table sets forth the assumptions used to determine the fair value of stock options granted during the nine months ended September 30, 2020:

	Nine Months Ended September 30, 2020
Risk-free interest rate	0.4% - 1.7%
Expected volatility	57.0% - 71.0%
Expected dividend yield	—
Expected life (years)	4.0 - 6.3 years

The following table presents total stock-based compensation expense included in each functional line item in the accompanying condensed consolidated statements of operations (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Cost of sales	$ 311	$ 59	$ 749	$ 161
Research and development	815	216	2,327	598
Selling and marketing	444	128	1,329	379
General and administrative	1,804	228	4,050	645
Total stock-based compensation expense	$ 3,374	$ 631	$ 8,455	$ 1,783

The weighted-average grant date fair value of options granted during the nine months ended September 30, 2020 and 2019 was $6.51 per option and $7.42 per option, respectively. At September 30, 2020 and December 31, 2019, there was $12.2 million and $4.1 million, respectively, of compensation cost related to unvested stock options expected to be recognized over a remaining weighted average vesting period of 3.01 years and 2.69 years, respectively.

12. Income Taxes

The Company calculates its interim income tax provision in accordance with ASC Topic 270, *Interim Reporting*, and Topic 740, *Accounting for Income Taxes*. At the end of each interim period, management estimates the annual effective tax rate and applies such rate to the Company's ordinary quarterly earnings to calculate income tax expense related to ordinary income. Due to maintenance of a full valuation allowance, the Company had a zero effective tax rate, prior to discretely recognized items, for the three and nine months ended September 30, 2020. The tax effects of items significant, unusual and infrequent in nature are discretely calculated and recognized in the period during which they occur.

On March 27, 2020, the CARES Act was enacted. The CARES Act includes several significant provisions for corporations, including those pertaining to net operating loss ("NOL") carryforwards, interest deductions and payroll tax benefits. Corporate taxpayers may carryback NOLs originating during 2018 through 2020 for up to five years. During the first quarter of 2020, the Company recorded a discrete tax benefit of $37.7 million related to the NOL carryback provisions available under the CARES Act legislation corresponding to anticipated tax refunds applicable to taxable years 2013, 2014, 2015, and 2017. If any tax refund is received that is more than $5.0 million in a single year, along with other civil settlements, damages awards, and tax refunds, the Company has agreed to pay 65% of all such amounts received to accelerate payments to the government in connection with the government settlement (see Note 9). During the nine months ended September 30, 2020, the Company received a tax refund of $38.4 million related to the NOL carryback provisions available under the CARES Act, including $15.7 million tax refund in the third quarter of 2020 related to the 2019 NOL.

The Company's NOL carryforwards and research and expenditure credit carryforwards may be subject to an annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), and similar state provisions if the Company experiences an ownership change within the meaning of such Code sections. In general, an ownership change, as defined by Sections 382 and 383 of the Code, occurs when there is a 50 percentage points or more shift in ownership, consisting of shareholders owning more than 5% in the Company, occurring within a three-year testing period. During the third quarter 2020, the Company completed a formal Section 382 study and concluded that an ownership change, within the meaning of Sections 382 and 383, limiting future utilization of existing tax attribute carry-forwards, had not occurred.

13. Net Loss Per Share

Net loss per share is computed by dividing net loss attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted loss per share reflects the additional dilution from potential issuances of common stock, such as stock issuable pursuant to the exercise of stock options, as well as from the possible conversion of the Company's preferred stock and exercise of the outstanding warrant. The treasury stock and if-converted methods are used to calculate the potential dilutive effect of these common stock equivalents. However, potentially dilutive shares are excluded from the computation of diluted loss per share when their effect is antidilutive. Due to the Company reporting a net loss attributable to common stockholders for all periods presented, all potentially dilutive securities were antidilutive and have been excluded from the computation of diluted loss per share.

The table below provides potentially dilutive securities in equivalent common shares not included in the Company's calculation of diluted loss per share because to do so would be antidilutive:

	September 30, 2020	September 30, 2019
Options to purchase common stock	3,531,577	2,571,297
Restricted stock units	1,194,077	316,481
Common stock warrant	400,160	—
Series A Preferred Stock	—	13,213,254
Series B Preferred Stock	—	10,187,272
Series B Preferred Stock Purchase Warrant	—	294,299
Total	5,125,814	26,582,603

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

General

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and notes thereto and other financial information included in this quarterly report on Form 10-Q, or this Quarterly Report, and the audited consolidated financial statements and notes thereto as of and for the years ended December 31, 2018 and 2019 and other financial information included in our final prospectus, or the Prospectus, filed with the Securities and Exchange Commission, or the SEC, pursuant to Rule 424(b) under the Securities Act of 1933, as amended, dated June 19, 2020. Unless the context requires otherwise, references in this Quarterly Report to "we," "us," and "our" refer to Progenity, Inc.

This Quarterly Report includes forward-looking statements that involve a number of risks, uncertainties and assumptions. These forward-looking statements can generally be identified as such because the context of the statement will include words such as "may," "will," "intend," "plan," "believe," "anticipate," "expect," "estimate," "predict," "potential," "continue," "likely," or "opportunity," the negative of these words or other similar words. Similarly, statements that describe our plans, strategies, intentions, expectations, objectives, goals or prospects and other statements that are not historical facts are also forward-looking statements. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Quarterly Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the time this Quarterly Report was filed with the SEC. These forward-looking statements are based largely on our expectations and projections about future events and future trends affecting our business, and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. These risks and uncertainties include, without limitation, the risk factors identified below and those discussed in the section titled "Risk Factors" included under Part II, Item 1A below. In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Except as required by law, we undertake no obligation to update publicly or revise our forward-looking statements.

OVERVIEW AND RECENT DEVELOPMENTS

We are a biotechnology company with an established track record of success in developing and commercializing molecular testing products as well as innovating in the field of precision medicine. We believe that we are a market-leading provider of in vitro molecular tests designed to improve lives by providing actionable information that helps guide patients and physicians in making critical and timely medical decisions during various life stages, such as family planning, pregnancy, or navigating a complex disease diagnosis. Our vision is to transform healthcare to become more precise and personal by improving diagnoses of disease and improving patient outcomes through localized treatment with targeted therapies. We apply a multi-omics approach, combining genomics, epigenomics, proteomics, and metabolomics, to our molecular testing products and to the development of a suite of investigational ingestible devices and drug/device combinations designed to provide precise diagnostic sampling and drug delivery solutions.

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. Our internal core competencies, deep research and development pipeline and strategic acquisitions of novel technologies have fueled our innovation in women's health, supporting the development and launch of complementary molecular testing products that inform critical healthcare decision-making across a woman's lifetime.

In 2015, we launched both our Innatal Prenatal Screen, a Non-Invasive Prenatal Testing, or NIPT, offering, and our Preparent Carrier Test, followed by the launch of our Riscover Hereditary Cancer Test in 2017. We offer molecular tests with market-leading performance and turnaround times, supported by end-to-end workflow solutions that increase administrative efficiencies. Along with our comprehensive menu of molecular tests, we offer patients pre-test education, clear and timely results, and on-demand genetic counseling. We are committed to providing patients and physicians with empathetic communication and support during critical moments to help empower and prepare patients and their families to make critical life decisions.

We generate revenue by providing tests. Our molecular tests are provided through our certified Clinical Laboratory Improvement Amendments, or CLIA, and College of American Pathologists, or CAP, accredited laboratory located in Ann Arbor, Michigan. We also provide anatomic and molecular pathology tests through our affiliation with Mattison Pathology, LLP, a Texas limited liability partnership doing business as Avero Diagnostics, located in Lubbock and Irving, Texas. The focus of our commercial operations is to distribute our molecular tests and our anatomic and molecular pathology tests through our dedicated direct sales force. Distribution of our tests is supported by a field operations team who provide all logistical functions in receiving clinical samples at the laboratory for analysis. In the second quarter of 2020, we added COVID-19 testing to our offering and in October 2020, we secured a substantial increase in our COVID-19 PCR testing capacity to more than 750,000 tests per annum as well as supply chain access through our existing business relationship.

During the three and nine months ended September 30, 2020, we accessioned approximately 84,067 and 237,908 tests, respectively.

We generate revenue through providing our tests and receiving payments for such tests from payors, laboratory distribution partners, and self-paying individuals. More than 95% of payments for our tests are received through reimbursement. We receive reimbursement from several distinct channels: commercial third-party payors, laboratory distribution partners, and government health benefits programs such as Medicare and Medicaid.

We are engaged in research and development activities with respect to molecular tests and precision medicine product candidates. Our molecular test portfolio and pipeline and our precision medicine product pipeline are each powered by a combination of symbiotic technology platforms exploiting advances in genetics, epigenetics, and proteomics, fortified by an innovative bioinformatics infrastructure. Our ecosystem is designed to enable rapid development and validation of products in an integrated fashion. We intend to continue to invest in our research and development activities as a public company. As a result, we expect to incur operating losses for the foreseeable future and may need to raise additional capital in order to fund our operations. Our ability to return to profitability will depend upon achieving our revenue growth objectives and successfully managing our costs.

In the third quarter of 2020, we successfully achieved a key milestone in the verification phase of our rule out assay for preeclampsia and announced an upcoming preeclampsia research and development day, which is scheduled for November 20, 2020.

Factors Affecting Our Performance.

We believe there are several important factors that impact our commercial performance and results of operations, including:

Report Volume

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. Our commercial team of more than 150 individuals actively engages with physicians and their staff to emphasize the clinical need for our products, provide education on the clinical value of our products, and facilitate the ability of physicians and their staff to order our tests. The 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. The historical ratio of the Innatal tests and the Preparent tests that we accession is approximately 1.2:1. As the types and categories of tests that are covered by reimbursement increase or decrease, the volume of testing may correspondingly increase or decrease, respectively. In 2019, we conducted a comprehensive review of our existing accounts and sought to eliminate accounts that did not contribute to our revenues and our gross margin. Our test volumes decreased as a result of this exercise.

Beginning in March 2020, we began to observe declines in the volumes of both our molecular tests and the pathology tests conducted by Avero Diagnostics due to the impact of the COVID-19 pandemic and resulting work-from-home policies and other operational limitations mandated by federal, state and local governments. However, we believe our business is resilient and we observed positive signs of recovery in the latter part of the second quarter and in the third quarter. While we have implemented and continue to monitor our 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 current 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 continue to change over time.

Reimbursement

Reimbursement fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- third-party payor coverage and, as we continually seek to transition to in-network coverage with commercial third-party payors, corresponding increases in our in-network covered lives;
- regulatory and medical society recommendations such CMS, the American College of Obstetricians and Gynecologists, or ACOG, ACMG, and SMFM, that potentially lead to positive coverage determinations by commercial third-party payors and government health benefits programs for our tests;
- third-party payor medical coverage and administrative policies, including reimbursement rates published by CMS;

- delays to third-party payors' processing due to the impact of the COVID-19 pandemic and resulting work-from-home policies and other operational limitations mandated by federal, state, and local governments;
- future CPT code and medical procedure code changes, such as obtaining appropriate codes for our new molecular tests, including our expanded carrier screening panels, NIPT, and Exon carrier screening;
- regulatory and payor fee schedule changes for CPT codes with respect to our products;
- requirements to refund any reimbursements already received;
- the overall mix of payor class for our products sold;
- changes in physician ordering trends;
- the mix of our products sold;
- the geographic regions in which our products are sold;
- competition in our industries and any change in the competitive landscape of our industries, including potential consolidation; and
- future accounting pronouncements or changes in our accounting policies.

Gross Margin

Our 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. Reducing the costs of goods sold for our tests represents another important opportunity for innovation and is a significant area of focus for our research and development organization. We regularly evaluate our operations in order to determine whether we can reduce costs by developing new technologies, improving the efficiency of our assay and laboratory processes, modifying our processes to use materials and technologies that provide equal or greater quality at lower cost, and improving how we manage our inventory and negotiating favorable terms for our materials purchases. In 2019, we conducted a comprehensive review of our existing accounts and sought to eliminate accounts that did not contribute to our revenues and gross margin. In future periods, we expect this to have a positive impact on our gross margin; however, such an impact cannot be assured. We are currently developing our next generation Innatal Prenatal Screen (Innatal 4th Generation), an improved platform with simplified and more cost-effective assay workflow, which we believe will allow us to substantially improve the gross margin of our NIPT. We also work with partner laboratories that complement our test portfolio offering, while developing in parallel new technologies that we expect could, over time, reduce our cost structure by internalizing the production of those tests when the commercial benefits dictate such conversion. We are now predominantly an in-network provider, with approximately 145 million covered lives nationwide under our agreements with commercial third-party payors following the recent additions of in-network contracts with Aetna and Cigna. While we continue our contract negotiation process with several additional large commercial third-party payors, the transition to establishing ourselves as an in-network provider is expected to lead to an increase in the proportion of tests paid and allow us to gain access to a larger in-network patient base.

New Product Development

Our business involves significant investment in research and development activities for the development of new products which we believe are strategic complements to our product portfolio and drive long-term revenue growth. We intend to continue investing in our pipeline of new products and technologies. We expect our investment in research and development to increase as we pursue regulatory approval of our product candidates and as we seek to expand our pipeline of product candidates. Due to the impact of the COVID-19 pandemic and resulting work-from-home policies and other operational limitations mandated by federal, state, and local governments, certain of our research and development activities have been delayed and may be further delayed until such operational limitations are lifted. While we are implementing mitigation strategies, where possible, certain preclinical and clinical activities were suspended during the implementation of these policies and will necessarily incur some delay following the resumption of normal operations. While some of our research and development laboratory work was impacted by the stay-at-home shutdown, especially in our Michigan facilities, our preeclampsia test verification work restarted in June and has now migrated to the operations laboratory, which is part of our essential services, and is, therefore, less exposed to further shutdowns caused by the COVID-19 pandemic. However, the development of our new products could continue to be delayed if any stay-at-home orders in the State of Michigan are reinstated.

The achievement of key development milestones (e.g., clinical verification and validation and CLIA certification for our molecular tests and clinical studies and regulatory approval for our precision medicine product platform) is a key factor in evaluating our performance.

Key Components of Our Results of Operations.

Revenue

Substantially all of our revenue is derived from molecular laboratory tests, principally from the sale of Innatal, Preparent, and pathology molecular testing. Historically, the revenue we derive from our Innatal tests and our Preparent tests has been roughly equal, although the ratio fluctuates from time to time. We bill and collect from third-party payors, laboratory distribution partners, and self-paying individuals. Third-party payors include commercial third-party payors and government payors, such as Medicare and Medicaid in the United States. We bill for these tests rendered upon completion of the testing process and delivery of test results to the customer.

Due to potential future changes in insurance coverage policies, contractual rates, and other trends in the reimbursement of our tests, payments received for our tests may fluctuate significantly over time. Our revenue incorporates an estimate of variable consideration, which is adjusted for estimates of disallowed cases, discounts, and refunds. 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. Our estimate of variable consideration included in the transaction price is also impacted by our ongoing transition to in-network contracts with commercial payors.

Currently, we operate primarily as an in-network provider of molecular tests and we continually seek to transition to in-network coverage with additional third-party payors, which we believe is crucial to our growth and long-term success. This transition is ongoing, and we are actively negotiating with a few remaining commercial payors. We are currently contracted with payors representing an estimated 145 million covered lives.

While the negotiated fees under our in-network contracts with third-party payors are typically lower than the out-of-network list price of our tests, the percentage of tests allowed by payors traditionally increases in accordance with payors' medical policies. While we expect the reduction in average reimbursement per test from in-network pricing to reduce our per test revenue and gross margins in the near term, in-network pricing is more predictable than out-of-network pricing, and we intend to continue to mitigate the impact by implementing a strategic focus for our most profitable accounts.

Delays to third-party payors' processing due to the impact of the COVID-19 pandemic and resulting work-from-home policies and other operational limitations mandated by federal, state, and local governments have and may continue to extend the typical timelines. These factors might delay the time period in which cash is collected from payors and impact our revenue recognition. We believe that the full impact of these delays may not yet have been reflected in our financial performance, as we customarily receive payment several months after completion of a molecular test.

Cost of Sales

Cost of sales includes the cost of materials, direct labor of laboratory personnel, third-party laboratory testing services, equipment, and infrastructure expenses associated with processing blood and other samples, quality control analyses, shipping charges to transport samples and specimens from ordering physicians, clinics, or individuals, and allocated overhead, including information technology, or IT, costs. Infrastructure expenses include allocated facility and related occupancy costs. Costs associated with the performance of molecular tests are recorded as tests are processed. We have implemented and continue to monitor mitigation strategies to address the work-from-home policies and other operational limitations mandated by federal, state, and local governments as a result of the COVID-19 pandemic. While largely yet to be determined, these mitigation strategies may cause increases in any or all of the aforementioned costs. The amount of cost of sales is related to our volume of accessioned tests, which is directly related to consumption of reagents and other laboratory support services. Therefore, growth in accessioned volume of tests results in increased cost of sales on an aggregate basis and potential modest reductions in cost of sales on a per-test basis.

Research and Development

Research and development expenses consist primarily of costs associated with performing research and development activities to improve our tests, to reduce product costs, and to develop new products including our preeclampsia test and our precision medicine product candidates. Research and development expenses also consist of personnel expenses, including salaries, bonuses, stock-based compensation expense, benefits, consulting costs, and allocated overhead costs. Research and development costs are expensed as incurred.

We plan to continue investing in research and development activities for the foreseeable future as we focus on developing innovative products, including our preeclampsia test and our precision medicine product candidates, through preclinical studies and

clinical trials. We also expect our investment in research and development to increase as we pursue regulatory approval of our product candidates and as we seek to expand our pipeline of product candidates.

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, certain of our research and development activities have been delayed and may be further delayed until such operational limitations are lifted or if they are reinstated. While we have implemented and continue to monitor mitigation strategies, where possible, certain preclinical and clinical activities are suspended during the implementation of these policies and will necessarily incur some delay following the resumption of normal operations.

Selling and Marketing

Selling and marketing expenses consist primarily of personnel costs, including salaries, commissions, bonuses, stock-based compensation expense, and benefits for our sales and marketing team. Selling and marketing expenses also include costs for communication, advertising, conferences, other marketing events, and allocated overhead costs. We expect selling and marketing expense to continue to increase as we increase the size of our selling and marketing function to support the growth of our business. We have implemented and continue to monitor mitigation strategies to address the work-from-home policies and other operational limitations mandated by federal, state, and local governments as a result of the COVID-19 pandemic. While largely yet to be determined, these mitigation strategies include virtual meetings and mobile phlebotomy services for patients preferring not to visit a physician’s office. These strategies and others may cause increases in our sales and marketing costs.

General and Administrative

General and administrative expenses consist primarily of personnel costs, including salaries, bonuses, stock-based compensation expense, and benefits, for our finance and accounting, legal, human resources, and other administrative teams. Additionally, these expenses include professional fees of audit, legal, and recruiting services. Following the listing of our common stock on Nasdaq, we expect to continue to incur additional expenses as a result of operating as a public company, including costs to comply with the rules and regulations applicable to companies listed on a U.S. securities exchange and costs related to compliance and reporting obligations pursuant to the rules and regulations of the SEC. In addition, as a public company, we expect to incur increased expenses in the areas of insurance, investor relations, and professional services. Furthermore, we expect to incur expenses related to maintaining compliance with the stipulations of the government settlement and the legal costs associated with the Natera lawsuit and IPO related litigation described in Part II, Item 1. “Legal Proceedings” in this Quarterly Report. As a result, we expect the dollar amount of our general and administrative expenses to increase for the foreseeable future. We expect, however, that our general and administrative expenses will decrease as a percentage of our revenue over time, although the percentage may fluctuate from period to period depending on fluctuations in our revenue and the timing and extent of our general and administrative expenses.

Interest Expense

Interest expense is primarily attributable to borrowings under our Credit Agreement (as defined below). Interest expense is also attributable to our outstanding mortgages and capital lease agreements.

Interest and Other Income (Expense), Net

Interest and other income, net primarily consists of loss on extinguishment of convertible note debt in the second quarter of 2020 and interest income earned from our cash and cash equivalents, and changes in fair value of short-term investments.

Income Tax Provision

We account for income taxes under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

We recognize the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is more than 50% likely of being realized. Changes in recognition or measurement are recognized in the period in which the change in judgment occurs. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. Due to losses generated in the past and projected future taxable losses anticipated in the future, we established a 100% valuation allowance on net deferred tax assets.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted. The CARES Act includes several significant provisions for corporations, including the usage of net operating losses, interest deductions and payroll benefits. Corporate taxpayers may carryback net operating losses, or NOLs, originating during 2018 through 2020 for up to five years. During the three months ended March 31, 2020, we recorded a discrete tax benefit of $37.7 million related to the NOL carryback provisions available under the CARES Act legislation for taxes paid in years 2013, 2014, 2015, and 2017. If any tax refund is received that is more than $5.0 million in a single year, along with other civil settlements, damages awards, and tax refunds, we have agreed to pay 65% of all such amounts received to accelerate payments to the government in connection with our proposed government settlement. During the nine months ended September 30, 2020, we received tax refunds totaling $38.4 million related to the NOL carryback provisions available under the CARES Act, including a $15.7 million tax refund related to NOLs originating during 2019, which we received in the third quarter of 2020. See Part II, Item 1. “Legal Proceedings—Federal Investigation” in this Quarterly Report.

Results of Operations.

Comparison of Three Months Ended September 30, 2020 and 2019

	Three Months Ended September 30,	
	2020	2019
Statement of Operations Data:	(in thousands) (unaudited)	
Revenues	$ 25,943	$ 18,772
Cost of sales	23,601	24,997
Gross profit (loss)	2,342	(6,225)
Operating expenses:		
Research and development	13,043	17,080
Selling and marketing	13,244	15,263
General and administrative	20,626	16,273
Total operating expenses	46,913	48,616
Loss from operations	(44,571)	(54,841)
Interest expense	(2,476)	(2,321)
Interest and other income (expense), net	(18)	29
Net loss	$ (47,065)	$ (57,133)

Percentage of Revenue Data:	Three Months Ended September 30, 2020 (unaudited)	2019 (unaudited)
Revenues	100%	100%
Cost of sales	91	133
Gross profit (loss)	9	(33)
Operating expenses:		
Research and development	50	91
Selling and marketing	51	81
General and administrative	80	87
Total operating expenses	181	259
Loss from operations	(172)	(292)
Interest expense	(10)	(12)
Interest and other income (expense), net	—	—
Net loss	(181)%	(304)%

Revenue

	Three Months Ended September 30, 2020 (in thousands) (unaudited)	2019 (in thousands) (unaudited)	Increase/ (Decrease)	% Change
Revenues	$ 25,943	$ 18,772	$ 7,171	38.2%

Revenue was $25.9 million for the three months ended September 30, 2020, compared to $18.8 million for the three months ended September 30, 2019, an increase of $7.2 million, or 38.2%.

The increase in revenue was primarily attributable to an accrual of $15.9 million related to the settlement with the DOJ and the participating State AGs in the third quarter of 2019 partially offset by a decrease in test volumes in the third quarter of 2020 as a result of the COVID-19 pandemic, and rate degradation due to payor policy changes.

Cost of Sales

	Three Months Ended September 30, 2020 (in thousands) (unaudited)	2019 (in thousands) (unaudited)	Increase/ (Decrease)	% Change
Cost of sales	$ 23,601	$ 24,997	$ (1,396)	(5.6)%

Cost of sales was $23.6 million for the three months ended September 30, 2020, compared to $25.0 million for the three months ended September 30, 2019, a decrease of $1.4 million, or 5.6%.

The decrease in cost of sales was primarily due to a decrease in test volumes during the three months ended September 30, 2020 compared to the three months ended September 30, 2019 as a result of the COVID-19 pandemic, partially offset by higher stock-based compensation expenses following our IPO in June 2020.

Research and Development Expenses

	Three Months Ended September 30,		Increase/	
	2020	2019	(Decrease)	% Change
	(in thousands) (unaudited)			
Research and development	$ 13,043	$ 17,080	$ (4,037)	(23.6)%

Research and development expenses were $13.0 million for the three months ended September 30, 2020, compared to $17.1 million for the three months ended September 30, 2019, a decrease of $4.0 million, or 23.6%.

The decrease in research and development expenses was primarily attributable to a $3.6 million decrease in consulting costs, as well as a $1.0 million decrease in supplies costs and other expenses, partially offset by a $0.8 million increase in salaries and stock-based compensation expenses.

The following table summarizes the changes in research and development expenses from the three months ended September 30, 2020, to the three months ended September 30, 2019, with costs broken down by program:

	Three Months Ended September 30,	
	2020	2019
	(in thousands) (unaudited)	
Molecular testing	$ 7,253	$ 8,114
Precision medicine	5,790	8,966
Total research and development expenses	$ 13,043	$ 17,080

Selling and Marketing Expenses

	Three Months Ended September 30,		Increase/	
	2020	2019	(Decrease)	% Change
	(in thousands) (unaudited)			
Selling and marketing	$ 13,244	$ 15,263	$ (2,019)	(13.2)%

Selling and marketing expenses were $13.2 million for the three months ended September 30, 2020, compared to $15.3 million for the three months ended September 30, 2019, a decrease of $2.0 million, or 13.2%.

The decrease in selling and marketing expenses was primarily attributable to a $1.4 million decrease in travel and entertainment costs due to a reduction in travel during the three months ended September 30, 2020 as a result of the COVID-19 related restrictions and associated work-from-home policies and a decrease of $0.5 million in advertising and promotion costs.

General and Administrative Expenses

	Three Months Ended September 30,		Increase/	
	2020	2019	(Decrease)	% Change
	(in thousands) (unaudited)			
General and administrative	$ 20,626	$ 16,273	$ 4,353	26.7%

General and administrative expenses were $20.6 million for the three months ended September 30, 2020, compared to $16.3 million for the three months ended September 30, 2019, an increase of $4.4 million, or 26.7%.

The increase in general and administrative expenses was primarily attributable to a $2.3 million increase in salaries and personnel-related costs, a $1.5 million increase in consulting and professional costs, primarily related to legal costs associated with our

government settlement negotiations, and a $1.5 million increase in our business insurance costs, partially offset by a decrease of $1.1 million in supplies costs.

Interest Expense

	Three Months Ended September 30,		Increase/ (Decrease)	% Change
	2020	2019		
	(in thousands) (unaudited)			
Interest expense	$ (2,476)	$ (2,321)	$ (155)	6.7%

Interest expense increased by $0.2 million, or 6.7%, from the three months ended September 30, 2019 to the three months ended September 30, 2020.

Comparison of Nine Months Ended September 30, 2020 and 2019

	Nine Months Ended September 30,	
	2020	2019
Statement of Operations Data:	(in thousands) (unaudited)	
Revenues	$ 60,037	$ 123,509
Cost of sales	72,006	75,531
Gross profit (loss)	(11,969)	47,978
Operating expenses:		
Research and development	36,517	48,791
Selling and marketing	40,416	45,510
General and administrative	54,915	44,823
Total operating expenses	131,848	139,124
Loss from operations	(143,817)	(91,146)
Interest expense	(7,285)	(6,872)
Interest and other income (expense), net	(3,594)	457
Loss before income taxes	(154,696)	(97,561)
Income tax benefit	(37,696)	—
Net loss	$ (117,000)	$ (97,561)

	Nine Months Ended September 30,	
	2020	2019
Percentage of Revenue Data:	(unaudited)	
Revenues	100%	100%
Cost of sales	120	61
Gross profit (loss)	(20)	39
Operating expenses:		
Research and development	61	40
Selling and marketing	67	37
General and administrative	91	36
Total operating expenses	220	113
Loss from operations	(240)	(74)
Interest expense	(12)	(5)
Interest and other income (expense), net	(6)	—
Loss before income taxes	(258)	(79)
Income tax benefit	(63)	—
Net loss	(195)%	(79)%

Revenue

	Nine Months Ended September 30,		Increase/	
	2020	2019	(Decrease)	% Change
	(in thousands) (unaudited)			
Revenues	$ 60,037	$ 123,509	$ (63,472)	(51.4)%

Revenue was $60.0 million for the nine months ended September 30, 2020, compared to $123.5 million for the nine months ended September 30, 2019, a decrease of $63.5 million, or 51.4%. The decrease in revenues during the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 was largely attributable to an accrual of $13.2 million related to the settlement with the DOJ and the participating State AGs in the first quarter of 2020, an accrual of $10.3 million for refunds to government payors, which we repaid in early October 2020, combined with a decrease in test volumes as a result of the COVID-19 pandemic during the second and third quarter of 2020, and rate degradation due to payor policy changes.

Cost of Sales

	Nine Months Ended September 30,		Increase/	
	2020	2019	(Decrease)	% Change
	(in thousands) (unaudited)			
Cost of Sales	$ 72,006	$ 75,531	$ (3,525)	(4.7)%

Cost of sales was $72.0 million for the nine months ended September 30, 2020, compared to $75.5 million for the nine months ended September 30, 2019, a decrease of $3.5 million, or 4.7%.

The decrease in cost of sales was primarily due to a decrease in test volumes in the second and third quarter of 2020 as a result of the COVID-19 pandemic, partially offset by higher stock-based compensation expense following the IPO in June 2020.

Research and Development Expenses

	Nine Months Ended September 30,		Increase/	
	2020	2019	(Decrease)	% Change
	(in thousands) (unaudited)			
Research and development	$ 36,517	$ 48,791	$ (12,274)	(25.2)%

Research and development expenses were $36.5 million for the nine months ended September 30, 2020, compared to $48.8 million for the nine months ended September 30, 2019, a decrease of $12.3 million, or 25.2%.

The decrease in research and development expenses was primarily attributable to a $11.9 million decrease in consulting costs, as well as a $3.5 million decrease in supplies costs and other expenses, partially offset by a $3.5 million increase in salaries and stock-based compensation expenses.

The following table summarizes the changes in research and development expenses from the nine months ended September 30, 2020, to the nine months ended September 30, 2019, with costs broken down by program:

	Nine Months Ended September 30,	
	2020	2019
	(in thousands) (unaudited)	
Molecular testing	$ 20,419	$ 24,695
Precision medicine	16,098	24,096
Total research and development expenses	$ 36,517	$ 48,791

Selling and Marketing Expenses

	Nine Months Ended September 30,		Increase/	
	2020	2019	(Decrease)	% Change
	(in thousands) (unaudited)			
Selling and marketing	$ 40,416	$ 45,510	$ (5,094)	(11.2)%

Selling and marketing expenses were $40.4 million for the nine months ended September 30, 2020, compared to $45.5 million for the nine months ended September 30, 2019, a decrease of $5.1 million, or 11.2%.

The decrease in selling and marketing expenses was primarily attributable to a $3.7 million decrease in travel and entertainment costs due to a reduction in travel during the nine months ended September 30, 2020 as a result of the COVID-19 related restrictions and associated work-from-home policies and a decrease of $0.7 million in salaries and personnel-related costs.

General and Administrative Expenses

	Nine Months Ended September 30,		Increase/	
	2020	2019	(Decrease)	% Change
	(in thousands) (unaudited)			
General and administrative	$ 54,915	$ 44,823	$ 10,092	22.5%

General and administrative expenses were $54.9 million for the nine months ended September 30, 2020, compared to $44.8 million for the nine months ended September 30, 2019, an increase of $10.1 million, or 22.5%.

The increase in general and administrative expenses was primarily attributable to a $5.5 million increase in salaries and stock-based compensation expenses, a $4.7 million increase in consulting and professional costs, primarily related to legal costs associated with our government settlement negotiations and litigation, and a $2.0 million increase in business insurance costs. These increases were partially offset by a decrease of $2.9 million in supplies costs.

Interest Expense

	Nine Months Ended September 30,		Increase/	
	2020	2019	(Decrease)	% Change
	(in thousands) (unaudited)			
Interest expense	$ (7,285)	$ (6,872)	$ (413)	6.0%

Interest expense increased by $0.4 million, or 6.0%, from the nine months ended September 30, 2019 to the nine months ended September 30, 2020.

Interest and Other Income (Expense), Net

	Nine Months Ended September 30,		Increase/	
	2020	2019	(Decrease)	% Change
	(in thousands) (unaudited)			
Interest and other income (expense), net	$ (3,594)	$ 457	$ (4,051)	*

* - The change is more than 100%

Interest and other expense, net, was $3.6 million for the nine months ended September 30, 2020, compared to interest and other income, net of $0.5 million for the nine months ended September 30, 2019. This change was primarily due to a $3.6 million loss on

extinguishment of debt associated with the conversion of an unsecured promissory note into shares of common stock upon completion of the IPO.

Income Tax Benefit

	Nine Months Ended September 30,		Increase/	
	2020	2019	(Decrease)	% Change
	(in thousands)			
	(unaudited)			
Income tax provision (benefit)	$ (37,696)	$ —	$ (37,696)	(100.0)%

Income tax benefit was $37.7 million for the nine months ended September 30, 2020, while income tax benefit was zero for the nine months ended September 30, 2019. The tax benefit during the nine months ended September 30, 2020 was recorded due to the net operating loss carryback provisions available under the CARES Act legislation enacted in March 2020. During the year ended December 31, 2018, we established a full valuation allowance on net deferred tax assets due to losses generated in 2018 and projected taxable losses anticipated in the future. Due to the valuation allowance on deferred tax assets, no tax benefit was recorded for our net loss in the nine months ended September 30, 2019.

Liquidity and Capital Resources.

Since our inception, our primary sources of liquidity have been generated by our operations, sales of common stock and preferred stock, and cash from debt financings.

As of September 30, 2020, we had $60.0 million of cash and cash equivalents, a $75.0 million term loan outstanding with a private equity firm, and mortgages outstanding of $3.1 million. Our accumulated deficit as of September 30, 2020, was $465.7 million. For the nine months ended September 30, 2020, we had a net loss of $117.0 million and cash used in operations of $95.7 million. Our primary requirements for liquidity have been to fund our working capital needs, capital expenditures, dividends, research and development, and general corporate needs, as well as to invest in or acquire companies or technologies that are synergistic with or complimentary to our business.

Based on our planned operations, we do not expect that our current cash and cash equivalents will be sufficient to fund our operations for at least 12 months from the issuance date of the condensed consolidated financial statements for the three and nine months ended September 30, 2020. We intend to raise additional capital through equity offerings and/or debt financings or from other potential sources of liquidity, which may include new collaborations, licensing or other commercial agreements for one or more of our research programs or patent portfolios. Adequate funding, if needed, may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or other operations. If any of these events occur, our ability to achieve our operational goals would be adversely affected. Our future capital requirements and the adequacy of available funds will depend on many factors, including those described in “Risk Factors.” Depending on the severity and direct impact of these factors on us, we may be unable to secure additional financing to meet our operating requirements on terms favorable to us, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

Credit and Security Agreements, Series B Preferred Stock, and Convertible Notes

On October 27, 2017, we entered into a credit and security agreement, or the Credit Agreement, with a fund managed by Athyrium, as collateral agent and a lender. The Credit Agreement provided for a term loan of $75.0 million. The Credit Agreement contains customary covenants, including a requirement to maintain a minimum unrestricted cash balance at all times of at least $5.0 million. The term loan is secured by all our tangible and intangible property assets, with the exception of our intellectual property. The term loan accrues interest at a rate per annum equal to 9.5% and is due October 27, 2022. We also entered into a Series B Preferred Stock Purchase Agreement, or the 2017 Series B Stock Purchase Agreement, with the same fund managed by Athyrium, which provided for the sale of 14,164,306 shares of Series B Preferred Stock at a purchase price of $3.53 per share for an aggregate purchase price of $50.0 million. The purchase price was paid in the form of (i) cash in an amount equal to $37.5 million and (ii) the delivery of 3,489,885 shares of our Series A-2 Preferred Stock, which shares of Series A-2 Preferred Stock had been purchased from Dr. Stylli, our Chairman and Chief Executive Officer, for $12.5 million. Concurrent with such transactions, Dr. Stylli converted the remaining 624,605 shares of Series A-2 Preferred Stock that he held into 633,766 shares of our common stock and we retired all shares of Series

A-2 Preferred Stock. In connection with the 2017 Series B Stock Purchase Agreement, the fund managed by Athyrium received a warrant to purchase an additional 1,416,431 shares of Series B Preferred Stock.

The total proceeds of $124.2 million were allocated to the term loan, the Series B Preferred Stock, and Series B Preferred Stock Purchase Warrant based on the relative fair values of the term loan, equity, and warrant issued. As a result, we allocated proceeds of $65.7 million to the term loan. As the proceeds allocated to the term loan were lower than the stated loan amount of $75.0 million, the resulting $9.3 million discount is amortized to interest expense using the effective interest method over the term of the loan.

During the three months ended September 30, 2020 and 2019, we recognized interest expense on the term loan of $2.4 million and $2.2 million, respectively. During the nine months ended September 30, 2020 and 2019, we recognized interest expense on the term loan of $7.1 million and $6.6 million, respectively.

In connection with the IPO, on June 18, 2020, the Series B Preferred Stock Purchase Warrant became exercisable for 400,160 shares of common stock.

On August 27, 2019, we entered into a Series B Preferred Stock Purchase Agreement with Athyrium Opportunities III Acquisition LP, a fund managed by Athyrium, pursuant to which we issued 9,090,910 shares of Series B Preferred Stock at $2.75 per share for an aggregate purchase price of $25.0 million. A 1.283636364-for-1 stock split for our Series B Preferred Stock shares and Series B Preferred Stock Purchase Warrant issued and outstanding previously was effected on August 27, 2019 pursuant to an amendment and restatement of our amended and restated certificate of incorporation. As a result of the stock split, we issued an additional 4,017,512 shares of Series B Preferred Stock and adjusted the Series B Preferred Stock Purchase Warrant to be a warrant to purchase 1,818,182 shares of Series B Preferred Stock. On August 27, 2019, we executed an exchange agreement with our Series A-1 Preferred Stock holders, pursuant to which 1,500,000 outstanding shares of Series A-1 Preferred Stock were exchanged for 35,664,240 shares of Series B Preferred Stock.

On November 12, 2019, we entered into a Series B Stock Preferred Stock Purchase Agreement, or the 2019 Series B Stock Purchase Agreement, with Athyrium Opportunities III Acquisition 2 LP, a fund managed by Athyrium, pursuant to which we issued an additional 11,111,111 shares of Series B Preferred Stock at $2.25 per share for an aggregate purchase price of $25.0 million. A 1.22222222-for-1 stock split for our Series B Preferred Stock shares and Series B Preferred Stock Purchase Warrant issued and outstanding previously was effected on November 12, 2019, pursuant to an amendment and restatement of our amended and restated certificate of incorporation. The conversion price of the Series B Preferred Stock and exercise price of the outstanding Series B Preferred Stock Purchase Warrant were lowered from $2.75 to $2.25 per share (or $13.90 per share as a result of the reverse stock split effected on June 10, 2020). As a result of the stock split effected on November 12, 2019, we issued an additional 13,985,993 shares of Series B Preferred Stock and adjusted the Series B Preferred Stock Purchase Warrant to be a warrant to purchase 2,222,222 shares of Series B Preferred Stock.

On November 22, 2019, we completed an additional equity financing pursuant to the 2019 Series B Stock Purchase Agreement executed on November 12, 2019 with Beaver Creek Intermediate Fund, Ltd., an existing investor and Dr. Stylli, our Chairman and Chief Executive Officer, for an aggregate purchase price of $6.1 million. We issued an aggregate of 2,722,222 shares of Series B Preferred Stock at a purchase price of $2.25 per share.

On December 19, 2019, we completed an additional equity financing pursuant to the 2019 Series B Stock Purchase Agreement executed on November 12, 2019 with Athyrium Opportunities III Acquisition 2 LP for an aggregate purchase price of $25.0 million. We issued on aggregate of 11,111,111 shares of Series B Preferred Stock at a purchase price of $2.25 per share.

On February 28, 2020, we completed an additional equity financing pursuant to the 2019 Series B Stock Purchase Agreement executed on November 12, 2019 with Athyrium Opportunities III Acquisition 2 LP and Dr. Stylli, our Chairman and Chief Executive Officer, for an aggregate purchase price of $11.4 million. We issued an aggregate of 5,066,666 shares of Series B Preferred Stock at a purchase price of $2.25 per share.

On March 31, 2020, we entered into the First Amendment to the Credit Agreement, or the Credit Agreement Amendment, with the collateral agent and lender party thereto, providing for the payment of interest due and payable as of March 31, 2020 in shares of our Series B Preferred Stock, and further providing for the payment of interest due and payable as of June 30, 2020 in shares of our Series B Preferred Stock in the event our IPO had not been consummated by such date. Pursuant to the Credit Agreement Amendment, we concurrently entered into a Series B Preferred Stock Subscription Agreement, or the Subscription Agreement, with the lender, which provided for the issuance of 967,130 shares of Series B Preferred Stock at a subscription price of $2.25 per share, as payment for interest due and payable as of March 31, 2020 and all applicable fees as set forth in the Credit Agreement Amendment. The Subscription Agreement further provided for a potential additional issuance of shares of Series B Preferred Stock as payment for

the interest due and payable under the Credit Agreement as of June 30, 2020, in the event our IPO had not been consummated by such date, with the amount of shares to be determined at such time.

On April 3, 2020, we entered into a Series B Preferred Stock Purchase Agreement with Athyrium Opportunities III Acquisition 2 LP, pursuant to which we issued an additional 4,444,444 shares of Series B Preferred Stock at $2.25 per share for an aggregate purchase price of $10.0 million.

On May 8, 2020, we entered into a Note Purchase Agreement with Athyrium Opportunities 2020 LP, a fund managed by Athyrium, pursuant to which we issued and sold an unsecured convertible promissory note, or the Convertible Note, with an annual interest rate of 8.0% and in an aggregate principal amount of $15.0 million. The Convertible Note had a maturity date of May 8, 2022 and was convertible at the option of the holder into shares of our common stock at a per share conversion price of the lesser of $13.90 and eighty percent of the public price. In connection with the issuance and sale of the Convertible Note, we entered into (i) the Second Amendment to the Credit Agreement, dated May 6, 2020, or the Second Credit Agreement Amendment, allowing for the creation or incurrence of certain indebtedness and the making of payments, in each case, in respect of the Convertible Note, among other matters, and (ii) the Second Amendment to Series B Preferred Stock Warrant, dated May 8, 2020, providing for the removal of certain restrictive exercise provisions in the Series B Preferred Stock Purchase Warrant. In June 2020, in connection with completion of our IPO, the Note was converted into 1,250,000 shares of common stock and all obligations under the Convertible Note were extinguished.

Mortgages

In January 2014, we executed a mortgage with Comerica Bank for $1.8 million for the purpose of acquiring a facility located in Ann Arbor, Michigan, which was previously leased by us and is used primarily for laboratory testing and research purposes. The outstanding balance was $1.4 million as of each of September 30, 2020 and December 31, 2019. The mortgage matures in 2024 and requires monthly principal and interest payments at a fixed interest rate of 2.94% plus a floating rate at LIBOR. We also have a mortgage with American Bank of Commerce (originally executed in February 2008) outstanding on Avero Diagnostic's property located in Lubbock, Texas, which is used primarily for laboratory testing. The outstanding balance was $1.8 million and $1.9 million as of September 30, 2020 and December 31, 2019, respectively. The mortgage matures in 2029 and requires monthly principal and interest payments at an interest rate of 3.25%.

Cash Flows

Our primary uses of cash are to fund our operations and research and development as we continue to grow our business. We expect to continue to incur operating losses in future periods as our operating expenses increase to support the growth of our business. We expect that our research and development, selling and marketing, and general and administrative expenses will continue to increase as we expand our marketing efforts and increase our internal sales force to drive increased adoption of and reimbursement for our tests, continue our research and development efforts with respect to our current tests and further develop our product pipeline, including our preeclampsia test and precision medicine products under development. Cash used to fund operating expenses is impacted by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

The following table summarizes our cash flows for the periods indicated:

	Nine Months Ended September 30,	
	2020	2019
Cash used in operating activities	$ (95,687)	$ (60,279)
Cash (used in) provided by investing activities	(3,109)	17,333
Cash provided by financing activities	125,767	19,991

Net cash used in operating activities in the nine months ended September 30, 2020 of $95.7 million was primarily attributable to a $117.0 million net loss, adjusted for $40.6 million of non-cash charges, primarily driven by $22.8 million of noncash revenue reserve, $8.5 million of stock-based compensation expense, and $3.8 million of depreciation and amortization expense. The net cash outflow from changes in operating assets and liabilities of $19.3 million was attributable to a $29.8 million increase in accrued expenses and other liabilities, offset by an $8.8 million decrease in accounts receivable.

Net cash used in operating activities in the nine months ended September 30, 2019 of $60.3 million was primarily attributable to a $97.6 million net loss, adjusted for $26.5 million of non-cash charges, primarily driven by $19.9 million of noncash revenue reserve, $3.5 million of depreciation and amortization, and $1.8 million of stock-based compensation expense. The net cash inflow from

changes in operating assets and liabilities of $10.7 million was primarily the result of a $10.7 million increase in accounts payable due to the timing of payments, a $6.2 million decrease in income tax receivable, and a $0.7 million decrease in accounts receivable. These cash inflows were partially offset by a $3.7 million increase in inventory and a $2.6 million increase in prepaid expenses and other current assets.

Net cash used in investing activities during the nine months ended September 30, 2020 of $3.1 million was attributable to the purchase of property and equipment. Net cash provided by investing activities during the nine months ended September 30, 2019 of $17.3 million was primarily driven by $31.4 million in proceeds from the sale of short-term investments. The cash inflow was partially offset by cash outflows of $11.2 million for purchases of short-term investments and $2.9 million for purchases of property and equipment.

Net cash provided by financing activities during the nine months ended September 30, 2020 of $125.8 million was primarily attributable to $90.3 million in net proceeds from the issuance of common stock, $21.3 million in net proceeds from the issuance of Series B Preferred Stock and $14.9 million in net proceeds from the issuance of a convertible note, partially offset by $0.6 million in principal payments on capital lease obligations and $0.2 million in principal payments on mortgages payable. Net cash provided by financing activities during the nine months ended September 30, 2019 of $20.0 million was primarily attributable to $25.0 million in proceeds from the issuance of Series B Preferred Stock and $0.5 million in proceeds from issuance of common stock, partially offset by $4.5 million in dividends paid, $0.8 million in principal payments on capital lease obligations, and $0.2 million in principal payments on mortgages payable.

Off-Balance Sheet Arrangements.

As of September 30, 2020, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities, that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical Accounting Policies and Significant Judgments and Estimates.

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in conformity with GAAP. The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions about future events that affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenue and expenses. These estimates and assumptions are based on management's best estimates and judgment. Management regularly evaluates its estimates and assumptions using historical experience and other factors; however, actual results could differ materially from these estimates and could have an adverse effect on our financial statements.

During the nine months ended September 30, 2020, there were no significant changes to the information discussed under "Critical Accounting Policies and Significant Judgments and Estimates" included in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of the Prospectus, except for the determination of the fair value of our common stock, which is used in estimating the fair value of stock options at the grant date. Prior to the IPO, our common stock was not publicly traded, therefore we estimated the fair value of our common stock as discussed in the Prospectus. Following the IPO, the fair value of our common stock is determined by reference to the closing selling price per share of our common stock as reported on the Nasdaq Global Market on the date of grant or other relevant determination date.

Recent Accounting Pronouncements.

Refer to Note 2, "Summary of Significant Accounting Policies" to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for information on recently issued accounting pronouncements.

JOBS Act Accounting Election.

We are an emerging growth company, as defined in the JOBS Act. Under this act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period and, as a result, our financial statements may not be comparable to companies that comply with public company effective dates. We also intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business.

Interest Rate Risk

Our exposure to risks related to interest rates is minimal. The interest rates for most of our indebtedness, including under our Credit Agreement and our equipment financing facility, are fixed rates. Our Ann Arbor mortgage, with an initial principal amount of $1.8 million, has a floating interest rate of 2.94% plus a floating rate at LIBOR. Such interest-bearing instruments carry a degree of risk; however, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements. Our cash and cash equivalents consist primarily of highly liquid investments in money market funds and cash on hand, and have an original maturity date of 90 days or less. The fair value of our cash and cash equivalents would not be significantly affected by either an increase or decrease in interest rates, due mainly to the short-term nature of these instruments.

Foreign Currency Risk

Our operations are currently conducted primarily in the United States. As we expand internationally, our results of operations and cash flows may become subject to fluctuations due to changes in foreign currency exchange rates. In periods when the U.S. dollar declines in value as compared to the foreign currencies in which we incur expenses, our foreign-currency based expenses will increase when translated into U.S. dollars. In addition, future fluctuations in the value of the U.S. dollar may affect the price at which we sell our tests outside the United States. To date, our foreign currency risk has been minimal, and we have not historically hedged our foreign currency risk; however, we may consider doing so in the future.

Item 4. Controls and Procedures.

Our management, with the participation and supervision of our President and Chief Executive Officer and our Executive Vice President and Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act) as of the end of the period covered by this Quarterly Report. Based on that evaluation, our President and Chief Executive Officer and our Executive Vice President and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our President and Chief Executive Officer and our Executive Vice President and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

Federal Investigations

In April 2018, we received a civil investigative demand from an Assistant U.S. Attorney for the Southern District of New York, or SDNY, and a HIPAA subpoena issued by an Assistant U.S. Attorney for the Southern District of California, or SDCA. In May 2018, we received a subpoena from the State of New York Medicaid Fraud Control Unit.

On July 21, 2020, July 23, 2020, and October 1, 2020, we entered into agreements with certain governmental agencies and the 45 states participating in the settlement, or the State AGs, to resolve, with respect to such agencies and State AGs, all of such agencies' and State AGs' outstanding civil, and, where applicable, federal criminal investigations regarding our discontinued legacy billing practices for our non-invasive prenatal tests and microdeletion tests and the provision of alleged kickbacks or inducements to physicians and patients. Specifically, we entered into:

- a civil settlement agreement, effective July 23, 2020, with the DOJ through SDNY, and on behalf of the Office of Inspector General of the Department of Health and Human Services, or the OIG, and with the relator named therein, or the SDNY Civil Settlement Agreement;
- a civil settlement agreement, effective July 23, 2020, with the DOJ through SDCA, and on behalf of the Defense Health Agency, the Tricare Program and the Office of Personnel Management, which administers the Federal Employees Health Benefits Program, or the SDCA Civil Settlement Agreement;
- a non-prosecution agreement, effective July 21, 2020, with SDCA, or the Non-Prosecution Agreement, in resolution of all criminal allegations;
- a corporate integrity agreement, effective July 21, 2020, with the OIG, or the Corporate Integrity Agreement; and
- civil settlement agreements, effective October 1, 2020, with the State AGs, or the State Settlement Agreements.

We refer to the SDNY Civil Settlement Agreement, the SDCA Civil Settlement Agreement, the Non-Prosecution Agreement, the Corporate Integrity Agreement, and the State Settlement Agreements collectively as the Agreements.

SDNY Civil Settlement Agreement

Pursuant to the SDNY Civil Settlement Agreement, we are required to pay a settlement amount of approximately $19.4 million, which includes approximately $9.7 million designated as restitution to the U.S. federal government. During the three months ended September 30, 2020, we paid approximately $9.1 million. We paid an additional approximately $4.1 million subsequent to September 30, 2020, for an aggregate of approximately $13.1 million paid to date. The outstanding settlement amount is payable in three installments as follows:

- approximately $1.6 million on or before December 31, 2020;
- approximately $2.0 million on or before December 31, 2021; and
- approximately $2.8 million on or before December 31, 2022.

The remaining amounts payable to the government will be subject to interest at a rate of 1.25% per annum, and any or all amounts may be paid earlier at our option.

Furthermore, we have agreed that, if during calendar years 2020 through 2023, and so long as amounts payable to the government remain unpaid, we receive any civil settlement, damages awards, or tax refunds, to the extent that the amounts exceed $5.0 million in a calendar year, we will pay 26% of the amount received in such civil settlement, damages award, or tax refunds as an accelerated payment of the scheduled amounts set forth above, up to a maximum total acceleration of $4.2 million. During the three months ended March 31, 2020, we recorded a discrete tax benefit of $37.7 million related to the net operating loss carryback provisions available under the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, for taxes we paid in years 2013, 2014, 2015 and 2017, or the CARES Act Tax Benefit. In June 2020, we received a tax benefit payment of approximately $22.7 million for a portion of the CARES Act Tax Benefit, and because this tax refund was received prior to the effective date of the SDNY Civil Settlement Agreement, the payment the initial settlement payment installment included an added payment of approximately $5.9 million. In addition, because we received a tax benefit payment of approximately $15.7 million in September 2020, an accelerated payment of approximately $4.1 million was made on October 1, 2020, with a corresponding reduction in the previously agreed upon payment term and subsequent payment amounts.

Additionally, under the SDNY Civil Settlement Agreement, the U.S. federal government and the relator agreed to dismiss all civil claims asserted by the relator under the qui tam provisions of the federal False Claims Act.

SDCA Civil Settlement Agreement

Pursuant to the SDCA Civil Settlement Agreement, we are required to pay a settlement amount of approximately $16.4 million, which includes approximately $10.0 million designated as restitution to the U.S. federal government. During the three months ended September 30, 2020, we paid approximately $7.7 million. We paid an additional $3.4 million subsequent to September 30, 2020, for an aggregate of $11.1 million paid to date. The outstanding settlement amount is payable in three installments as follows:

- approximately $1.4 million on or before December 31, 2020;
- approximately $1.8 million on or before December 31, 2021; and
- approximately $2.2 million on or before December 31, 2022.

The remaining amounts payable to the government will be subject to interest at a rate of 1.25% per annum, and any or all amounts may be paid earlier at our option.

On July 21, 2020, we issued a promissory note to the U.S. federal government for the full settlement amount in connection with the SDCA Civil Settlement Agreement, or the Promissory Note. The Promissory Note contains customary events of default and related acceleration of payment provisions. In addition, the Promissory Note provides, among other terms, that, if during calendar years 2020 through 2023, and so long as amounts payable to the government remain unpaid, we receive any civil settlement, damages awards, or tax refunds, to the extent that the amounts exceed $5.0 million in a calendar year, we will pay 22% of the amount received in such civil settlement, damages award, or tax refunds as an accelerated payment of the scheduled amounts set forth above, up to a maximum total acceleration of approximately $3.4 million. Because we received a tax benefit payment of approximately $22.7 million for a portion of the CARES Act Tax Benefit in June 2020 and because this tax refund was received prior to the effective date of the Promissory Note, the initial settlement payment installment included an added payment of $4.9 million. In addition, because we received a tax benefit payment of approximately $15.7 million in September 2020, an accelerated payment of approximately $3.4 million was made on October 1, 2020, with a corresponding reduction in the previously agreed upon payment term and subsequent payment amounts.

Non-Prosecution Agreement

Effective July 21, 2020, we entered into the Non-Prosecution Agreement, pursuant to which we agreed with the DOJ to (i) pay the restitution provided for under the SDCA Civil Settlement Agreement, (ii) not commit any felonies, (iii) continue to implement a compliance and ethics program designed to prevent and detect violations of applicable fraud and kickback laws throughout our operations and (iv) fulfill certain other disclosure, reporting and cooperation obligations. The DOJ agreed that it will not prosecute us for any conduct described in the Non-Prosecution Agreement provided that we perform our obligations under the Non-Prosecution Agreement during the period from July 21, 2020 through July 21, 2021. The Non-Prosecution Agreement provides that the DOJ may unilaterally, upon notice to us, extend the term of the agreement in 6-month increments, for a maximum total term of 24 months (that is, two 6-month extensions).

Corporate Integrity Agreement

In connection with the resolution of the investigated matters, and in exchange for the OIG's agreement not to exercise its authority to permissively exclude us from participating in federal healthcare programs, effective July 21, 2020, we entered into a five-year Corporate Integrity Agreement with the OIG. The Corporate Integrity Agreement requires, among other matters, that we maintain a Compliance Officer, a Compliance Committee, board review and oversight of certain federal healthcare compliance matters, compliance programs, and disclosure programs; provide management certifications and compliance training and education; engage an independent review organization to conduct claims and arrangements reviews; and implement a risk assessment and internal review process. If we fail to comply with our obligations under the Corporate Integrity Agreement, we could face monetary penalties and/or be excluded from participating in federal healthcare programs.

State Settlement Agreements

Effective October 1, 2020, we entered into agreements with the State AGs with respect to the investigated matters. The State Settlement Agreements require the Company to pay a settlement amount of approximately $13.2 million to the participating states. The State Settlement Agreements include acceleration provisions similar to the SDNY Civil Settlement Agreement and the SDCA Civil Settlement Agreements described above upon our receipt of civil settlements, damages awards, and tax refunds, with the amount to be accelerated and the timing of accelerated payment subject to such receipts. Because we received the June 2020 and September

2020 tax benefits totaling approximately $38.4 million, the initial payment to the participating states included added payments reflecting 17% of that amount, for a total initial payment on October 2, 2020 of approximately $8.7 million. The outstanding settlement amount is payable in four installments as follows:

- approximately $1.1 million on or before December 31, 2020;
- approximately $1.4 million on or before December 31, 2021;
- approximately $1.9 million on or before December 31, 2022; and
- approximately $0.2 million on or before December 31, 2023.

Settlement Accruals

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 quarter 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. As of September 30, 2020, the Company's accrual consists of $20.2 million included in accrued expenses and other current liabilities and $12.1 million included in other long-term liabilities.

OIG Inquiry

On October 16, 2019, we received an inquiry from the Texas Health & Human Services Commission Office of Inspector General, or the TX OIG, alleging that we did not hold the required CLIA Laboratory Certificate of Accreditation to perform, bill for, or be reimbursed by the Texas Medicaid Program for certain tests performed by us from January 1, 2015 through December 31, 2018. Although we believe that we hold and have held all required CLIA certificates and/or subcontract with third-party laboratories that hold and have held such certificates to perform all of the tests subject to the TX OIG inquiry, there can be no assurance that the TX OIG will agree with this position. We submitted a written response to the inquiry on October 23, 2019 and are awaiting a response from the TX OIG on the matter. It is not possible to predict the outcome of these matters and the timing for resolution.

Natera Lawsuit

On June 17, 2020, Natera, Inc., or Natera, filed suit in the Western District of Texas (W.D. Texas Civil Action No. 6:20-cv-532) asserting our infringement of six Natera patents based on a portion of our NIPT product offering. On June 19, 2020, Natera filed a substantially similar second suit in the Northern District of Texas (N.D. Texas Civil Action No. 3:20-cv-1634). On July 31, 2020, Progenity filed a motion to dismiss the Western District of Texas case based on improper venue. The parties are now conducting limited discovery related to this motion, after which Natera will file its responsive pleadings. The Northern District of Texas case has been stayed until a decision with respect to the motion to dismiss is made.

On July 2, 2020, we filed a Complaint for Declaratory Judgment of Non-Infringement against Natera in the Southern District of California (S.D. California Civil Action No. 3:20-cv-1252). This case has been stayed pending the outcome of our venue motion in the Western District of Texas.

We believe that the claims in Natera's complaints are without merit and we are vigorously defending against them.

IPO Litigation

On June 23, 2020, we closed our initial public offering of our common stock, or the IPO. Subsequent to the IPO, two lawsuits were filed against the Company, certain of its executive officers and directors, and the underwriters of the IPO. The lawsuits allege that our registration statement and related prospectus for the IPO made false and misleading statements and omissions in violation of the Securities Act of 1933 by failing to disclose that we (i) had overbilled government payors by $10.3 million in 2019 and early 2020; (ii) would need to refund this overpayment in the second quarter of 2020; and (iii) were allegedly suffering from accelerating negative trends with respect to testing volumes, revenues, and product pricing during the second quarter of 2020. Both lawsuits seek, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. We intend to vigorously defend against these claims. Given the uncertainty of litigation, the preliminary stages of these cases, and the legal standards that must be met for, among other things, success on the merits, we are unable to predict the ultimate outcome of these actions, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from these actions. Subject to a reservation of rights, we are advancing expenses subject to indemnification by the underwriters of the IPO. More details on each lawsuit are below:

- *Soe Action*. On August 28, 2020, a putative securities class action was filed in the U.S. District Court for the Southern District of California, entitled *Aung Kyaw Soe v. Progenity, Inc., et al.*, No. 3:20-cv-01683-CAB-AHG. The plaintiff, Aung Kyaw Soe, seeks to bring this action on behalf of all purchasers of Progenity common stock pursuant to or traceable to the registration statement issued in connection with the IPO. On September 23, 2020, the court ordered that no defendant has any obligation to answer or otherwise respond to the complaint in this action pending appointment of a lead plaintiff and the lead plaintiff's filing of an amended complaint or designation of the existing complaint as the operative complaint.
- *Brickman Investments Inc. Action*. On September 11, 2020, another putative securities class action was filed in the U.S. District Court for the Southern District of California, entitled *Brickman Investments Inc. v. Progenity, Inc., et al.*, No. 3:20-cv-01795-BEN-LL. The plaintiff, Brickman Investments Inc., seeks to bring this action on behalf of all purchasers of Progenity common stock pursuant to or traceable to the registration statement and related prospectus issued in connection with the IPO. In addition to the remedies described above, the plaintiff seeks rescission or rescissory damages.

Motions for appointment of lead plaintiff and lead counsel, as well as to consolidate the two actions, are pending.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q, including "Management's Discussion & Analysis" and our financial statements and related notes, before deciding to make an investment decision with respect to shares of our common stock. If any of the following risks actually occurs, our business, financial condition, operating results, reputation, and prospects could be materially and adversely affected. In that event, the price of our common stock could decline and you could lose part or all of your investment. We caution you that the risks, uncertainties and other factors referred to below and elsewhere in this Quarterly Report on Form 10-Q may not contain all of the risks, uncertainties and other factors that may affect our future results and operations. Moreover, new risks will emerge from time to time. It is not possible for our management to predict all risks.

Risk Factor Summary

- The recent and ongoing COVID-19 pandemic could further materially affect our operations, as well as the business or operations of third parties with whom we conduct business. Our business could be adversely affected by the effects of other future health epidemics or pandemics in regions where we or third parties on which we rely have significant business operations.
- We currently receive and expect to continue to receive a significant portion of our revenues from our women's health-related NIPT and carrier screening products, and if our efforts to further increase the use and adoption of these products fail, our business will be harmed.
- We have incurred losses in the past, and we may not be able to achieve or sustain profitability in the future.
- We operate in a highly competitive business environment.
- Our success depends on our ability to improve and enhance our current products and develop new product candidates, which is complex and costly and the results are uncertain.
- We are still developing our precision medicine platform and to date have generated no products or product revenue. There can be no assurance that we will develop any precision medicine products that deliver diagnostic or therapeutic solutions, or, if developed, that such product candidates will be authorized for marketing by regulatory authorities, or will be commercially successful. This uncertainty makes it difficult to assess our future prospects and financial results.
- Although we have implemented compliance policies and have an internal audit function, we cannot ensure that our employees will fully adhere to such policies.
- Operating 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, and if we cannot raise additional capital when needed, we may have to curtail or cease operations.
- We may not be able to obtain and maintain the third-party relationships that are necessary to develop, commercialize, and manufacture some or all of our product candidates.
- We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers.
- We have increased the size of our organization and expect to further increase it in the future, and we may experience difficulties in managing this growth. If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be adversely affected.
- If third-party payors do not adequately reimburse us or our customers for any new products, they might not be purchased or used, which may adversely affect our revenue and profits.
- We may be unable to expand or maintain third-party payor coverage and reimbursement for our Innatal, Preparent, and other tests, or may be required to refund any reimbursements already received.
- If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected.
- Third-party claims of intellectual property infringement could result in litigation or other proceedings, which would be costly and time-consuming, and could limit our ability to commercialize our products.

Risks Related to Our Business and Industry

The recent and ongoing COVID-19 pandemic could further materially affect our operations, as well as the business or operations of third parties with whom we conduct business. Our business could be adversely affected by the effects of other future health epidemics or pandemics in regions where we or third parties on which we rely have significant business operations.

Our business and its operations, including but not limited to our laboratory operations, sales and marketing efforts, supply chain operations, research and development activities, and capital raising activities, could be adversely affected by health epidemics in regions where we have business operations, and such health epidemics could also cause significant disruption in the operations of third parties with whom we do business, including third parties upon whom we rely. For example, in December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to other countries and throughout the United States. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the U.S. government imposed restrictions on travel between the United States, Europe, and certain other countries. Since March 2020, numerous state and local jurisdictions, including the jurisdictions where our headquarters and laboratories are located, have imposed, and others in the future may impose, quarantines, shelter-in-place orders, executive, and similar government orders for their residents to control the spread of COVID-19.

In response to these public health directives and orders, we have implemented work-from-home policies for most of our employees. The effects of the executive orders, the shelter-in-place orders, and our work-from-home policies have negatively impacted, and may further negatively impact, productivity, and our preclinical and clinical programs and timelines, and disrupt our business in other ways, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition. We continue to monitor state and local quarantine, shelter-in-place, executive, and similar government orders and will reopen our offices to allow employees to return to the office, as needed, in accordance with our reopening plan, which is based on a phased approach that is appropriately tailored for each of our offices, with a focus on state and local orders, employee safety and optimal work environment.

Quarantines, shelter-in-place, executive, and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases, could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials we use or require to conduct our business, including product development, which would disrupt our supply chain. In particular, some of our suppliers of certain materials used in our laboratory operations and research and development activities are located in areas that are subject to executive orders and shelter-in-place orders. While many of these materials may be obtained from more than one supplier, port closures and other restrictions resulting from the COVID-19 pandemic or future pandemics may disrupt our supply chain or limit our ability to obtain sufficient materials to operate our business. To date, we are aware of certain suppliers for our research and development activities who have experienced operational delays directly related to the COVID-19 pandemic.

The spread of COVID-19, which has caused a broad impact globally, has affected and may further materially affect us economically, including a continuing and significant reduction in laboratory testing volumes. In addition, reimbursements for our tests have been delayed and may continue to be delayed if third-party payors' processing continues to be impacted by 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. While the potential economic impact brought by COVID-19, and the duration of such impact, may be difficult to assess or predict, the widespread pandemic has resulted in significant disruption of global financial markets, which could reduce our ability to access capital and negatively affect our future liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 and related government orders and restrictions could materially affect our business and the value of our common stock.

In addition, we expect our preclinical and clinical trials may be affected by the COVID-19 pandemic. For example, while we originally intended to commence our pilot clinical study for PIL Dx in 2020, we now expect that timeline will be delayed due to circumstances and uncertainties created by the COVID-19 pandemic and expect to instead commence this study in 2021. If COVID-19 continues to spread in the United States and elsewhere, we may experience additional disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving authorization from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 pandemic that may require us to change the ways in which our clinical trials are conducted, may result in unexpected costs, or require us to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruptions or delays in preclinical studies due to restricted or limited operations at our research and development laboratory facilities;
- delays in necessary interactions with local regulators, ethics committees, and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- refusal of the U.S. Food and Drug Administration, or FDA, to accept data from clinical trials in affected geographies; and
- interruption or delays to our sourced discovery and clinical activities.

The COVID-19 pandemic continues to evolve rapidly. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems, or the global economy as a whole.

We currently receive and expect to continue to receive a significant portion of our revenues from our women's health-related NIPT and carrier screening products, and if our efforts to further increase the use and adoption of these products fail, our business will be harmed.

We 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. We undertake efforts to increase the awareness and adoption of Innatal and Preparent among laboratories, clinics, clinicians, physicians, payors, and patients. Continued and additional market acceptance of Innatal and Preparent and our ability to attract new customers are key elements to our future success. The market demand for NIPT and carrier screening tests has grown in recent years and is evolving. For example, in August 2020, ACOG issued a new set of guidelines recommending that prenatal aneuploidy screening be offered to all pregnant women regardless of their age or other risk factors. However, this market trend may not continue. Demand for Innatal and Preparent is affected by a number of factors, many of which are beyond our control, including the recommendation of our products by physicians, the timing and development of new products by our competitors, and reimbursement from payors. Despite the recent ACOG guidelines, payors may elect not to cover prenatal aneuploidy screening for average risk women and such recommendations may not result in an increase in market demand.

Our ability to increase sales of our products and establish greater levels of adoption and reimbursement for our products is uncertain for many reasons, including, among others:

- we may be unable to demonstrate to laboratories, clinics, clinicians, physicians, payors, and patients that our products are superior to alternatives with respect to value, convenience, accuracy, scope of coverage, and other factors;
- third-party coverage and reimbursement are currently primarily limited to high-risk pregnancies and, despite recent ACOG guidelines regarding average-risk pregnancies, may not gain acceptance for use in the average-risk pregnancy population or for the screening of microdeletions, limiting the overall addressable market;
- third-party payors may set the amounts of reimbursement at prices that reduce our profit margins or do not allow us to cover our expenses;
- we may not be able to maintain and grow effective sales and marketing capabilities;
- our sales and marketing efforts may fail to effectively reach customers or communicate the benefits of our products;
- superior alternatives to our products may be developed and commercialized;
- we may experience supply constraints, including due to the failure of our key suppliers to provide required sequencing instruments and reagents;
- the FDA may initiate rulemaking to impose premarket review, clearance, or approval or other requirements over laboratory developed tests, or LDTs; and
- the FDA or other U.S. or foreign regulatory or legislative bodies may adopt new regulations or policies or take other actions that impose significant restrictions on our ability to market our products.

If the market and our market share for our women's health-related NIPT and carrier screening products fail to grow or grow more slowly than expected, our business, operating results, and financial condition would be adversely affected.

In addition, as our products may have different reimbursement rates and reimbursement amounts, a change in product mix could negatively impact our average selling price and total revenue. For example, during the COVID-19 pandemic, which has caused an overall decrease in demand for our products, demand for our NIPT product has been more resilient than for our carrier screening products, leading to a higher proportion of NIPT tests in our product mix. The average reimbursement rate for our NIPT product tends to be slightly lower than for our carrier screening products. In addition, we added COVID-19 testing to our product mix, which has a lower reimbursement amount per test. As a result, our average selling price and revenue was negatively impacted.

We have incurred losses in the past, and we may not be able to achieve or sustain profitability in the future.

In the future, we expect to incur significant costs in connection with the development, approval, and commercialization of enhanced, improved, or new products. Even if we succeed in creating such products from these investments, those innovations still may fail to result in commercially successful products.

Other than revenues from our laboratory testing business, we do not expect to generate revenues from other sources in the immediate future. It is possible that we will not generate sufficient revenue from the sale of our products to cover our costs, including research and development expenses related to furthering our product pipeline, and achieve or sustain profitability. A significant element of our business strategy is to increase and maintain our in-network coverage with third-party payors; however, the negotiated fees under our contracts with third-party payors are typically lower than the list price of our tests, and in some cases the third-party payors with whom we contract may have negative coverage determinations for some of our offerings. Therefore, being in-network with third-party payors has had, and may continue to have, an adverse impact on our revenues especially if we are unable to increase the adoption of, and obtain favorable coverage determinations and reimbursement for, our products.

Since we or any collaborators or licensees may not successfully develop additional products, obtain required regulatory authorizations, manufacture products at an acceptable cost or with appropriate quality, or successfully market and sell such products with desired margins, our expenses may continue to exceed any revenues we may receive. Our operating expenses also will increase as and if, among other things:

- our earlier-stage product candidates move into later-stage clinical development, which is generally more expensive than early-stage development;
- additional technologies or products are selected for development;
- we pursue development of our molecular tests or other product candidates for new uses;

- we increase the number of patents we are prosecuting or otherwise expend additional resources on patent prosecution or defense; or
- we acquire or in-license additional technologies, product candidates, products, or businesses.

We operate in a highly competitive business environment.

The industries in which we operate are highly competitive and require an ongoing, extensive search for technological innovation. They also require, among other things, the ability to effectively develop, test, commercialize, market, and promote products, including communicating the effectiveness, safety, and value of products to actual and prospective healthcare providers. Other competitive factors in our industries include quality and price, product technology, reputation, customer service, and access to technical information.

Our women's health-related NIPT and carrier screening tests are molecular tests, which are used by obstetricians and gynecologists, maternal fetal medicine specialists, and *in vitro* fertilization specialists. The principal competition for our NIPT and carrier screening tests comes from existing testing methods, technologies, and products, including other molecular NIPT and carrier screening tests offered by our competitors. The molecular testing field is characterized by rapid technological changes, frequent new product introductions, changing customer preferences, emerging competition, evolving industry standards, reimbursement uncertainty, and price competition. Many companies in this market are offering, or may soon offer, products and services that compete with our tests, in some cases at a lower cost than ours, and healthcare providers may choose to recommend the tests of our competitors.

Moreover, established, traditional first-line testing prenatal methods, such as serum protein measurement, where doctors measure certain hormones in the blood, and invasive prenatal diagnostics tests like amniocentesis, have been used for many years and are therefore practices that are difficult to change or supplement. Our conception and pre-implantation genetic screening products face competition from various laboratories that offer or seek to offer similar solutions. We also compete against companies providing hereditary cancer screening tests.

We expect any of our future precision medicine products to face substantial competition from major pharmaceutical companies, biotechnology companies, academic institutions, government agencies, and public and private research institutions. The larger competitors have substantially greater financial and human resources, as well as a much larger infrastructure than we do.

Additionally, we compete to acquire the intellectual property assets that we require to continue to develop and broaden our product portfolio. In addition to our in-house research and development efforts, we may seek to acquire rights to new intellectual property through corporate acquisitions, asset acquisitions, licensing, and joint venture arrangements. Competitors with greater resources may acquire intellectual property that we seek, and even where we are successful, competition may increase the acquisition price of such intellectual property or prevent us from capitalizing on such acquisitions, licensing opportunities, or joint venture arrangements. If we fail to compete successfully, our growth may be limited.

It is possible that developments by our competitors could make our products or technologies less competitive or obsolete. Our future growth depends, in part, on our ability to provide products that are more effective than those of our competitors and to keep pace with rapid medical and scientific change. Sales of our existing products and any future products may decline rapidly if a new product is introduced by a competitor, particularly if a new product represents a substantial improvement over any of our existing products. In addition, the high level of competition in our industry could force us to reduce the price at which we sell our products or require us to spend more to market our products.

Many of our competitors have greater resources than we have. This enables them, among other things, to spread their marketing and promotion costs over a broader revenue base. In addition, we may not be able to compete effectively against our competitors because their products and services are superior. Our current and future competitors could have greater experience, technological and financial resources, stronger business relationships, broader product lines and greater name recognition than us, and we may not be able to compete effectively against them. Increased competition is likely to result in pricing pressures, which could harm our revenues, operating income, or market share. If we are unable to compete successfully, we may be unable to increase or sustain our revenues or achieve or sustain profitability.

Our success depends on our ability to improve and enhance our current products and new product candidates, which is complex and costly and the results are uncertain.

Effective execution of research and development activities and the timely introduction of enhanced, improved, or new products and product candidates to the market are important elements of our business strategy. However, the development of enhanced, improved, or new products and product candidates is complex, costly, and uncertain and requires us to, among other factors,

accurately anticipate patients', clinicians', and payors' needs, and emerging technology trends.

In the development of enhanced, improved, or new products and product candidates, we can provide no assurance that:

- we will develop any products that meet our desired target product profile and address the relevant clinical need or commercial opportunity;
- any products that we develop will prove to be effective in clinical trials, platform validations, or otherwise;
- we will obtain necessary regulatory authorizations, in a timely manner or at all;
- any products that we develop will be successfully marketed to and ordered by healthcare providers;
- any products that we develop will be produced at an acceptable cost and with appropriate quality;
- our current or future competitors will not introduce products similar to ours that have superior performance, lower prices, or other characteristics that cause healthcare providers to recommend, and consumers to choose, such competitive products over ours; or
- third parties do not or will not hold patents in any key jurisdictions that would be infringed by our products.

These and other factors beyond our control could delay our launch of enhanced, improved, or new products and product candidates.

The research and development process in our industries generally requires a significant amount of time from the research and design stage through commercialization. The launch of such new products requires the completion of certain clinical development and/or assay validations in the commercial laboratory. This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals and will not be able to complete clinical development for any planned product in a timely manner. Such development and/or validation failures could prevent or significantly delay our ability to obtain FDA clearance or approval as may be necessary or desired, obtain approval by entities that provide oversight over LDTs, such as the State of New York, or launch any of our planned products and product candidates. At times, it may be necessary for us to abandon a product in which we have invested substantial resources. Without the timely introduction of new product candidates and improvements or enhancements of our current products, our products may become obsolete over time and our competitors may develop products that are more competitive, in which case our business, operating results, and financial condition will be harmed.

We are still developing our precision medicine platform and to date have generated no precision medicine products or product revenue. There can be no assurance that we will develop any precision medicine products that deliver diagnostic or therapeutic solutions, or, if developed, that such product candidates will be authorized for marketing by regulatory authorities, or will be commercially successful. This uncertainty makes it difficult to assess our future prospects and financial results.

Our operations with respect to our precision medicine platform to date have been limited to developing our platform technology, undertaking pre-clinical studies and clinical trials, and conducting research to identify potential product candidates. To date, we have only conducted clinical trials to evaluate whether our platform technology enables identification of the location of our ingestible medical device, which we refer to as an ingestible capsule, within the gastrointestinal tract.

We seek to develop a suite of ingestible capsules for both diagnostic and therapeutic solutions. However, medical device and related diagnostic and therapeutic product development is a highly speculative undertaking and involves a substantial degree of uncertainty. Our precision medicine platform has not yet demonstrated an ability to generate revenue or successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields such as ours for precision medicine. Consequently, the ability to accurately assess the future operating results or business prospects of our precision medicine platform is significantly more limited than if we had an operating history or approved commercial precision medicine products. Our success in developing commercial products that are based on our precision medicine platform will depend on a variety of factors, many of which are beyond our control, including, but not limited to:

- the outcomes from our product development efforts;
- competition from existing products or new products;
- the timing of regulatory review and our ability to obtain regulatory marketing authorizations of our product candidates;
- potential side effects of our product candidates that could delay or prevent receipt of marketing authorizations or cause an approved or cleared product to be taken off the market;
- our ability to attract and retain key personnel with the appropriate expertise and experience to potentially develop our

product candidates; and

- the ability of third-party manufacturers to manufacture our product candidates in accordance with current good manufacturing practices, or cGMP, for the conduct of clinical trials and, if approved or cleared, for successful commercialization.

Even if we are able to develop one or more commercial precision medicine products, we expect that the operating results of these products will fluctuate significantly from period to period due to the factors above and a variety of other factors, many of which are beyond our control, including, but not limited to:

- market acceptance of our product candidates, if approved or cleared;
- our ability to establish and maintain an effective sales and marketing infrastructure for our products;
- the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products;
- our ability, as well as the ability of any third-party collaborators, to obtain, maintain and enforce intellectual property rights covering our products, product candidates and technologies, and our ability to develop, manufacture and commercialize our products, product candidates, and technologies without infringing on the intellectual property rights of others; and
- our ability to attract and retain key personnel with the appropriate expertise and experience to manage our business effectively.

Accordingly, the likelihood of the success of our precision medicine platform must be evaluated in light of these many potential challenges and variables.

The development of new product candidates will require us to undertake clinical trials, which are costly, time-consuming, and subject to a number of risks.

The development of new product candidates, including development of the data necessary to obtain clearance or approval for such product candidates, is costly, time-consuming, and carries with it the risk of not yielding the desired results. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in future clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and even if we achieve positive results in earlier trials, we could face similar setbacks. The design of a clinical trial can determine whether its results will support a product candidate’s marketing authorization, to the extent required, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing authorization for the product candidates. Furthermore, limited results from earlier-stage studies may not predict results from studies in larger numbers of subjects drawn from more diverse populations over a longer period of time.

Unfavorable results from ongoing preclinical studies and clinical trials could result in delays, modifications, or abandonment of ongoing or future analytical or clinical trials, or abandonment of a product development program, or may delay, limit, or prevent marketing authorizations, where required, or commercialization of our product candidates. Even if we, or our collaborators, believe that the results of clinical trials for our product candidates warrant marketing authorization, the FDA and other regulatory authorities may disagree and may not grant marketing authorizations for our product candidates.

Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as the Good Clinical Practice, or GCP, requirements, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, safety, and welfare of trial participants are protected. Other countries’ regulatory agencies also have requirements for clinical trials with which we must comply. We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, enforcement action, adverse publicity, and civil and criminal sanctions.

The initiation and completion of any clinical studies may be prevented, delayed, or halted for numerous reasons. We may experience delays in initiation or completion of our clinical trials for a number of reasons, which could adversely affect the costs, timing, or success of our clinical trials, including related to the following:

- we may be required to submit an investigational device exemption, or IDE, application to the FDA with respect to our medical device product candidates, which must become effective prior to commencing certain human clinical trials of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators and/or institutional review boards, or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we or our investigators may have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks or based on a requirement or recommendation from regulators, IRBs or other parties due to safety signals or noncompliance with regulatory requirements;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- the cost of clinical trials may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- we may be unable to recruit a sufficient number of clinical trial sites;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- marketing authorization policies or regulations of the FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for authorization; and
- our products may have undesirable side effects or other unexpected characteristics.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting, or completing our planned and ongoing clinical trials.

Any of these occurrences may significantly harm our business, financial condition, and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of a product candidate, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product candidate. In addition, patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

Clinical trials must be also conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with the FDA's GCP requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP requirements, or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays, or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

The clinical trial process is lengthy and expensive with uncertain outcomes. We have limited data and experience regarding the safety and efficacy of our products. Results of earlier studies may not be predictive of future clinical trial results, or the safety or efficacy profile for such products.

Clinical testing is difficult to design and implement, can take many years, can be expensive, and carries uncertain outcomes. The results of preclinical studies and clinical trials of our products conducted to date and ongoing or future studies and trials of our current, planned, or future products and product candidates may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

Interim "top-line" and preliminary data from studies or trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim "top-line" or preliminary data from preclinical studies or clinical trials. Interim data are subject to the risk that one or more of the outcomes may materially change as more data become available. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Additionally, interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could seriously harm our business.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, and our results of operations, liquidity and financial condition. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the top-line data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain marketing authorization for, and commercialize, product candidates may be harmed, which could seriously harm our business.

The results of our clinical trials may not support the use of our tests and other product candidates, or may not be replicated in later studies required for marketing authorizations.

As the healthcare reimbursement system in the United States evolves to place greater emphasis on comparative effectiveness and outcomes data, we cannot predict whether we will have sufficient data, or whether the data we have will be presented to the satisfaction of any payors seeking such data for determining coverage for our tests, particularly in the average-risk pregnancy

population for which such data is expected to be of particular interest, in new test areas such as preeclampsia, or in precision medicine diagnostic or therapeutic applications.

The administration of clinical and economic utility studies is expensive and demands significant attention from certain members of our management team. Data collected from these studies may not be positive or consistent with our existing data, or may not be statistically significant or compelling to the medical community or payors. If the results obtained from our ongoing or future studies are inconsistent with certain results obtained from our previous studies, adoption of our products would suffer and our business would be harmed.

Peer-reviewed publications regarding our products and product candidates may be limited by many factors, including delays in the completion of, poor design of, or lack of compelling data from clinical studies, as well as delays in the review, acceptance, and publication process. If our products or product candidates or the technology underlying our current or future products or product candidates do not receive sufficient favorable exposure in peer-reviewed publications, or are not published, the rate of healthcare provider adoption of our tests and positive reimbursement coverage decisions for our tests and other products could be negatively affected. The publication of clinical data in peer-reviewed journals can be a crucial step in commercializing and obtaining reimbursement for tests, diagnostic and therapeutic products and other products, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenues from any test, diagnostic or therapeutic product that is the subject of a study. The performance achieved in published studies may not be repeated in later studies that may be required to obtain FDA clearance or marketing authorizations should we decide for business reasons, or be required to submit applications to the FDA or other health authorities seeking such authorizations.

In response to the COVID-19 pandemic, we are providing molecular testing for diagnosing COVID-19 through Avero Diagnostics. The demand for such testing may decrease in the future and our investment in such testing capabilities may not pay off.

The COVID-19 pandemic has created an opportunity for our diagnostic tests and the Avero Diagnostics laboratory is providing molecular testing for diagnosing COVID-19. Avero Diagnostics' molecular testing utilizes certain third-party in-vitro diagnostics that have received Emergency Use Authorization, or EUA, from the FDA. The FDA has the authority to issue an EUA during a public health emergency if it determines that based on the totality of the scientific evidence that it is reasonable to believe that the product may be effective, that the known and potential benefits of a product outweigh the known and potential risks, that there is no adequate, approved, and available alternative, and if other regulatory criteria are met. These standards for marketing authorization are lower than if FDA had reviewed these tests under its traditional marketing authorization pathways, and we cannot assure you that these would be cleared or approved under those more onerous clearance and approval standards. Moreover, FDA's policies regarding EUAs can change unexpectedly, and FDA may revoke an EUA where it determines that the underlying health emergency no longer exists or warrants such authorization or if problems are identified with the authorized product. We cannot predict how long these authorizations will remain in place. FDA policies regarding diagnostic tests, therapies and other products used to diagnose, treat or mitigate COVID-19 remain in flux as the FDA responds to new and evolving public health information and clinical evidence. Changes to FDA regulations or requirements could require changes to authorized tests, necessitate additional measures, or make it impractical or impossible for Avero to continue utilizing these tests. The termination of any of the EUAs for the COVID-19 testing being run by Avero Diagnostics could adversely impact our business, financial condition and results of operations. We are expecting to increase our testing capacity for our COVID-19 diagnostic testing program in the near term to meet the rising demand for rapid and accurate testing. We expect that this expansion will contribute significantly to our revenue and test volumes for the remainder of 2020 and for 2021. However, there is no assurance that our COVID-19 diagnostic testing program will continue to be accepted by the market or that other diagnostic tests will become more accepted, produce quicker results, or be more accurate. Further, the longevity and extent of the COVID-19 pandemic is uncertain. If the pandemic were to dissipate, whether due to a significant decrease in new infections, due to the availability of vaccines, or otherwise, the need for a COVID-19 diagnostic test could decrease significantly and this could have an adverse effect on our results of operations and profitability. As a result, the increase in revenue due to any increase in demand for these diagnostic tests may not be indicative of our future revenue.

Operating 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, and if we cannot raise additional capital when needed, we may have to curtail or cease operations.

In the future, we expect to incur significant costs in connection with our operations, including but not limited to the development, marketing authorization, and commercialization of new tests, medical devices, therapeutics, and other products. These development activities generally require a substantial investment before we can determine commercial viability, and the proceeds from our IPO will not be sufficient to fully fund these activities. We expect to need to raise additional funds through public or private equity or debt financings, collaborations or licensing arrangements to continue to fund or expand our operations.

Our actual liquidity and capital funding requirements will depend on numerous factors, including:

- the scope and duration of and expenditures associated with our discovery efforts and research and development programs, including for our precision medicine platform;
- the costs to fund our commercialization strategies for any product candidates for which we receive marketing authorization or otherwise launch and to prepare for potential product marketing authorizations, as required;
- the costs of any acquisitions of complementary businesses or technologies that we may pursue;
- potential licensing or partnering transactions, if any;
- our facilities expenses, which will vary depending on the time and terms of any facility lease or sublease we may enter into, and other operating expenses;
- the scope and extent of the expansion of our sales and marketing efforts;
- the settlement of the government investigation described below, potential and pending litigation, potential payor recoupments of reimbursement amounts, and other contingencies;
- the commercial success of our products;
- our ability to obtain more extensive coverage and reimbursement for our tests and therapeutic products, if any, including in the general, average-risk patient population; and
- our ability to collect our accounts receivable.

The availability of additional capital, whether from private capital sources (including banks) or the public capital markets, fluctuates as our financial condition and market conditions in general change. There may be times when the private capital sources and the public capital markets lack sufficient liquidity or when our securities cannot be sold at attractive prices, or at all, in which case we would not be able to access capital from these sources. In addition, a weakening of our financial condition or deterioration in our credit ratings could adversely affect our ability to obtain necessary funds. Even if available, additional financing could be costly or have adverse consequences.

Additional capital, if needed, may not be available on satisfactory terms or at all. Furthermore, any additional capital raised through the sale of equity or equity-linked securities will dilute our stockholders' ownership interests and may have an adverse effect on the price of our common stock. In addition, the terms of any financing may adversely affect stockholders' holdings or rights. Debt financing, if available, may include restrictive covenants. To the extent that we raise additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies or grant licenses on terms that may not be favorable to us.

If we are not able to obtain adequate funding when needed, we may be required to delay development programs or sales and marketing initiatives. If we are unable to raise additional capital in sufficient amounts or on satisfactory terms, we may have to make reductions in our workforce and may be prevented from continuing our discovery, development, and commercialization efforts and exploiting other corporate opportunities. In addition, it may be necessary to work with a partner on one or more of our tests or products under development, which could lower the economic value of those products to us. Each of the foregoing may harm our business, operating results, and financial condition, and may impact our ability to continue as a going concern.

Our outstanding debt, and any new debt, may impair our financial and operating flexibility.

As of each of December 31, 2019 and September 30, 2020, we had approximately $72.3 million and $72.8 million of outstanding indebtedness, respectively, composed of mortgages payable and a note payable. Certain of our debt agreements contain various restrictive covenants and are secured by substantially all of our assets, excluding our intellectual property.

Our existing debt permits us to incur significant additional debt. Our existing debt and any additional debt we incur could:

- make it more difficult for us to satisfy our obligations under our existing debt instruments;
- increase our vulnerability to general adverse economic and industry conditions;
- limit our ability to obtain additional financing to fund our research, development, and commercialization activities, particularly when the availability of financing in the capital markets is limited;
- require a substantial portion of our cash flows from operations for the payment of principal and interest on our debt, reducing our ability to use our cash flows to fund working capital, research and development, and other general corporate requirements;
- limit our flexibility in planning for, or reacting to, changes in our business and the industries in which we operate;
- further dilute our current stockholders, to the extent that such debt is convertible into equity; and
- place us at a competitive disadvantage to less leveraged competitors or competitors with a lower cost of capital.

Our ability to make principal and interest payments will depend on our ability to generate cash in the future. If we do not generate sufficient cash to meet our debt service requirements and other operating requirements, we may need to seek additional financing. In that case, it may be more difficult, or we may be unable, to obtain financing on terms that are acceptable to us or at all.

Although we have implemented compliance policies and have an internal audit function, we cannot ensure that our employees have adhered or will fully adhere to such policies.

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 identified and are analyzing situations in which employees may have failed to fully adhere to our policies and applicable laws in the past. For example, as part of our work to improve our compliance program and our obligations under our Corporate Integrity Agreement (as defined below), including our internal auditing and monitoring function, we commissioned a third-party analysis of our coding and billing processes. In connection with that audit, we identified that we had not timely and appropriately transitioned to the implementation of a new CPT code in 2019, and as a result we received an overpayment of approximately $10.0 million from government payors during 2019 and early 2020. We also conducted a similar review of our historic practices regarding the collection of patient responsibility amounts, including copayments and deductibles, from government health program beneficiaries between May 2018 and May 2020. We reported the overpayments identified in both audits to the Office of Inspector General of the Department of Health and Human Services, or the OIG, in compliance with our Corporate Integrity Agreement. For additional information on our transition for this CPT code, see Notes 4 and 9 to our unaudited condensed consolidated financial statements. There can be no assurance that we will not identify further compliance, billing, or other failures or 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. For additional information regarding recent government investigations regarding our compliance with certain policies and laws, see Part II, Item 1. “Legal Proceedings.” In addition, in the event of failure by our sales, billing, marketing, or other personnel to follow our policies and comply with applicable laws, commercial third-party payors may refuse to provide all or any reimbursement for tests administered and seek repayment from us of amounts previously reimbursed, which failures may harm our ability to secure network contracts with third-party payors. Any of the foregoing could adversely affect our revenue, cash flow, and financial condition, and reduce our growth prospects. For additional information regarding these risks, see the risk factor titled “If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected.”

Compliance with the terms and conditions of our Corporate Integrity Agreement requires significant resources and, if we fail to comply, we could be subject to penalties or excluded from participation in government healthcare programs, which could harm our results of operations, liquidity and financial condition.

In connection with settlement of the government investigations described in Part II, Item 1. “Legal Proceedings,” effective July 21, 2020, we entered into a five-year corporate integrity agreement, or the Corporate Integrity Agreement, with the OIG. The Corporate Integrity Agreement requires, among other matters, that we maintain a Compliance Officer, a Compliance Committee, board review and oversight of healthcare compliance matters, compliance programs, and disclosure programs; provide management certifications and compliance training and education; engage an independent review organization to conduct claims and arrangements reviews; implement a risk assessment and internal review process; and submit periodic reports to the OIG regarding our compliance program and Corporate Integrity Agreement implementation. The Corporate Integrity Agreement requires us to report substantial

overpayments that we discover we have received from federal health care programs, as well as probable violations of federal health care laws. See “Risk Factors—“Although we have implemented compliance policies and have an internal audit function, we cannot ensure that our employees have adhered or will fully adhere to such policies.” We are in the process of implementing the processes, policies and procedures required under the Corporate Integrity Agreement. Implementing and administering such processes, policies and procedures will require significant management attention and cash and other resources. Furthermore, while we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable federal healthcare laws or all requirements of the Corporate Integrity Agreement. Our failure to comply with our obligations under the Corporate Integrity Agreement could result in monetary penalties and our exclusion from participating in federal healthcare programs. The costs associated with compliance with the Corporate Integrity Agreement, or any liability or consequences associated with its breach, could have an adverse effect on our operations, liquidity and financial condition.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal, and foreign laws, requirements, and regulations governing the collection, use, disclosure, retention, and security of personal information. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer, use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations, and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, the manner in which we collect, use, access, disclose, transmit and store protected health information, or PHI, is subject to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and the health data privacy, security and breach notification regulations issued pursuant to these statutes.

HIPAA establishes a set of national privacy and security standards for the protection of PHI, by health plans, healthcare clearinghouses, and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services that involve the use or disclosure of PHI. HIPAA requires healthcare providers like us to develop and maintain policies and procedures with respect to PHI that is used or disclosed, including the adoption of administrative, physical, and technical safeguards to protect such information.

HIPAA further requires covered entities to notify affected individuals “without unreasonable delay and in no case later than 60 calendar days after discovery of the breach” if their unsecured PHI is subject to an unauthorized access, use or disclosure. If a breach affects 500 patients or more, covered entities must report it to the U.S. Department of Health and Human Services, or HHS, and local media without unreasonable delay (and in no case later than 60 days after discovery of the breach), and HHS will post the name of the entity on its public website. If a breach affects fewer than 500 individuals, the covered entity must log it and notify HHS at least annually. HIPAA also implemented the use of standard transaction code sets and standard identifiers that covered entities must use when submitting or receiving certain electronic healthcare transactions, including activities associated with the billing and collection of healthcare claims.

Penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly depending on the failure and could include requiring corrective actions, and/or imposing civil monetary or criminal penalties. HIPAA also authorizes state attorneys general to file suit under HIPAA on behalf of state residents. Courts can award damages, costs and attorneys’ fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for HIPAA violations, its standards have been used as the basis for a duty of care claim in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, California enacted the California Consumer Privacy Act, or CCPA, on June 28, 2018, which went into effect on January 1, 2020. The CCPA creates

individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and proposed or enacted in other states. Any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

In Europe, the European Union General Data Protection Regulation (2016/679), or the GDPR, went into effect in May 2018 and introduces strict requirements for processing the personal data of European Union data subjects. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Moreover, the United Kingdom leaving the European Union could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the European Union will be regulated, especially following the United Kingdom's departure from the European Union on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the European Union. In addition to the GDPR, individual countries in Europe, and elsewhere in the world, including but not limited to Brazil, have enacted similar data privacy legislation that applies to data subjects in those countries. This legislation imposes increased compliance obligations and regulatory risk, including the potential for significant fines for noncompliance.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, CROs, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and reputation.

In the ordinary course of our business, we collect and store sensitive data, including PHI (such as patient medical records, including test results), and personally identifiable information. We also store business and financial information, intellectual property, research and development information, trade secrets and other proprietary and business critical information, including that of our customers, payors, and collaboration partners. We manage and maintain our data utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. We are highly dependent on information technology networks and systems, including the internet, to securely process, transmit, and store critical information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party billing and collections provider and other service providers, may be vulnerable to attacks by hackers, viruses, disruptions and breaches due to employee error or malfeasance.

A security breach or privacy violation that leads to unauthorized access, disclosure or modification of, or prevents access to, patient information, including PHI, could compel us to comply with state and federal breach notification laws, subject us to mandatory corrective action and require us to verify the correctness of database contents. Such a breach or violation also could result in legal claims or proceedings brought by a private party or a governmental authority, liability under laws and regulations that protect the privacy of personal information, such as HIPAA, HITECH, and laws and regulations of various U.S. states and foreign countries, as well as penalties imposed by the Payment Card Industry Security Standards Council for violations of the Payment Card Industry Data Security Standards. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, we may suffer loss of reputation, financial loss and civil or criminal fines or other penalties because of lost or misappropriated information. In addition, these breaches and other forms of inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Unauthorized access, loss or dissemination of information could disrupt our operations, including our ability to perform tests, provide test results, bill payors or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, develop and commercialize tests, collect, process and prepare company financial information, provide information about our tests, educate patients and healthcare providers about our service, and manage the administrative aspects of our business, any of which could damage our reputation and adversely affect our business. Any breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position.

In addition, health-related, privacy, and data protection laws and regulations in the United States and elsewhere are subject to interpretation and enforcement by various governmental authorities and courts, resulting in complex compliance issues and the potential for varying or even conflicting interpretations, particularly as laws and regulations in this area are in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business and our reputation. Complying with these laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business, operating results, and financial condition.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations, or any data security incidents or other security breaches that result in the accidental, unlawful or unauthorized access to, use of, release of, processing of, or transfer of sensitive information, including personally identifiable information, may result in negative publicity, harm to our reputation, governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties, including those that assert that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. We could be subject to fines and penalties (including civil and criminal) under HIPAA for any failure by us or our business associates to comply with HIPAA's requirements. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented data security measures intended to protect our information, data, information technology systems, applications and infrastructure, and recently hired a Chief Information Officer to supervise such measures, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents.

We have increased the size of our organization and expect to further increase it in the future, and we may experience difficulties in managing this growth. If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be adversely affected.

As of September 30, 2020, we had 702 full-time employees worldwide. We have significantly expanded the size of our organization over the past several years, particularly personnel within our sales and marketing and research and development groups, and we expect to continue to do so in the future. As we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial, and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial, and management controls, reporting systems, and procedures.

Our future financial performance and our ability to successfully develop, market, and sell our products and product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. As we continue to grow our sales force, the impact of such growth on our revenue may be delayed as a result of time needed for onboarding and training of new sales force members.

We are engaged in extensive research and development activities, including innovation within our molecular testing business as well as furthering our novel pipeline of precision medicine product candidates. Conducting these activities will entail significant organizational complexity and require extensive effort on the part of our personnel. If we are unable to execute on our operational goals it would have a material and adverse effect on our business, financial condition, results of operations, and prospects.

If we lose the services of members of our senior management team or other key employees, we may not be able to execute our business strategy.

Our success depends in large part upon the continued service of our senior management team and certain other key employees who are important to our vision, strategic direction, and culture. Our current long- term business strategy was developed in large part by our senior management team and depends in part on their skills and knowledge to implement. We may not be able to offset the impact on our business of the loss of the services of any member of our senior management or other key officers or employees or attract additional talent. The loss of any members of our senior management team or other key employees could have a material and adverse effect on our business, operating results, and financial condition.

An inability to attract and retain highly skilled employees could adversely affect our business.

To execute our business plan, we must attract and retain highly qualified personnel. Competition for qualified personnel is intense, especially for sales, scientific, medical, laboratory, and technical personnel and especially in the areas where our headquarters and laboratory facilities are located. We have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we have. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees have breached their legal obligations to their former employees, resulting in a diversion of our time and resources. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived value of our stock awards declines, it may adversely affect our ability to attract and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business, operating results, and financial condition could be adversely affected.

We may not be able to obtain and maintain the third-party relationships that are necessary to develop, commercialize, and manufacture some or all of our product candidates.

We expect to depend on collaborators, partners, licensees, manufacturers, and other third parties to support our product candidate development efforts, to manufacture our product candidates and to market, sell, and distribute any products we successfully develop. Any problems we experience with any of these third parties could delay the development, commercialization, and manufacturing of our product candidates, which could harm our results of operations.

We cannot guarantee that we will be able to successfully negotiate agreements for, or maintain relationships with, collaborators, partners, licensees, manufacturers, and other third parties on favorable terms, if at all. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, manufacture, obtain regulatory authorizations for, or commercialize any future product candidates, which will in turn adversely affect our business.

We expect to expend substantial management time and effort to enter into relationships with third parties and, if we successfully enter into such relationships, to manage these relationships. In addition, substantial amounts will be paid to third parties in these relationships. However, we cannot control the amount or timing of resources our future contract partners will devote to our research and development programs, product candidates, or potential product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all. In addition, while we manage the relationships with third parties, we cannot control all of the operations of and protection of intellectual property by such third parties.

We rely on third-party laboratories to perform some of our testing and further rely on third parties for sample collection, including phlebotomy services, and commercial courier delivery services, and if these services are disrupted, our business will be harmed.

A portion of our tests are performed by third-party CLIA certified laboratories. These third-party laboratories are subject to contractual obligations but are not otherwise under our control. We, therefore, do not control the capacity and quality control efforts of these third-party laboratories other than through our ability to enforce contractual obligations on volume and quality systems. In the event of any adverse developments with these third-party laboratories or their ability to perform this testing in accordance with the legal, regulatory, or commercial standards, our ability to provide test results to customers may be delayed, interrupted, or suspended. Any natural or other disasters, pandemics, acts of war or terrorism, shipping embargoes, labor unrest, or political instability or similar events at our third- party laboratories' facilities that cause a loss of testing capacity would heighten the risks that we face.

Changes to or termination of our agreements or inability to renew our agreements with these parties or enter into new agreements with other laboratories that are able to perform such testing could impair, delay, or suspend our efforts to market and commercialize our tests. Such interruption could harm our reputation and lead to the loss of customers, and we may be unable to regain those customers in the future. In addition, certain third-party payors may take the position that sending out this testing to third- party laboratories is contrary to the terms of their coverage policies and/or our contract in cases where we are in-network with the payor, and may refuse to pay us for testing that we have outsourced. If any of these events occur, our business, operating results, and financial condition could suffer.

Federal and certain state laws impose anti-markup restrictions that prevent an entity from realizing a profit margin on outsourced testing. Whether we will be able to realize a profit margin on outsourced testing will be determined by the application of those laws. If we or our subsidiaries are unable to markup outsourced testing, our operating results would suffer.

Our molecular testing business depends on our ability to quickly and reliably deliver test results to our customers. We rely on third parties to perform sample collection, including phlebotomy services, and to transport samples to our laboratory facility or the

third-party laboratories that we contract with in a timely and cost-efficient manner. Disruptions in these services, whether due to any natural or other disasters, pandemics, acts of war or terrorism, shipping embargoes, labor unrest, political instability, or similar events, could adversely affect specimen integrity and our ability to process samples in a timely manner and to service our customers, and ultimately our reputation and our business. In addition, if we are unable to continue to obtain expedited delivery services on commercially reasonable terms, our operating results may be adversely affected.

In addition, our relationships with these third-party providers could be scrutinized under federal and state healthcare laws such as the federal Anti-Kickback Statute and the Stark Law to the extent these services provide a financial benefit to or relieve a financial burden for a potential referral source, or are subsequently found not to be for fair market value. If our operations are found to be in violation of any of these laws and regulations, we may be subject to administrative, civil and criminal 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, any of which could harm our reputation and adversely affect our business, operating results, and financial condition. For additional information regarding these risks, see the risk factor titled “If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected.”

We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers on a cost-effective basis, or at all.

We source components of our technology from third parties and certain components are sole sourced. Obtaining substitute components may be difficult or require us to re-design our products or, for any product candidates for which we may obtain marketing authorization from the FDA, obtain new marketing authorization from the FDA to use a new supplier. Any natural or other disasters, acts of war or terrorism, shipping embargoes, labor unrest or political instability or similar events at our third-party manufacturers’ facilities that cause a loss of manufacturing capacity or a reduction in the quality of the items manufactured would heighten the risks that we face. Changes to, failure to renew or termination of our existing agreements or our inability to enter into new agreements with other suppliers could result in the loss of access to important components of our tests and could impair, delay or suspend our commercialization efforts. Our failure to maintain a continued and cost-effective supply of high-quality components could materially and adversely harm our business, operating results, and financial condition.

For example, Illumina, Inc., or Illumina, in San Diego, California, is currently the sole supplier of our sequencing instruments and certain reagents for Innatal and Preparent, pursuant to a supply agreement that, unless extended by mutual agreement, expires in June 2022. Without such inputs, we would be unable to run our tests and commercialize our products. In early 2013, prior to our entering into our agreement with Illumina, Illumina completed its acquisition of Verinata Health Inc., or Verinata, a direct competitor in the NIPT market. We understand Illumina supplies the same or similar instruments and related reagents to Verinata. As a result, we face heightened risk and uncertainty regarding our supply relationship with Illumina. If required, alternative sequencing platforms may not perform as well or may be more expensive and we may be unsuccessful employing such platforms in a commercially sustainable way. Any disruptions to our laboratory performance and ability to deliver our products could adversely affect our business, operating results, financial condition, and reputation. In addition, if we were required by the FDA to obtain approval for Innatal or Preparent through a pre-market approval application, or PMA, we may also be required to obtain approval of a PMA supplement prior to making any changes to Innatal or Preparent as a result of implementing an alternative sequencing platform.

The manufacturing of our products, including our precision medicine product candidates, is highly exacting and complex, and we depend on third parties to supply materials and manufacture all our products and product candidates.

Manufacturing is highly exacting and complex due, in part, to strict regulatory requirements governing the manufacture of our current and future products and product candidates, including medical devices, diagnostic products, and pharmaceutical products. We have limited personnel with experience in, and we do not own facilities for, manufacturing any products. We depend upon our collaborators and other third parties, including sole source suppliers, to provide raw materials meeting FDA quality standards and related regulatory requirements, manufacture devices, diagnostic products, and drug substances, produce drug products and provide certain analytical services with respect to our products and product candidates. The FDA and other regulatory authorities require that many of our products be manufactured according to cGMP regulations and that proper procedures be implemented to assure the quality of our sourcing of raw materials and the manufacture of our products. Any failure by us, our collaborators, or our third-party manufacturers to comply with cGMP and/or scale-up manufacturing processes could lead to a delay in, or failure to obtain, marketing authorizations. In addition, such failure could be the basis for action by the FDA, including issuing a warning letter, initiating a product recall or seizure, fines, imposing operating restrictions, total or partial suspension of production or injunctions and/or withdrawing marketing authorizations for products previously granted to us. To the extent we rely on a third-party manufacturer, the risk of noncompliance with cGMPs may be greater and the ability to effect corrective actions for any such noncompliance may be compromised or delayed.

Moreover, we expect that certain of our precision medicine product candidates, including PGN-600, PGN-001, PGN-300, and PGN-OB2, are drug/device combination products that will be regulated under the drug and biological product regulations of the Federal Food, Drug, and Cosmetic Act, or the FD&C Act, and Public Health Service Act, or PHSA, based on their primary modes of action as drugs and biologics. Third-party manufacturers may not be able to comply with cGMP regulations, applicable to drug/device combination products, including applicable provisions of the FDA's drug and biologics cGMP regulations, device cGMP requirements embodied in the Quality System Regulation, or QSR, or similar regulatory requirements outside the United States.

In addition, we or third parties may experience other problems with the manufacturing, quality control, storage or distribution of our products, including equipment breakdown or malfunction, failure to follow specific protocols and procedures, problems with suppliers and the sourcing or delivery of raw materials and other necessary components, problems with software, labor difficulties, and natural disaster-related events or other environmental factors. These problems can lead to increased costs, lost sales, damage to customer relations, failure to supply penalties, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches of products. If problems are not discovered before the product is released to the market, recalls, corrective actions, or product liability- related costs also may be incurred. Problems with respect to the manufacture, storage, or distribution of products could materially disrupt our business and have a material and adverse effect on our operating results and financial condition.

We rely on third parties to design our product candidates and conduct our preclinical research and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We rely and expect to continue to rely on third parties, such as engineering firms, CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct and manage our molecular testing and therapeutic product candidate design, preclinical testing, and clinical trials. Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with GCP requirements, the general investigational plan, and the protocols established for such trials.

These third parties may be slow to recruit patients and complete the studies. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, do not meet expected deadlines, experience work stoppages, terminate their agreements with us or need to be replaced, or do not conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed, or terminated or may need to be repeated. If any of the foregoing occur, we may not be able to obtain, or may be delayed in obtaining, marketing authorizations for our product candidates and may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

If our laboratory facilities become inoperable, we will be unable to perform our tests and our business will be harmed.

Our laboratory or other facilities may be harmed or rendered inoperable (or samples could be damaged or destroyed) by natural or manmade disasters, including earthquakes, flooding, power outages, disease outbreaks and contamination, which may render it difficult or impossible for us to perform our tests for some period of time. The inability to perform our tests or the backlog of tests that could develop if any of our laboratory or other facilities is inoperable for even a short period of time may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers in the future.

Our tests may not perform as expected and may result in reduced confidence in our products or legal claims.

Our success depends on the market's confidence that we can provide timely, reliable, high-quality test results. There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue as our business grows. We believe that our customers (healthcare providers and their patients) are likely to be particularly sensitive to test limitations and errors, including inaccurate test results and the need on occasion to perform redraws on patients. As a result, if our tests do not perform as expected, our business, operating results, financial condition, and reputation will suffer. In addition, we may be subject to legal claims arising from such limitations, errors, or inaccuracies.

Our tests use a number of complex and sophisticated biochemical and bioinformatics processes, many of which are highly sensitive to external factors. An operational or technology failure in one of these complex processes or fluctuations in external variables may result in sensitivity and specificity rates that are lower than we anticipate or that vary between test runs or in a higher than anticipated number of tests which fail to produce results. In addition, we regularly evaluate and refine our testing process. These refinements may initially result in unanticipated issues that may reduce our sensitivity and specificity rates.

Even if our newly developed product candidates receive marketing authorizations, to the extent required, they may fail to achieve market acceptance.

If we can develop enhanced, improved, or new product candidates that receive marketing authorizations, they may nonetheless fail to gain sufficient market acceptance by healthcare providers, patients, third- party payors, and others in the medical community to be commercially successful. The degree of market acceptance of any of our new product candidates following receipt of marketing authorizations, if any, will depend on a number of factors, including:

- our ability to anticipate and meet customer and patient needs;
- the timing of regulatory approvals or clearances, to the extent such are required for marketing;
- the efficacy, safety and other potential advantages, such as convenience and ease of administration, of our product candidates as compared to alternative tests or treatments;
- the clinical indications for which our product candidates are approved or cleared, or in the case of our LDTs, validated;
- concordance with clinical guidelines established by relevant professional colleges;
- compliance with state guidelines and licensure, if applicable;
- our ability to offer our product candidates for sale at competitive prices;
- the willingness of the target patient population to try our new products, and of physicians to prescribe these products;
- the strength of our marketing and distribution support;
- the availability and requirements of third-party payor insurance coverage and adequate reimbursement for our product candidates;
- the prevalence and severity of side effects and the overall safety profiles of our product candidates;
- any restrictions on the use of our product candidates together with other products and medications;
- our ability to manufacture quality products in an economic and timely manner;
- interactions of our product candidates with other medications patients are taking; and
- for ingestible product candidates, the ability of patients to take and tolerate our product candidates.

If our newly developed product candidates are unable to achieve market acceptance, our business, operating results, and financial condition will be harmed.

Additional time may be required to obtain marketing authorizations for certain of our precision medicine product candidates because they are combination products.

Some of our precision medicine product candidates are drug/device combination products that require coordination within the FDA and similar foreign regulatory agencies for review of their device and drug components. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process.

Our precision medicine product candidates under development include complex medical devices that, if authorized for marketing, will require training for qualified personnel and care for data analysis.

Our precision medicine product candidates under development include complex medical devices that, if authorized for marketing, will require training for qualified personnel, including physicians, and care for data analysis. Although we will be required to ensure that our precision medicine product candidates are prescribed only by trained professionals, the potential for misuse of our precision medicine product candidates, if authorized for marketing, still exists due to their complexity. Such misuse could result in adverse medical consequences for patients that could damage our reputation, subject us to costly product liability litigation, and otherwise have a material and adverse effect on our business, operating results, and financial condition.

The successful discovery, development, manufacturing, and sale of biologics is a long, expensive, and uncertain process and carries unique risks and uncertainties. Moreover, even if successful, our biologic products may be subject to competition from biosimilars.

We may develop product candidates regulated as biologics in the future in connection with our precision medicine platform. The successful development, manufacturing, and sale of biologics is a long, expensive, and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the testing, development, approval, manufacturing, distribution, and sale of biologics is subject to applicable provisions of the FD&C Act, PHSA, and regulations issued thereunder that are often more complex and extensive than the regulations applicable to other pharmaceutical products, to medical devices, or to the LDTs we currently commercialize. Manufacturing biologics, especially in large quantities, is often complicated and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture because production inputs are derived from living animal or plant material, and some biologics cannot be made synthetically.

Failure to successfully discover, develop, manufacture, and sell biologics could adversely impact our business, operating results, and financial condition.

Even if we are able to successfully develop biologics in the future, the Biologics Price Competition and Innovation Act, or BPCIA, created a framework for the approval of biosimilars in the United States that could allow competitors to reference data from any future biologic products for which we receive marketing approvals and otherwise increase the risk that any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the original biologic was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full Biologics License Application, or BLA, for the competing product containing the sponsor's own pre-clinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity, and potency of their product. The BPCIA is complex and is still being interpreted and implemented by the FDA. As a result, the law's ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological product candidates.

In addition, there is a risk that any of our product candidates regulated as a biologic and licensed under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have been the subject of litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In Europe, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In addition, companies are developing biosimilars in other countries that could compete with any biologic products that we develop. If competitors are able to obtain marketing approval for biosimilars referencing any biologic products that we develop, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Expiration or successful challenge of our applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired. As a result, we could face more litigation and administrative proceedings with respect to the validity and/or scope of patents relating to our biologic products.

If our future pharmaceutical product candidates are not approved by regulatory authorities, including the FDA, we will be unable to commercialize them.

In the future, we may develop pharmaceutical product candidates using our precision medicine platform that require FDA approval of a New Drug Application, or NDA, or a BLA before marketing or sale in the United States. In the NDA or BLA process, we, or our collaborative partners, must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that our product candidates are safe and effective, or in the case of biologics, safe, pure, and potent, for a defined indication before they can be approved for commercial distribution. The FDA or foreign regulatory authorities may disagree with our clinical trial designs and our interpretation of data from preclinical studies and clinical trials. The processes by which regulatory approvals are obtained from the FDA and foreign regulatory authorities to market and sell a new product are complex, require a number of years, depend upon the type, complexity, and novelty of the product candidate, and involve the expenditure of substantial resources for research, development, and testing. The FDA and foreign regulatory authorities have substantial discretion in the drug approval process and may require us to conduct additional nonclinical and clinical testing or to perform post-marketing studies. Further, the implementation of new laws and regulations, and revisions to FDA clinical trial design guidance, may lead to increased uncertainty regarding the approvability of new drugs.

Applications for our drug or biologic product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our or our collaborators' clinical trials;
- the FDA or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- we or our collaborators may be unable to demonstrate to the FDA, or comparable foreign regulatory authorities that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our or our collaborators' interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our or our collaborators' clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would seriously harm our business. In addition, the FDA may recommend advisory committee meetings for certain new molecular entities, and if warranted, require a Risk Evaluation and Mitigation Strategy, or REMS, to assure that a drug's benefits outweigh its risks. Even if we receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed or impose significant restrictions or limitations on the use and/or distribution of such product.

In addition, in order to market any pharmaceutical or biological product candidates that we develop in foreign jurisdictions, we, or our collaborative partners, must obtain separate regulatory approvals in each country. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Conversely, failure to obtain approval in one or more jurisdictions may make approval in other jurisdictions more difficult. These laws, regulations, additional requirements and changes in interpretation could cause non-approval or further delays in the FDA's or other regulatory authorities' review and approval of our and our collaborative partner's product candidates, which would materially harm our business and financial condition and could cause the price of our securities to fall.

The marketing authorization process is expensive, time-consuming, and uncertain, and we may not be able to obtain or maintain authorizations for the commercialization of some or all of our product candidates.

The product candidates associated with our precision medicine platform and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, export, and import, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the European Medicines Agency and comparable regulatory authorities in other countries. We have not received authorization to market any of our product candidates from regulatory authorities in any jurisdiction. Failure to obtain marketing authorization for a product candidate will prevent us from commercializing the product candidate.

Securing marketing authorizations may require the submission of extensive preclinical and clinical data and other supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy, or in the case of product candidates regulated as biologics, such product candidate's safety, purity, and potency. Securing regulatory authorization generally requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing authorization or prevent or limit commercial use.

The process of obtaining marketing authorizations, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if authorization is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing authorization policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application we submit, or may decide that our data is insufficient for approval and require additional preclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing authorization of a product candidate. Any marketing authorization we or our collaborators ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved medicine not commercially viable.

Accordingly, if we or our collaborators experience delays in obtaining authorization or if we or they fail to obtain authorization of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired.

Our products or product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory authorization, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if granted.

The use of our current products and precision medicine product candidates could be associated with side effects or adverse events, which can vary in severity (from minor reactions to death) and frequency (infrequent or prevalent). Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or when a product is commercialized. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory authorization by the FDA or other comparable foreign authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects such as toxicity or other safety issues and could require us or our collaboration partners to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits, which would harm our business and financial results. In such an event, we may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of our product candidates, which we have not planned or anticipated or our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications. There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any other regulatory agency in a timely manner, if ever, which could harm our business, operating results, financial condition and prospects.

Additionally, product quality characteristics have been shown to be sensitive to changes in process conditions, manufacturing techniques, equipment or sites and other such related considerations, hence any manufacturing process changes we implement prior to or after regulatory authorization could impact product safety and efficacy.

Product-related side effects could affect patient recruitment for clinical trials, the ability of enrolled patients to complete our studies or result in potential product liability claims. We currently carry product liability insurance and we are required to maintain product liability insurance pursuant to certain of our license agreements. We believe our product liability insurance coverage is

sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability, or such insurance coverage may not be sufficient to cover all losses. A successful product liability claim or series of claims brought against us could adversely affect our business, operating results, and financial condition. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical study participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if authorized for commercial sale. Additionally, if one or more of our product candidates receives marketing authorization, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may suspend, limit or withdraw marketing authorizations for such products, or seek an injunction against their manufacture or distribution;
- regulatory authorities may require additional warnings on the label including "boxed" warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- the product may become less competitive;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm our business, operating results, financial condition, and prospects.

If we receive marketing authorization, regulatory agencies including the FDA and foreign authorities enforce requirements that we report certain information about adverse medical events. For example, under FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of our device (or any similar future product) were to recur. We may fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to investigate and report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, including any legal action taken against us, will require us to devote significant time and capital to the matter, distract management from operating our business, and may harm our reputation and financial results.

Our products, including our precision medicine product candidates under development, if authorized for marketing, may be subject to product recalls.

The FDA and similar foreign governmental authorities have the authority to require the recall of certain commercialized products over which they exercise oversight in the event of material deficiencies or defects in design or manufacture or a public health/safety issue. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture or a public health/safety issue. Manufacturers may, under their own initiative, recall a product if any material deficiency is found. The FDA requires that certain recalls of medical devices be reported to the FDA within 10 working days after the recall is initiated. We may initiate voluntary recalls involving our products in the future that we determine do not require us to notify the FDA. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. In addition, the FDA could bring an enforcement action against us based on our failure to report the recalls when they were conducted. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Once marketed, recalls of any of our products, including our precision medicine products, would divert managerial and financial resources and could have a material and adverse effect on our

business, operating results, and financial condition. A future recall announcement could harm our reputation with customers and negatively affect our sales.

Our relationship with Avero Diagnostics may be challenged, and a successful challenge could adversely affect our operating structure.

We provide anatomic and molecular pathology testing through our affiliation with Mattison Pathology, LLP, a Texas limited liability partnership doing business as Avero Diagnostics, located in Lubbock and Irving, Texas. The laws of certain states in which we operate or may operate in the future prohibit non-physician entities from practicing medicine, exercising control over physicians or engaging in certain practices such as fee-splitting with physicians. Although we believe that we have structured our affiliation with Avero Diagnostics to ensure that the physicians maintain exclusive authority regarding the delivery of medical care, there can be no assurance that these laws will be interpreted in a manner consistent with our practices or that other laws or regulations will not be enacted in the future that could have a material and adverse effect on our business, operating results, and financial condition. Regulatory authorities and other parties, including our associated physicians, may assert that, despite the management service agreement and other arrangements through which we operate, we are engaged in the prohibited corporate practice of medicine, and/or that our arrangement with Avero Diagnostics constitutes unlawful fee-splitting. If a corporate practice of medicine or fee-splitting law is interpreted in a manner that is inconsistent with our practices, we would be required to restructure or terminate our relationship with Avero Diagnostics to bring its activities into compliance with such law. A determination of noncompliance, the termination of or failure to successfully restructure this relationship could result in disciplinary action, penalties, damages, fines, and/or a loss of revenue, any of which could have a material and adverse effect on our business, operating results, and financial condition.

Defects or failures associated with our products could lead to recalls or safety alerts and negative publicity.

Manufacturing flaws, component failures, design defects, off-label uses, or inadequate disclosure of product-related information could result in an unsafe condition or the injury or death of a patient. These problems could lead to a recall of, or issuance of a safety alert relating to, our commercialized products, and result in significant costs and negative publicity. A material adverse event involving one of our products could result in reduced market acceptance and demand for all products within that brand, and could harm our reputation and our ability to market our products in the future. In some circumstances, material adverse events arising from or associated with the design, manufacture or marketing of our products could result in among other things, labeling changes reflecting the updated safety information, regulatory requirements to issue communications to prescribers and/or conduct additional studies, or the suspension or delay of regulatory reviews of our applications for new marketing authorizations. We also may undertake a voluntary recall of products, or temporarily shut down production lines based on performance relative to our own internal safety and quality monitoring and testing data. Any of these problems could disrupt our business and have a material and adverse effect on our business, operating results, and financial condition.

We may not comply with laws regulating the protection of the environment and health and human safety.

Our research and development involves, or may in the future involve, the use of hazardous materials and chemicals and certain radioactive materials and related equipment. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Insurance may not provide adequate coverage against potential liabilities, and we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state, and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Our failure to comply with radio frequency regulations could impair our ability to commercially distribute and market our precision medicine product candidates in the applicable country or region.

Our PIL Dx precision medicine product candidate under development includes a wireless radio frequency transmitter and receiver, and is therefore subject to equipment authorization requirements in the United States and elsewhere. In the United States and certain other countries, authorities often require advance clearance of radio frequency devices before they can be sold or marketed in these jurisdictions, subject to limited exceptions. Modifications to our precision medicine product candidate's design and specifications may require new or further marketing authorizations before we are permitted to market and sell modified precision medicine products. If we are unable to obtain any required marketing authorizations from the authorities responsible for the radio frequency regulations, the sale or use of our precision medicine product candidate could be prevented in such countries. Any such action could negatively affect our business, operating results, and financial condition.

The marketing, sale, and use of our products could result in substantial damages arising from product liability or professional liability claims that exceed our insurance coverage and resources.

The marketing, sale and use of our products could lead to product liability claims against us if someone were to allege that our test or other product failed to perform as it was designed, or caused harm to an individual, or if someone were to misinterpret test results. We may be subject to liability for errors in, a misunderstanding of, or inappropriate reliance upon, the information we provide as part of the results generated by our tests. For example, Innatal could provide a low-risk result for a chromosomal abnormality upon which a patient or physician may rely to make a conclusion about the health of the fetus, which may, in fact, have the condition because the Innatal result was a false negative. As another example, Preparent could provide a low-risk result regarding the carrier status of a disorder of an expectant parent upon which a patient or physician may rely to make a conclusion about the health of the fetus, which may, in fact, have the condition because the Preparent result was a false negative. If the resulting baby is born with the condition, the family may file a lawsuit against us claiming product liability or professional liability.

In addition, we may be subject to product liability claims and lawsuits, including potential class actions, alleging that our products have resulted in or could result in an unsafe condition or injury. The product candidates we are developing using our precision medicine platform are designed to be ingested, and there are a number of factors that could result in an unsafe condition or injury to, or death of, a patient with respect to these or other products that we sell. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend. Although we maintain product and professional liability insurance, our insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims or any judgments, fines or settlement costs arising out of any such claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability or professional liability lawsuit could harm our reputation, result in a cessation of our testing, or cause our partners to terminate existing agreements and potential partners to seek other partners, any of which could adversely impact our business, operating results, and financial condition.

Our operating results may fluctuate significantly, which could adversely impact the value of our common stock.

Our operating results, including our revenues, gross margin, 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. Accordingly, our results should not be relied upon as an indication of future performance. Our operating results, including quarterly financial results, may fluctuate as a result of a variety of factors, many of which are outside of our control. Fluctuations in our results may adversely impact the value of our common stock. Factors that may cause fluctuations in our financial results include, without limitation, those listed elsewhere in this “Risk Factors” section. In addition, our results may fluctuate due to the fact that we recognize costs as they are incurred, but there is typically a delay in the related revenue recognition as we record most revenue only upon receipt of payment.

Accordingly, to the extent our revenues increase, we may experience increased costs unless and until the related revenues are recognized. In addition, as we increase our internal sales and marketing and research and development efforts, we expect to incur costs in advance of achieving the anticipated benefits of such efforts. 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.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders, or reduce our financial resources.

We have in the past entered into, and may in the future enter into, transactions to acquire other businesses, products, or technologies. Successful acquisitions require us to correctly identify appropriate acquisition candidates and to integrate acquired products or operations and personnel with our own.

Should we make an error in judgment when identifying an acquisition candidate, should the acquired operations not perform as anticipated, or should we fail to successfully integrate acquired technologies, operations, or personnel, we will likely fail to realize the benefits we intended to derive from the acquisition and may suffer other adverse consequences. Acquisitions involve a number of other risks, including:

- we may not be able to make such acquisitions on favorable terms or at all;
- the acquisitions may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors;
- we may decide to incur debt with debt repayment obligations that we are unable to satisfy or that could otherwise require the use of a significant portion of our cash flow;
- we may decide to issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders;
- we may incur losses resulting from undiscovered liabilities of the acquired business that are not covered by any indemnification we may obtain from the seller;
- the acquisitions may reduce our cash available for operations and other uses;
- the acquisitions may divert of the attention of our management from operating our existing business; and
- the acquisitions may result in charges to earnings in the event of any write-down or write-off of goodwill and other assets recorded in connection with acquisitions.

We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our business, operating results, and financial condition.

The development and expansion of our business through joint ventures, licensing and other strategic transactions may result in similar risks that reduce the benefits we anticipate from these strategic alliances and cause us to suffer other adverse consequences.

Ethical, legal, and social issues related to the use of genetic information could reduce demand for our tests.

DNA testing, such as testing that is conducted using Innatal, Preparent and our other products, has raised ethical, legal and social issues regarding privacy and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genomic information or genomic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Patients may also refuse to use genetic tests even if permissible, for similar reasons; they may also refuse genetic testing due to concerns regarding eligibility for life or other insurance. Ethical and social concerns may also influence U.S. and foreign patent offices and courts with regard to patent protection for technology relevant to our business.

Although the Genetic Information Non-discrimination Act has criminalized the disallowance of health insurance on the basis of genetic information, modification or retraction of this federal law could dramatically reduce public demand for genetic testing. These and other ethical, legal and social issues may limit market acceptance of our tests or reduce the potential markets for products enabled by our technology platform, either of which could harm our business, operating results, and financial condition.

We may be significantly impacted by changes in tax laws and regulations or their interpretation.

U.S. and foreign governments continue to review, reform and modify tax laws. Changes in tax laws and regulations could result in material changes to the domestic and foreign taxes that we are required to provide for and pay. In addition, we are subject to regular audits with respect to our various tax returns and processes in the jurisdictions in which we operate. Errors or omissions in tax returns, process failures, or differences in interpretation of tax laws by tax authorities and us may lead to litigation, payments of additional taxes, penalties, and interest. On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or TCJA, was passed into law. The TCJA has given rise to significant one-time and ongoing changes, including but not limited to a federal corporate tax rate decrease to 21% for tax years beginning after December 31, 2017, limitations on interest expense deductions, the immediate expensing of certain capital expenditures, the adoption of elements of a partially territorial tax system, new anti-base erosion provisions, a reduction to the maximum deduction allowed for net operating losses generated in tax years after December 31, 2017 and providing for indefinite carryforwards for losses generated in tax years after December 31, 2017. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable tax laws and regulations, or their interpretation and application, could have a material and adverse effect on our business, operating results, and financial condition.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2019, we had net operating loss, or NOL, carryforwards of approximately $173.6 million for federal income tax purposes, and $94.7 million for state income tax purposes. The federal NOLs will be carried forward indefinitely and the state NOLs began expiring in 2019. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. Some of these NOLs could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage point change, by value, in its equity ownership by 5% stockholders over a rolling three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income may be limited. If we determine that an ownership change has occurred and our ability to use our historical NOLs is materially limited, it could harm our future operating results by effectively increasing our future tax obligations. In addition, under the TCJA, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely but generally may not be carried back and the deductibility of such NOLs is limited to 80% of taxable income. On March 27, 2020, Congress enacted the Coronavirus Aid, Relief and Economic Security Act, known as the CARES Act, which provides some relief from the limitations on the utilization of NOLs and certain other tax attributes described above. During the three months ended March 31, 2020, we recorded a discrete tax benefit of $37.7 million related to the NOL carryback provisions available under the CARES Act for taxes paid in years 2013, 2014, 2015, and 2017, which we refer to as the CARES Act Tax Benefit. If any tax refund is received that is more than $5.0 million in a single year, along with other civil settlements, damages awards, and tax refunds, we have agreed to pay 65% of all such amounts received to accelerate payments to the government in connection with our government settlement. During the three months ended September 30, 2020, we received a tax refund of $15.7 million related to the NOL carryback provisions available under the CARES Act. See Part II, Item 1. "Legal Proceedings—Federal Investigation."

Reimbursement Risks Related to Our Business

If third-party payors do not adequately reimburse for our products, they might not be purchased or used, which may adversely affect our revenue and profits.

Our 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, including any potential products such as a test for preeclampsia, precision medicine devices, and pharmaceutical products. Coverage and reimbursement by governmental and commercial third-party payors may depend upon a number of factors, including the determination that the product and its use or administration for a particular patient is:

- a covered benefit;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- supported by guidelines established by the relevant professional college;
- approved in any states where specific assay approval is necessary;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from each third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical, and cost- effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to satisfy third-party payors that the product should be covered and reimbursed. There is substantial uncertainty whether any particular payor will cover and reimburse the use of any product incorporating new technology. Even when a payor determines that a product is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA or a comparable authority. Moreover, eligibility for coverage does not imply that any product will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. In some instances, payment may only be obtained by engaging in lengthy and costly appeals processes. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products, may reflect budgetary constraints and/or imperfections in Medicare, Medicaid or other data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products, which may affect payments for our products. Governmental and private entities that establish reimbursement policies, including the Centers for Medicare and Medicaid Services, or CMS, frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both CMS and other third-party payors may have sufficient market power to demand significant price reductions. Due in part to actions by third-party payors, the healthcare industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage, and negotiating reduced payment schedules with service providers for certain products.

Our inability to promptly obtain coverage and profitable reimbursement rates from third-party payors for our products could have a material and adverse effect on our business, operating results, and financial condition.

We may be unable to expand or maintain third-party payor coverage and reimbursement for our Innatal, Preparent, and other tests or other products.

Our business depends on our ability to obtain or maintain adequate reimbursement coverage from third- party payors. Third-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. In particular, we believe that for us to achieve commercial success it will be necessary to gain acceptance from third-party payors for the screening of microdeletions and for use of NIPT in the average-risk pregnancy population, which population represents roughly 80% of the U.S. pregnancy market, and to obtain positive coverage determinations and favorable reimbursement rates from third-party payors for our tests. We did not receive reimbursement for a significant number of Innatal tests for average-risk patients that we performed in the year ended December 31, 2019. In addition, it is to be determined whether and to what extent certain of our other products, including those under development, will be covered or reimbursed. If we are unable to obtain or maintain coverage or adequate reimbursement from, or achieve in-network status with, third-party payors for our existing or future tests or other products, our ability to generate revenues will be limited. For example, healthcare providers may be reluctant to order our tests or other products due to the potential of a substantial cost to the patient if coverage or reimbursement is unavailable or insufficient.

Leading professional societies may recommend alternatives to our tests in average-risk patient populations, which may provide a basis for third-party payors not to cover or reimburse our tests in those populations.

In making coverage determinations, third-party payors often rely on practice guidelines issued by professional societies. ACOG has issued updated guidelines recommending informing pregnant women that Non-Invasive Prenatal Screening, or NIPS, is the most sensitive screening option for trisomy 13, trisomy 18, and Down syndrome, as well as of the availability of the expanded use of NIPT to screen for clinically relevant copy number variants, or CNVs, in the context of counseling that includes the risks/benefits and limitations of screening for CNVs. A CNV is a genetic mutation in which a segment of the genome has been deleted or duplicated, including microdeletions in which a small segment of a chromosome is deleted. The International Society for Prenatal Diagnosis has issued guidelines that are supportive of performing NIPT in average-risk pregnancies, as well as high-risk pregnancies. ACOG and the American College of Medical Genetics, or ACMG, have also provided support for the use of NIPT in the general population, with ACOG noting, however, that NIPT is not equivalent to diagnostic testing because of its potential for false-positive and false-negative results. However, the Society for Maternal Fetal Medicine, or SMFM, has issued guidelines for NIPT stating that, while all pregnant women should be informed of the option to receive NIPT, conventional screening methods, such as traditional serum screening, rather than NIPT, remain the most appropriate choice for first-line screening for average-risk pregnancies. Therefore, while we expect the ACOG and SMFM guidelines to result in an increase in the number of average-risk women who are informed of NIPT and that may request it as a result, not all third-party payors reimburse for NIPT for these average-risk patients.

Currently, Aetna has determined that it will reimburse for NIPT for patients in the average-risk population through the end of 2020. However, UnitedHealthcare and a number of other third-party payors have negative coverage determinations for NIPT in average-risk patient populations, meaning that their policy is not to reimburse for NIPT for patients in the average-risk or general population. The SMFM guidelines also echoed a previous statement from SMFM that routine screening for microdeletions should not be performed. Many third-party payors do not cover microdeletions screening. We have experienced, and may continue to experience, a negative impact on third-party payors' coverage for Innatal for microdeletions, at least until additional validation data on the sensitivity and specificity of our tests becomes available. We may not be able to obtain positive coverage determinations for our tests. If third-party payors do not reimburse for NIPT for average-risk pregnancies or microdeletions in the future, our operating results would be adversely affected, particularly to the extent that we continue to perform large volumes of tests for which third-party payors do not cover.

New reimbursement methodologies applicable to our tests, including new CPT codes, may decrease reimbursement rates from third-party payors.

In the United States, the American Medical Association, or AMA, generally assigns specific billing codes for laboratory tests under a coding system known as Current Procedure Terminology, or CPT, which we and our ordering healthcare providers must use to bill and receive reimbursement for our tests. Once the CPT code is established, CMS establishes payment levels and coverage rules under Medicare while private payors independently establish rates and coverage rules. A CPT code specific to NIPT for aneuploidies was implemented, effective January 1, 2015, and a CPT code for microdeletions was implemented, effective January 1, 2017. CMS has established a pricing benchmark of $802 for aneuploidy and microdeletions testing. However, our microdeletions reimbursement has decreased under this new code because third-party payors are declining to reimburse under this new code or reimbursing at a much lower rate than we had previously received. Furthermore, we cannot guarantee that we will be able to negotiate favorable rates for this code or receive reimbursement at all if we are unable to collect and publish additional data and obtain positive coverage determinations for Innatal for microdeletions. In addition, 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. We do not currently have assay-specific CPT codes assigned for all of our tests, and there is a risk that we may not be able to obtain such codes or, if obtained, we may not be able to negotiate favorable rates for such codes.

We currently submit for reimbursement using CPT codes based on the guidance of outside coding experts and legal counsel. There is a risk that the codes we currently submit may be rejected or withdrawn, including as a result of a change in the applicable code due to the use of a new technology for our tests, or that third-party payors will seek refunds of amounts that they claim were inappropriately billed based on either the CPT code used, or the number of units billed. In addition, third-party payors may not establish positive coverage policies for our tests or adequately reimburse for any CPT code we may use, or may seek recoupment for testing previously performed, which have occurred in the past.

Billing disputes with third-party payors may decrease realized revenue and may lead to requests for recoupment of past amounts paid.

Payors dispute our billing or coding from time to time and we deal with requests for recoupment from third-party payors from time to time in the ordinary course of our business, and we expect these disputes and requests for recoupment to continue. 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. We have entered into settlement agreements with government and commercial payors in order to settle claims related to past billing practices that have since been discontinued. Additionally, 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. Failure to identify and return such overpayments exposes the provider or supplier to liability under federal false claims laws and the OIG's healthcare enforcement authorities, and would be a potential violation of our obligations under our Corporate Integrity Agreement to report substantial overpayments to the OIG. Claims for recoupment also require the time and attention of our management and other key personnel, which can be a distraction from operating our business.

If third-party payors deny payment for testing, reimbursement revenue for our testing could decline. If a third-party payor successfully challenges that payment to us 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. In the past, we have negotiated and settled these types of claims with third-party payors. We may be required to resolve further disputes in the future. We are aware of one commercial payor that is reviewing historical payments and may make a claim for recoupment in the future. 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.

"Most favored nation" provisions in contracts with third-party payors may limit potential for revenue growth and may lead to claims for recoupment.

Some of our contracts with third-party payors contain "most favored nation" provisions, pursuant to which we have agreed that we will not bill the third-party payor more than we bill any other third-party payor. These contract provisions limit the amount we are able to charge for our products. These most favored nation provisions may require us to forego revenues from some third-party payors or reduce the amount we bill to each third-party payor with a most favored nation clause in its contract, which could have a material and adverse effect on our business, operating results, and financial condition. We monitor our billing and claims submissions for compliance with these contractual requirements with third-party payors. If we do not successfully manage compliance with these

provisions, this could also subject us to claims for recoupment, which could result in an obligation to repay amounts previously earned.

When third-party payors deny coverage, we are often unable to collect from the patient or any other source and risk disputes if we attempt to do so.

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 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. Guidance from third-party payors regarding billing and patient collection practices will continue to evolve and may also impact our compliance with applicable requirements. While we have addressed these inquiries as and when they have arisen, there is no guarantee that we will be successful in addressing such concerns, and if we are unsuccessful, this may result in a third-party payor deciding to reimburse for our tests at a lower rate or not at all, seeking recoupment of amounts previously paid to us, or bringing legal action to seek reimbursement of previous amounts paid. Any of such occurrences could cause reimbursement revenue for our testing, which constitutes the large majority of our revenue, to decline. Additionally, if we were required to make a repayment, such repayment could be significant, which could have a material and adverse effect on our business, operating results, and financial condition.

Our revenues may be adversely impacted if third-party payors withdraw coverage or provide lower levels of reimbursement due to changing policies, billing complexities or other factors.

We are in-network, or under contract, with some of the third-party payors from whom we receive reimbursement; this means that we have agreements with such third-party payors that govern approval or payment terms. However, these contracts do not guarantee reimbursement for all testing we perform. For example, many third-party payors with whom we have written agreements have policies that state they will not reimburse for use of NIPT for average-risk pregnancies or for the screening of microdeletions, or do not have a policy in place to reimburse for microdeletions screening. In addition, the terms of certain of our agreements require a physician or qualified practitioner's signature on test requisitions or require other controls and procedures prior to conducting a test. In particular, third-party payors have been increasingly requiring prior authorization to be obtained prior to conducting a test as a condition to reimbursing for the test. This has placed a burden on our billing operations as we have to dedicate resources to monitor that these prior authorization requirements are met and to conduct follow-up and address issues as they arise, and has also impacted our operating results, including our gross margins, since these requirements began to take effect in 2017. To the extent we or the healthcare providers ordering our tests do not follow the prior authorization requirements, we may be subject to claims for recoupment of reimbursement amounts previously paid to us, or may not receive some or all of the reimbursement payments to which we would otherwise be entitled. This has occurred in some cases in the past and may occur in the future, which could have a material and adverse effect on our business, operating results, and financial condition.

We have experienced, and may continue to experience, delays in reimbursement when we transition to being an in-network provider with a third-party payor. In addition, while we expect to gradually see an increase in test volume through broader access to in-network patients and an increase in percentage of tests paid upon transitioning to in-network status with a payor, we also expect to experience a negative impact in revenues per test due to lower rates. We can provide no assurance that we will see the benefits of this transition to in-network status and that the increase in volume of tests and tests paid will be sufficient to compensate for the decrease in per test revenues.

Where we are considered to be an out-of-network provider, which is the case with some larger third-party payors from whom we currently receive reimbursement, such third-party payors could withdraw coverage and decline to reimburse for our tests in the future, for any reason. They can also impose prior authorization requirements through the terms of the patients' health plans. Managing reimbursement on a case-by-case basis is time-consuming and contributes to an increase in the number of days it takes us to collect on accounts, which also increases our risk of non-payment. Negotiating reimbursement on a case-by-case basis also typically results in the receipt of reimbursement at a significant discount to the list price of our tests.

Even if we are being reimbursed for our tests, third-party payors may unilaterally review and adjust the rate of reimbursement, require co-payments from patients or stop paying for our tests. Government healthcare programs and other third-party payors continue to increase their efforts to control the cost, utilization, and delivery of healthcare services by demanding price discounts or rebates and limiting coverage of, and amounts they will pay for, molecular tests. These measures have resulted in reduced payment rates and, in some instances, decreased utilization in the clinical laboratory industry. Because of these cost- containment measures, governmental and commercial third-party payors—including those that currently reimburse our tests—may reduce, suspend, revoke or discontinue

payments or coverage at any time.

Reduced reimbursement of our tests may harm our business, operating results, and financial condition. Billing for clinical laboratory testing services is complex. We perform tests in advance of payment and without certainty as to the outcome of the billing process. In cases where we expect to receive a fixed fee per test due to our reimbursement arrangements, we may nevertheless encounter variable reimbursement, leading to disputes over pricing and billing. Each third-party payor typically has different billing requirements, and the billing requirements of many payors have become increasingly difficult to meet. Among the factors complicating our billing of third-party payors are:

- disparity in coverage among various payors;
- disparity in information and billing requirements among payors, including with respect to prior authorization requirements and procedures and establishing medical necessity; and
- incorrect or missing billing information, which is required to be provided by the ordering healthcare provider.

These risks related to billing complexities, and the associated uncertainty in obtaining payment for our tests, could harm our business, operating results, and financial condition.

Our status as an out-of-network provider with large commercial third-party payors may cause healthcare providers to avoid recommending our tests.

We are considered to be an out-of-network provider with respect to some larger commercial third-party payors from whom we currently receive reimbursement. Physician groups and other healthcare providers may view this negatively and may insist upon only using clinical laboratories that are in-network with their patients' insurance companies. These types of decisions could reduce our revenue, and harm our financial condition.

Changes in government healthcare policy could increase our costs and negatively impact coverage and reimbursement for our tests by governmental and other third-party payors.

The U.S. government has shown significant interest in pursuing healthcare reform and reducing healthcare costs. Government healthcare policy has been and will likely continue to be a topic of extensive legislative and executive activity in the U.S. federal government and many U.S. state governments. As a result, our business could be affected by significant and potentially unanticipated changes in government healthcare policy, such as changes in reimbursement levels by government third-party payors. Any such changes could substantially impact our revenues, increase costs, and divert management attention from our business strategy. We cannot predict the impact of governmental healthcare policy changes on our future business, operating results, and financial condition. In the United States, the ACA was signed into law in March 2010 and significantly impacted the U.S. pharmaceutical and medical device industries, including the diagnostics sector, in a number of ways. Among other things, the ACA expanded healthcare fraud and abuse laws such as the False Claims Act and the Anti-Kickback Statute, including but not limited to required disclosures of financial arrangements with physician customers, required reporting of discovered overpayments, lower thresholds for violations, new government investigative powers, and enhanced penalties for such violations. The ACA restricts insurers from charging higher premiums or denying coverage to individuals with pre-existing conditions, and requires insurers to cover certain preventative services without charging any copayment or coinsurance, including screening for lung, breast, colorectal and cervical cancers. The ACA also created a new system of health insurance "exchanges" designed to make health insurance available to individuals and certain groups through state- or federally-administered marketplaces in addition to existing channels for obtaining health insurance coverage. In connection with such exchanges, certain "essential health benefits" are intended to be made more consistent across plans, setting a baseline coverage level. The states (and the federal government) have some discretion in determining the definition of "essential health benefits" and we do not know whether our tests or other products will fall into a benefit category deemed "essential" for coverage purposes across the plans offered in any or all of the exchanges. If any of our tests are not covered by plans offered in the health insurance exchanges, our business, operating results, and financial condition could be adversely affected. There have been multiple attempts to repeal ACA or significantly scale back its applicability, which could negatively impact reimbursement for our testing, adversely affect our test volumes, and adversely affect our business, operating results, and financial condition. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the entire ACA is invalid based primarily on the fact that the legislation enacted on December 22, 2017, informally known as the Tax Cuts and Jobs Act, repealed the tax-based shared responsibility payment imposed by the ACA, on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." On December 18, 2019, the 5th Circuit Court of Appeals upheld the Texas District Court's ruling that the individual mandate was unconstitutional, but remanded the case back to the Texas District Court to determine whether the remaining provisions of the ACA were nonetheless valid. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case and a decision is expected before the end of 2020, although it is unclear how the Supreme Court will rule. The repeal of this mandate would mean that fewer consumers will

carry insurance coverage and therefore may be less likely to elect to receive our testing because they would be required to pay out of pocket for such tests. The attempts to repeal the ACA have resulted in considerable uncertainty and concern regarding, for example, a patient's election to undergo genetic screening and whether doing so may impact health insurance eligibility. Because it is unclear whether or how the ACA may change, and whether and to what extent NIPT, cancer screening or other genetic screening may be affected, we are uncertain how our business may be impacted.

In addition to the ACA, various healthcare reform proposals have also emerged from federal and state governments. The Protecting Access to Medicare Act of 2014, or PAMA, introduced a multi-year pricing program for services payable under the Clinical Laboratory Fee Schedule, or CLFS, that is designed to bring Medicare allowable amounts in line with the amounts paid by private payors. The rule issued by CMS to implement PAMA required certain laboratories to report third-party payor rates and test volumes. Since January 1, 2018, the Medicare payment rate for these tests is equal to the weighted median private payor rate reported to CMS, which for many tests is lower than the previous CLFS payment rates due to the often lower negotiated private payor rates applicable to large commercial laboratories that were required to report data to CMS. While we believe that the new rates will have minimal impact on our business, the rates have been the subject of controversy in the industry, including a lawsuit by the American Clinical Laboratory Association, and it is unclear whether and to what extent the new rates may change. The implementation of the PAMA rates has negatively impacted overall pricing and reimbursement for many clinical laboratory testing services. In addition, federal budgetary limitations and changes in healthcare policy, such as the creation of broad limits for our tests and requirements that beneficiaries of government health plans pay for, or pay for higher portions of, clinical laboratory tests or services received, could substantially diminish the utilization of our tests, increase costs and adversely affect our ability to generate revenues and achieve and sustain profitability.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or how any such future legislation, regulation, or initiative may affect us. Current or potential future federal legislation and the expansion of government's role in the U.S. healthcare industry, as well as changes to the reimbursement amounts paid by third-party payors for our current and future tests, may adversely affect our test volumes and adversely affect our business, operating results, and financial condition.

Our revenues may be adversely affected if we are unable to successfully obtain reimbursement from the Medicare program and state Medicaid programs.

Our revenues from Medicare are currently very small and were only 2.8% of our total revenues in 2019, given our current product mix and the fact that our testing generally is not received by Medicare beneficiaries. As a result, we do not expect those revenues to change materially with regard to our current commercial products. However, our other products in development may be used by Medicare beneficiaries in the future. 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, set by CMS pursuant to a statutory formula established by Congress. Our current Medicare Part B coverage was not set pursuant to a national coverage determination by CMS. Although we believe that coverage is available under Medicare Part B even without such a determination, we currently lack the certainty afforded by a formal national coverage determination by CMS. Thus, CMS or a regional Medicare Administrative Contractor, or MAC, could issue an adverse coverage determination as to Innatal or Preparent or our future products, if any, which could influence other third-party payors, including Medicaid, and could have a material and adverse effect on our business, operating results, and financial condition.

It is estimated that nearly half of all births in the United States are to state Medicaid program recipients. 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. Even if our testing is covered by a state Medicaid program, we must be recognized as a Medicaid provider by the state in which the Medicaid recipient receiving the services resides in order for us to be reimbursed by a state's Medicaid program. In addition, many Medicaid programs have entered into agreements with managed care plans to have the managed care plans manage the provision of healthcare to that Medicaid program's beneficiaries. In order for us to enter into contracts to offer our tests to beneficiaries who are enrolled with a Medicaid managed care plan, we must first be recognized as a Medicaid provider in that state, and then contract with the applicable Medicaid managed care program. We are currently recognized by 43 states as a Medicaid provider. It is likely that we will not be able to be recognized as a provider by additional Medicaid programs because some states require that a provider maintain a physical laboratory in that state in order to be recognized; furthermore, some states have closed provider panels, which means that the state does not intend to expand its current provider network and therefore does not intend to recognize additional Medicaid providers. Even if we are recognized as a provider in a state, 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. Low or zero-dollar Medicaid reimbursement rates for our tests could have a material and adverse effect on our business, operating results, and financial condition.

Federal legislation will increase the pressure to reduce prices of pharmaceutical products paid for by Medicare or may otherwise seek to limit healthcare costs.

The Medicare Modernization Act, or MMA, changed the way Medicare covers and reimburses for pharmaceutical products. The legislation introduced a new reimbursement methodology based on average sales prices for pharmaceutical products that are used in hospital settings or under the direct supervision of a physician and, starting in 2006, expanded Medicare coverage for pharmaceutical product purchases by the elderly. In addition, the MMA requires the creation of formularies for self- administered pharmaceutical products and provides authority for limiting the number of pharmaceutical products that will be covered in any therapeutic class and provides for plan sponsors to negotiate prices with manufacturers and suppliers of covered pharmaceutical products. As a result of the MMA and the expansion of federal coverage of pharmaceutical products, we expect continuing pressure to contain and reduce costs of pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we may receive for any pharmaceutical product candidates that we may develop using our precision medicine platform in the future and could materially adversely affect our business, operating results and overall financial condition. While the MMA generally applies only to pharmaceutical product benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement policies and any reduction in coverage or payment that results from the MMA may result in a similar reduction in coverage or payments from private payors.

If the validity of an informed consent from a patient is challenged, we could be precluded from billing for such patient's testing or be forced to stop performing certain tests or exclude the patient's data from clinical trial results.

We are required to ensure that all clinical data and blood samples that we receive have been collected from subjects who have provided appropriate informed consent for us to perform our testing, both commercially and in clinical trials. We seek to ensure that the subjects from whom the data and samples are collected do not retain or have conferred on them any proprietary or commercial rights to the data or any discoveries derived from them. A subject's informed consent could be challenged in the future, and the informed consent could prove invalid, unlawful, or otherwise inadequate for our purposes. Any such findings against us, or our partners, could deny us access to, or force us to stop, testing samples in a particular territory or could call into question the results of our clinical trials. We could also be precluded from billing third-party payors for tests for which informed consents are challenged, or we could be requested to refund amounts previously paid by third-party payors for such tests. We could become involved in legal challenges, which could require significant management and financial resources and adversely affect our operating results.

Regulatory and Legal Risks Related to Our Business

If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected.

We are subject to healthcare fraud and abuse regulation and enforcement by both the U.S. federal government and the states in which we conduct our business, including:

- federal and state laws and regulations governing the submission of claims, as well as billing and collection practices, for healthcare services;
- the federal Anti-Kickback Statute, which prohibits, among other things, the knowing and willful solicitation, receipt, offer or payment of remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid; a person does not need to have knowledge of the statute or specific intent to violate it to have committed a violation; a violation of the Anti-Kickback Statute may result in imprisonment for up to ten years and significant fines for each violation and administrative civil money penalties, plus up to three times the amount of the remuneration paid; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, which, among other things, prohibits knowingly or willfully paying, offering to pay, soliciting or receiving any remuneration (including any kickback, bribe, or rebate), whether directly or indirectly, overtly or covertly, in cash or in kind, to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory, or in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory; violation of EKRA may result in significant fines and imprisonment of up to 10 years for each occurrence;

- the federal False Claims Act which prohibits, among other things, the presentation of false or fraudulent claims for payment from Medicare, Medicaid, or other government-funded third-party payors discussed in more detail below;
- federal laws and regulations governing the Medicare program, providers of services covered by the Medicare program, and the submission of claims to the Medicare program, as well as the Medicare Manuals issued by CMS and the local medical policies promulgated by the Medicare Administrative Contractors with respect to the implementation and interpretation of such laws and regulations;
- the federal Stark Law, also known as the physician self-referral law, which, subject to certain exceptions, prohibits a physician from making a referral for certain designated health services covered by the Medicare program (and according to case law in some jurisdictions, the Medicaid program as well), including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services; a person who attempts to circumvent the Stark Law may be fined up to approximately $165,000 for each arrangement or scheme that violates the statute; in addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to significant civil monetary penalties, plus up to three times the amount of reimbursement claimed;
- the federal Civil Monetary Penalties Law, which, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program; any violation of these prohibitions may result in significant civil monetary penalties for each wrongful act;
- the prohibition on reassignment by the program beneficiary of Medicare claims to any party;
- HIPAA, which, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making false, fictitious or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, and their implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates, individuals or entities that perform services for them that involve individually identifiable health information; HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal transparency requirements under the Physician Payments Sunshine Act, created under the ACA, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to annually report to CMS information related to payments and other transfers of value provided to physicians, certain other healthcare professionals beginning in 2022, and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members; we believe that we are currently exempt from these reporting requirements; we cannot assure you, however, that regulators, principally the federal government, will agree with our determination, and a determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business;
- federal and state laws and regulations governing informed consent for genetic testing and the use of genetic material;
- state law equivalents of the above U.S. federal laws, such as the Stark Law, Anti-Kickback Statute and false claims laws, which may apply to items or services reimbursed by any third- party payor, including commercial insurers; and
- similar healthcare laws in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Furthermore, a development affecting our industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "*qui tam*" provisions. The False Claims Act imposes liability for, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment by a federal governmental payor program. The *qui tam* provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government for violations of the False Claims Act and permit such individuals to share in any amounts paid by the defendant to the government in fines or settlement.

When an entity is determined to have violated the False Claims Act, it is subject to mandatory damages of three times the actual damages sustained by the government, plus mandatory significant civil penalties for each false claim. In addition, various states have enacted false claim laws analogous to the federal False Claims Act, and in some cases apply more broadly because many of these state laws apply to claims made to private payors and not merely governmental payors.

The rapid growth and expansion of our business may increase the potential for violating these laws or our internal policies and procedures designed to comply with these laws. The evolving interpretations of these laws and regulations by courts and regulators increase the risk that we may be alleged to be, or in fact found to be, in violation of these or other laws and regulations, including pursuant to private *qui tam* actions brought by individual whistleblowers in the name of the government as described above.

For example, in April 2018, we received a civil investigative demand from SDNY and a HIPAA subpoena issued by SDCA. In May 2018, we received a subpoena from the State of New York Medicaid Fraud Control Unit. The civil and criminal investigations related to discontinued legacy billing practices for our NIPT and microdeletion tests and the provision of alleged kickbacks or inducements to physicians and patients and the civil investigations also involved inquiries about our laboratory licenses, our enrollment in state Medicaid programs, and the laboratories that performed testing for us.

On July 21, 2020, July 23, 2020, and October 1, 2020, we entered into agreements with certain governmental agencies and the 45 states participating in the settlement, or the State AGs, to resolve, with respect to such agencies and State AGs, all of such agencies' and State AGs' outstanding civil, and, where applicable, federal criminal, investigations regarding our discontinued legacy billing practices for our non-invasive prenatal tests and microdeletion tests and the provision of alleged kickbacks or inducements to physicians and patients. Specifically, we entered into:

- a civil settlement agreement, effective July 23, 2020, with the DOJ through SDNY, and on behalf of the OIG and with the relator named therein, or the SDNY Civil Settlement Agreement;
- a civil settlement agreement, effective July 23, 2020, with the DOJ through SDCA, and on behalf of the Defense Health Agency, the Tricare Program and the Office of Personnel Management, which administers the Federal Employees Health Benefits Program, or the SDCA Civil Settlement Agreement;
- a non-prosecution agreement, effective July 21, 2020, with SDCA, or the Non-Prosecution Agreement, in resolution of all criminal allegations;
- a corporate integrity agreement, effective July 21, 2020, with the OIG, or the Corporate Integrity Agreement; and
- civil settlement agreements, effective October 1, 2020, with the State AGs.

The terms of these agreements require that we pay $49.0 million in the aggregate plus applicable interest. As of October 31, 2020, we have paid approximately $32.9 million towards this amount. We will pay the remaining portion of the settlement over an approximately three-year period, structured as follows: $4.0 million in December 2020; $5.0 million in December 2021; approximately $6.9 million in December 2022; and approximately $0.2 million in December 2023. For additional information regarding these agreements, please see Part II, Item 1. "Legal Proceedings—Federal Investigations."

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 quarter 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. As of September 30, 2020, our accrual for these matters consists of $20.2 million in accrued expenses and other current liabilities and $12.1 million in other long-term liabilities.

Our inability to obtain, on a timely basis or at all, any necessary marketing authorizations for new device products, or improvements to our current offerings, could adversely affect our future product commercialization and operating results.

Our planned medical device product candidates, and potentially some of our molecular testing products such as our planned preeclampsia test, are expected to be subject to regulation by the FDA, and numerous other federal and state governmental authorities. The process of obtaining regulatory approvals or clearances to market a medical device, particularly from the FDA and regulatory authorities outside the United States, can be costly and time-consuming, and approvals or clearances might not be granted for future products on a timely basis, if at all. To ensure ongoing customer safety, regulatory agencies such as the FDA may re-evaluate their current approval or clearance processes and may impose additional requirements. In addition, the FDA and other regulatory authorities may impose increased or enhanced regulatory inspections for domestic or foreign facilities involved in the manufacture of medical devices.

We may develop new medical devices in connection with our precision medicine platform and new molecular test candidates that are regulated by the FDA as medical devices. Unless otherwise exempted, medical devices must receive one of the following marketing authorizations from the FDA before being marketed in the United States: "510(k) clearance," *de novo* classification, or PMA. The FDA determines whether a medical device will require 510(k) clearance, *de novo* classification, or the PMA process based on statutory criteria that include the risk associated with the device and whether the device is similar to an existing, legally marketed product. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. The process to obtain either 510(k) clearance or PMA will likely be costly, time- consuming, and uncertain. However, we believe the PMA process is generally more challenging. Even if we design a product that we expect to be eligible for the 510(k) clearance process, the FDA may require that the product undergo the PMA process. There can be no assurance that the FDA will approve or clear the marketing of any new medical device product that we develop. Even if regulatory approval or clearance is granted, such approval may include significant limitations on indicated uses, which could materially and adversely affect the prospects of the new medical device product.

If a medical device is novel and has not been previously classified by the FDA as Class I, II, or III, it is automatically classified into Class III regardless of the level of risk it poses. The Food and Drug Administration Modernization Act of 1997 established a route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device would automatically be classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application.

FDA marketing authorization could not only be required for new products we develop, but also could be required for certain enhancements we may seek to make to our existing tests and other products. Delays in receipt of, or failure to obtain, marketing authorizations could materially delay or prevent us from commercializing our products or result in substantial additional costs that could decrease our profitability. In addition, even if we receive FDA or other regulatory marketing authorizations for a new or enhanced product, the FDA or such other regulator may condition, withdraw, or materially modify its marketing authorization.

If we fail to comply with laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations require clinical laboratories to obtain a certificate and mandate specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management and quality assurance. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third- party payors, for our tests. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical laboratory.

We are also required to maintain state licenses to conduct testing in our laboratories. We cannot provide assurance that state authorities will at all times in the future find us to be in compliance with all applicable laws. If a clinical laboratory is out of compliance, the state authority may suspend, restrict or revoke the license to operate the clinical laboratory, assess substantial civil money penalties, or impose specific corrective action plans. Any such actions could materially affect our business.

Moreover, several other states require that we hold licenses to test samples from patients in those states. We have obtained licenses from states where we believe we are required to be licensed. From time to time, we may become aware of other states that require out-of-state laboratories to obtain licensure in order to accept specimens from the state, and it is possible that other states do have such requirements or will have such requirements in the future. If we identify any other state with such requirements or if we are contacted by any other state advising us of such requirements, we expect to seek to comply with such requirements. However, there is no assurance that we will be able to obtain any such required license for the particular state.

Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state license or accreditation, could have a material and adverse effect on our business, operating results and financial condition. For a discussion of an inquiry from the State of Texas regarding our CLIA certification, see Part II, Item 1. “Legal Proceedings—Texas OIG Inquiry.” CMS also has the authority to impose a wide range of sanctions, including revocation of the CLIA certification along with a bar on the ownership or operation of a CLIA- certified laboratory by any owners or operators of the deficient laboratory. If we were to lose our CLIA certification or required state licensure, we would not be able to operate our clinical laboratory and conduct our tests, in full or in particular states, which would adversely impact our business, operating results, and financial condition.

We are subject to costly and complex laws and governmental regulations.

Our precision medicine product candidates are subject to a complex set of regulations and rigorous enforcement, including by the FDA, DOJ, HHS, and numerous other federal, state, and non-U.S. governmental authorities. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our products. As a part of the regulatory process of obtaining marketing authorization for new products and modifications to existing products, we may conduct and participate in numerous clinical trials with a variety of study designs, patient populations, and trial endpoints. Unfavorable or inconsistent clinical data from existing or future clinical trials or the market’s or FDA’s perception of this clinical data, may adversely impact our ability to obtain product approvals, our position in, and share of, the markets in which we participate, and our business, operating results, and financial condition. We cannot guarantee that we will be able to obtain or maintain marketing authorization for our product candidates and/or enhancements or modifications to existing products, and the failure to maintain or obtain marketing authorization in the future could have a material and adverse effect on our business, operating results, financial condition.

Both before and after a product is commercially released, we and our products are subject to ongoing and pervasive oversight of government regulators. For instance, in the case of any product candidates subject to regulation by the FDA, including those products candidates in connection with our precision medicine platform, our facilities and procedures and those of our suppliers will be subject to periodic inspections by the FDA to determine compliance with applicable regulations. The results of these inspections can include inspectional observations on FDA’s Form-483, warning letters, or other forms of enforcement. If the FDA or a non-U.S. regulatory agency were to conclude that we are not in compliance with applicable laws or regulations, or that any of our product candidates, if authorized for marketing, are ineffective or pose an unreasonable health risk, the FDA or such other non-U.S. regulatory agency could ban products, withdraw marketing authorizations for such products, detain or seize adulterated or misbranded products, order a recall, repair, replacement, or refund of such products, refuse to grant pending marketing applications, require certificates of non-U.S. governments for exports, and/or require us to notify health professionals and others that the products present unreasonable risks of substantial harm to the public health. The FDA and other non-U.S. regulatory agencies may also assess civil or criminal penalties against us, our officers, or employees and impose operating restrictions on a company-wide basis. The FDA may also recommend prosecution to the DOJ. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future marketing authorizations, and could result in a substantial modification to our business practices and operations. Furthermore, we occasionally receive investigative demands, subpoenas, or other requests for information from state and federal governmental agencies, and we cannot predict the timing, outcome, or impact of any such investigations. See Part II, Item 1. “Legal Proceedings.” Any adverse outcome in one or more of these investigations could include the commencement of civil and/or criminal proceedings, substantial fines, penalties, and/or administrative remedies, including exclusion from government reimbursement programs and/or amendments to our corporate integrity agreement with the OIG. In addition, resolution of any of these matters could involve the imposition of additional, costly compliance obligations. These potential consequences, as well as any adverse outcome from government investigations, could have a material and adverse effect on our business, operating results, and financial condition.

Even if we obtain regulatory authorizations, our marketed products will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and foreign regulations, we could lose any marketing authorizations we have obtained and our business would be seriously harmed.

Even after authorization, any medical products we develop will be subject to ongoing regulatory review, including requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post- market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. Any marketing authorizations that we obtain for our product candidates may also be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw marketing authorizations;
- suspend or terminate any of our clinical studies;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products, or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory authorization is withdrawn, our business could be seriously harmed.

Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory authorization of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or to the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing authorization that we may have obtained and we may not achieve or sustain profitability.

Similarly, our commercial activities are subject to comprehensive compliance obligations under state and federal reimbursement, Sunshine Act, anti-kickback and government pricing regulations. If we make false price reports, fail to implement adequate compliance controls or our employees violate the laws and regulations governing relationships with healthcare providers, we could also be subject to substantial fines and penalties, criminal prosecution and debarment from participation in the Medicare, Medicaid, or other government reimbursement programs. For additional information regarding these risks, see the risk factor titled "If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected." Noncompliance with European Union requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with the European Union requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

We and our commercial partners and contract manufacturers are subject to significant regulation with respect to manufacturing medical devices and therapeutic products. The manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands.

Entities involved in the preparation of medical devices and/or therapeutic products for clinical studies or commercial sale, including our manufacturers for the therapeutic products that we may develop, are subject to extensive regulation. Components of a finished medical device or therapeutic product approved for commercial sale or used in late-stage clinical studies must be

manufactured in accordance with cGMP and/or QSR requirements. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaboration partners or our contract manufacturers must supply all necessary documentation in support of an NDA, a BLA, a PMA, a 510(k) application, a request for *de novo* classification, or a Marketing Authorization Application, or MAA, on a timely basis and must adhere to cGMP regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our contract manufacturers may have never produced a commercially approved pharmaceutical product and therefore have not been subject to the review of the FDA and other regulators. The facilities and quality systems of some or all of our collaboration partners and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our drug and biologic product candidates and may be subject to inspection in connection with a MAA for any of our other potential product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee our contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, such contract manufacturing partners for compliance with these regulatory requirements. If these facilities do not pass a pre-approval plant inspection, marketing authorizations for the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval or clearance of a product for sale, audit the manufacturing facilities of our collaboration partners and third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time- consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility.

Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we, our collaboration partners or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product candidate, withdrawal of a marketing authorization or suspension of production. As a result, our business, operating results, and financial condition may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer will need to be qualified and we may need to obtain marketing authorization for a change in the manufacturer through submission of a PMA supplement, 510(k) pre-market notification, NDA or BLA supplement, MAA variation or other regulatory filing to the FDA or other foreign regulatory agencies, which could result in further delay.

These factors could cause us to incur additional costs and could cause the delay or termination of clinical studies, regulatory submissions, required marketing authorizations or commercialization of our products, including product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue.

The FDA initiate rulemaking to impose premarket review, clearance, or approval or other requirements on LDTs, and we may become subject to extensive regulatory requirements and may be required to conduct additional clinical trials prior to continuing to sell our existing tests or launching any other tests we may develop, which may increase the cost of conducting, or otherwise harm, our business.

We currently market all of our commercial molecular tests as LDTs and may in the future market other tests as LDTs. The FDA has adopted a policy of enforcement discretion with respect to LDTs whereby the FDA does not actively enforce its regulatory requirements for such tests. However, the FDA may choose to initiate rulemaking to impose premarket review, clearance, or approval or other regulatory requirements on LDTs. If there are changes in FDA regulations, or if the FDA disagrees that our marketed tests are LDTs or determines that we are marketing our tests outside the scope of the FDA's current policy of enforcement discretion, we may become subject to extensive regulatory requirements and may be required to stop selling our existing tests or launching any other tests we may develop and to conduct additional clinical trials or take other actions prior to continuing to market our tests. If the FDA allows our tests to remain on the market but there is uncertainty about our tests, if they are labeled investigational by the FDA or if labeling claims the FDA allows us to make are very limited, orders from physicians or reimbursement may decline. If required, the regulatory authorization process may involve, among other things, successfully completing additional clinical trials and submitting a 510(k) notice, or filing a *de novo* classification request or a PMA application with the FDA. If the FDA adopts regulations requiring premarket review, our tests may not be cleared or approved on a timely basis, if at all. This could significantly increase the costs and expenses of conducting, or otherwise harm, our business.

While we believe that we are currently in material compliance with applicable laws and regulations as historically enforced by the FDA with respect to LDTs, we cannot assure you that the FDA will agree with our determination. A determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations, and financial condition.

On July 31, 2014, the FDA notified Congress of its intent to modify, in a risk-based manner, its policy of enforcement discretion with respect to LDTs. On October 3, 2014, the FDA issued two draft guidances, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)," or the Framework Guidance, and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)." The Framework Guidance stated that the FDA intended to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the existing classification of medical devices. Thus, pursuant to the Framework Guidance, the FDA planned to begin to enforce its medical device requirements, including premarket submission requirements, on LDTs that have historically been marketed without FDA premarket review and oversight. In August 2020, HHS announced that the FDA will not require premarket review for any LDTs without first conducting notice-and-comment rulemaking proceedings. Although, as a result of this decision, the FDA may not rely on guidance documents, policy statements, or other informal decision-making to impose premarket review requirements on LDTs, the FDA could ultimately adopt rules that modify its current approach to LDTs in a way that would subject our products marketed as LDTs to the enforcement of regulatory requirements. Additionally, if and when the FDA begins to actively enforce its premarket submission regulations with respect to LDTs, we may be required to obtain premarket clearance or approval for our currently marketed tests and other products we plan to commercialize as LDTs. Moreover, legislative measures have recently been proposed in Congress that, if ultimately enacted, could provide the FDA with additional authority to require premarket review of and regulate LDTs. For example, in late 2018, the FDA proposed to Congress significant reforms to the agency's regulation of LDTs that would bring all *in vitro* clinical tests, including LDTs, under a unified framework and would dramatically increase FDA oversight of LDTs. The FDA's proposal included premarket review for certain tests, a precertification program to permit approval or clearance of a group of tests based on the review of a representative test, registration and notification requirements, quality system requirements, adverse event reporting, labeling requirements, and explicit authorities for the FDA to revoke the marketing authorization of tests and to take corrective action against test developers. However, in August 2020, the HHS issued a rescission order stating that the FDA will not require premarket review of LDTs absent changes in policy implemented through formal notice-and-comment rulemaking procedures. The outcome and ultimate impact of such proposals on our business is difficult to predict at this time. Potential future increased regulation of our LDTs could also result in increased costs and administrative and legal actions for noncompliance, including warning letters, fines, penalties, product suspensions, product recalls, injunctions and other civil and criminal sanctions, which could have a material and adverse effect upon our business, operating results, and financial condition.

We may be adversely impacted by changes in laws and regulations, or in their application.

The industries in which we operate are highly regulated, and failure to comply with applicable regulatory, supervisory, accreditation, registration, or licensing requirements may adversely affect our business, operating results, and financial condition. The laws and regulations governing our research and marketing efforts are extremely complex and in many instances there are no clear regulatory or judicial interpretations of these laws and regulations, which increases the risk that we may be found to be in violation of these laws.

Furthermore, the industries in which we operate are growing, and regulatory agencies such as HHS or the FDA may apply heightened scrutiny to new developments. While we have taken steps to ensure compliance with current regulatory regimes in all material respects, given the nature of such regimes and our geographical diversity, there could be areas where we are noncompliant. Any change in the federal or state laws or regulations relating to our business may require us to implement changes to our business or practices, and we may not be able to do so in a timely or cost-effective manner. Should we be found to be noncompliant with current or future regulatory requirements, we may be subject to sanctions which could include changes to our operations, adverse publicity, substantial financial penalties and criminal proceedings, which may adversely affect our business, operating results, and financial condition by increasing our cost of compliance or limiting our ability to develop, market and commercialize our products. For additional information regarding these risks, see the risk factor titled "If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected."

In addition, there has been a recent trend of increased U.S. federal and state regulation of payments made to physicians, which are governed by laws and regulations including the Stark Law, the federal Anti- Kickback Statute, the Physician Payments Sunshine Act and the federal False Claims Act as well as state equivalents of such laws. Among other requirements, the Stark Law requires laboratories to track, and places a cap on, non-monetary compensation provided to referring physicians.

While we have a compliance plan intended to address compliance with government laws and regulations, including applicable fraud and abuse laws and regulations such as those described in this risk factor, the evolving commercial compliance environment and

the need to build and maintain robust and scalable systems to comply with regulations in multiple jurisdictions with different compliance and reporting requirements increases the possibility that we could inadvertently violate one or more of these requirements.

Changes in the way the FDA regulates the reagents, other consumables, and testing equipment we use when developing, validating, and performing our tests could result in delay or additional expense in bringing our tests to market or performing such tests for our customers.

Many of the sequencing instruments, reagents, kits and other consumable products used to perform our testing, as well as the instruments and other capital equipment that enable the testing, are offered for sale as analyte specific reagents, or ASRs, or for research use only, or RUO. ASRs are medical devices and must comply with FDA QSR provisions and other device requirements, but most are exempt from 510(k) and PMA review. Products that are intended for RUO and are labeled as RUO, including our epigenetics platform, are exempt from compliance with FDA requirements, including the approval or clearance and other product quality requirements for medical devices. A product labeled RUO but which is actually intended for clinical diagnostic use may be viewed by the FDA as adulterated and misbranded under the FD&C Act and subject to FDA enforcement action. The FDA has said that when determining the intended use of a product labeled RUO, it will consider the totality of the circumstances surrounding distribution and use of the product, including how the product is marketed and to whom. The FDA could disagree with a supplier's assessment that the supplier's products are RUOs, or could conclude that products labeled as RUO are actually intended for clinical diagnostic use, and could take enforcement action against the supplier, including requiring the supplier to cease offering the product while it seeks clearance or approval. Suppliers of RUO products that we employ in our other tests may cease selling their respective products, and we may be unable to obtain an acceptable substitute on commercially reasonable terms or at all, which could significantly and adversely affect our ability to provide timely testing results to our customers or could significantly increase our costs of conducting business.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared, or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and clear or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs, medical devices, and biologics or modifications to cleared or approved drugs, medical devices, and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA temporarily postponed routine surveillance inspections of domestic and foreign manufacturing facilities and inspections of foreign products. The FDA recently announced that it was beginning to work toward resuming prioritized domestic inspections, where possible to do so safely, and, on a case-by-case basis, conducting "mission-critical" inspections. Routine foreign facility inspections have not resumed, however the FDA has expanded its use of other tools, when possible, to ensure the quality and safety of products being imported into the United States. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We are developing proprietary product candidates, such as PGN-600, a GI-targeted tofacitinib, for which we may seek FDA approval through the Section 505(b)(2) regulatory pathway. We expect that PGN-600 will be regulated as a drug/device combination product under the drug provisions of the FD&C Act, enabling us to submit NDAs for approval of this product candidate. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the

FD&C Act. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FD&C Act, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidate by potentially decreasing the amount of nonclinical and/or clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional nonclinical studies and/or clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for this product candidate, and complications and risks associated with this product candidate, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than our product candidate, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidate will receive the requisite approval for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to certain requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. Even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to streamlined product development or earlier approval.

Moreover, even if our product candidate is approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the product may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

The misuse or off-label use of our products or product candidates may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, and any of these consequences could be costly to our business.

We are developing certain precision medicine product candidates, including pharmaceutical products and medical devices, which if authorized for marketing by the FDA or other regulatory authorities, will be authorized for use in specific indications and patient populations. We expect to train our marketing personnel and direct sales force not to promote our product candidates for uses outside of the FDA-approved or -cleared indications for use, which are sometimes referred to as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those authorized for marketing by the FDA or any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, a warning letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil, and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

In addition, physicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. As described above, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

Risks Related to Our Intellectual Property

Third-party claims of intellectual property infringement could result in litigation or other proceedings, which would be costly and time-consuming, and could limit our ability to commercialize our products.

Our success depends in part on our freedom-to-operate with respect to the patents or intellectual property rights of third parties. We operate in industries in which there have been substantial litigation and other proceedings regarding patents and other intellectual property rights. For example, we have identified a number of third-party patents that may be asserted against us with respect to certain of our current molecular testing products and certain of our future products in the molecular testing and precision medicine space. We believe that we do not infringe the relevant claims of these third-party patents and/or that the relevant claims of these patents are likely invalid or unenforceable. We may choose to challenge the validity of these patents, though the outcome of any challenge that we may initiate in the future is uncertain. We may also decide in the future to seek a license to those third-party patents, but we might not be able to do so on reasonable terms. Certain third parties, including our competitors or collaborators, have asserted and may in the future assert that we are employing their proprietary technology without authorization or that we are otherwise infringing their intellectual property rights. The risk of intellectual property proceedings may increase as the number of products and the level of competition in our industry segments grows. Defending against infringement claims is costly and may divert the attention of our management and technical personnel. If we are unsuccessful in defending against patent infringement claims, we could be required to stop developing or commercializing products, pay potentially substantial monetary damages, and/or obtain licenses from third parties, which we may be unable to do on acceptable terms, if at all, and which may require us to make substantial royalty payments. In addition, we could encounter delays in product introductions while we attempt to develop alternative non-infringing products. Any of these or other adverse outcomes could prevent us from offering our tests, which would have a material and adverse effect on our business, operating results, and financial condition. See Part II, Item 1. “Legal Proceedings—Natera Lawsuit” for more information regarding a patent infringement suit filed by Natera.

As we move into new markets and develop enhancements to and new applications for our products, competitors have asserted and may in the future assert their patents and other proprietary rights against us as a means of blocking or slowing our entry into such markets or our sales of such new or enhanced products or as a means to extract substantial license and royalty payments from us. Our competitors and others may have significantly stronger, larger, and/or more mature patent portfolios than we have, and additionally, our competitors may be better resourced and highly motivated to protect large, well-established markets that could be disrupted by our product candidates. In addition, future litigation may involve patent holding companies or other patent owners or licensees who have no relevant product revenues and against whom our own patents may provide little or no deterrence or protection.

In addition, our agreements with some of our customers, suppliers, and other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties if we determine it to be in the best interests of our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, and financial condition.

Because the industries in which we operate are particularly litigious, we are susceptible to intellectual property suits that could cause us to incur substantial costs or pay substantial damages or prohibit us from selling our products or conducting our other business.

There is a substantial amount of litigation over patent and other intellectual property rights in the industries in which we operate, including but not limited to the biotechnology, life sciences, pharmaceuticals, and medical device industries. Whether a product infringes a patent involves complex legal and factual issues that may be open to different interpretations. Searches typically performed to identify potentially infringed patents of third parties are often not conclusive and because patent applications can take many years to issue, there may be applications now pending, which may later result in issued patents which our current or future products may infringe. In addition, our competitors or other parties may assert that our product candidates and the methods they employ may be covered by patents held by them. If any of our products infringes a valid patent, we could be prevented from manufacturing or selling it unless we can obtain a license or redesign the product to avoid infringement. A license may not always be available or may require us to pay substantial royalties. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate and could divert our management’s attention from operating our business.

Any inability to effectively protect our proprietary technologies could harm our competitive position.

Our success and ability to compete depend to a large extent on our ability to develop proprietary products and technologies and to maintain adequate protection of our intellectual property in the United States and elsewhere. The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant challenges in establishing and enforcing their proprietary rights outside of the United States. These challenges can be caused by the absence of rules and methods for the establishment and enforcement of intellectual property rights in certain jurisdictions outside of the United States. In addition, the proprietary positions of companies in the industries in which we operate generally are uncertain and involve complex legal and factual questions. This is particularly true in the diagnostics area where the U.S. Supreme Court has issued

a series of decisions setting forth limits on the patentability of natural phenomena, natural laws, abstract ideas and their applications (see, *Mayo Collaborative v. Prometheus Laboratories (2012), Association for Molecular Pathology v. Myriad Genetics (2013), and Alice Corporation v. CLS Bank (2014)*, which has made it difficult to obtain certain patents and to assess the validity of previously issued patents). This uncertainty may materially affect our ability to defend or obtain patents or to address the patents and patent applications owned or controlled by our collaborators and licensors.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. Any finding that our patents or patent applications are invalid or unenforceable could harm our ability to prevent others from practicing the related technology. We cannot be certain that we were the first to invent the inventions covered by pending patent applications or that we were the first to file such applications, and a finding that others have claims of inventorship or ownership rights to our patents and applications could require us to obtain certain rights to practice related technologies, which may not be available on favorable terms, if at all. There may be times when we choose to retain advisors with academic employers who limit their employees' rights to enter into agreements which provide the kind of confidentiality and assignment provisions congruent with our consulting agreements. We may decide that obtaining the services of these advisors is worth any potential risk, and this may harm our ability to obtain and enforce our intellectual property rights. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing similar or alternative competing products, or design around our patented technologies, and may therefore fail to provide us with any competitive advantage. Furthermore, as our issued patents expire, we may lose some competitive advantage as others develop competing products that would have been covered by the expired patents, and, as a result, may adversely affect our business, operating results, and financial condition.

We may be required to file or defend infringement lawsuits and other contentious proceedings, such as *inter partes* reviews, reexaminations, oppositions, and declaratory judgement actions, to protect our interests, which can be expensive and time-consuming. We cannot assure you that we would prevail over an infringing third party, and we may become subject to counterclaims by such third parties. Our patents may be declared invalid or unenforceable, or narrowed in scope, as a result of such litigation or other proceedings. Some third-party infringers may have substantially greater resources than us and may be able to sustain the costs of complex infringement litigation more effectively than we can. Even if we have valid and enforceable patents, competitors may still choose to offer products that infringe our patents.

Further, preliminary injunctions that bar future infringement by the competitor are not often granted; therefore, remedies for infringement are not often immediately available. Even if we prevail in an infringement action, we cannot assure you that we would be fully or partially financially compensated for any harm to our business. We may be forced to enter into a license or other agreement with the third parties on terms less profitable or otherwise less commercially acceptable to us than those negotiated between a willing licensee and a willing licensor. Any inability to stop third-party infringement could result in loss in market share of some of our products, or lead to a delay, reduction, and/or inhibition of our development, manufacture, or sale of some of our products. A product produced and sold by a third- party infringer may not meet our or other regulatory standards or may not be safe for use, which could cause irreparable harm to the reputation of our products, which in turn could result in substantial loss in our market share and profits. See Part II, Item 1. "Legal Proceedings—Natera Lawsuit" for more information regarding a patent infringement suit filed by Natera.

There is also the risk that others may independently develop similar or alternative technologies or design around our patented technologies, and our competitors or others may have filed, and may in the future file, conflicting patent claims covering technology similar or identical to ours. The costs associated with challenging conflicting patent claims could be substantial, and it is possible that our efforts would be unsuccessful and may result in a loss of our patent position and the issuance or validation of the competing claims. Should such competing claims cover our technology, we could be required to obtain rights to those claims at substantial cost.

Any of these factors could adversely affect our ability to obtain commercially relevant or competitively advantageous patent protection for our products.

"Submarine" patents may be granted to our competitors, which may significantly alter our launch timing expectations, reduce our projected market size, cause us to modify our product or process or block us from the market altogether.

The term "submarine" patent is used to denote a patent issuing from an application that was not published, publicly known or available prior to its grant. Submarine patents add substantial risk and uncertainty to our business. Submarine patents may issue to our competitors covering our product candidates or our pipeline candidates and thereby cause significant market entry delay, defeat our ability to market our products or cause us to abandon development and/or commercialization of a product or molecule.

The issuance of one or more submarine patents may harm our business by causing substantial delays in our ability to introduce a product candidate or other product into the U.S. market.

If we are not able to adequately protect our trade secrets, know-how, and other proprietary information, the value of our technology and products could be significantly diminished.

We rely on trade secret protection and proprietary know-how protection for our confidential and proprietary information, and we have taken security measures to protect this information. These measures, however, may not provide adequate protection for our trade secrets, know-how, or other proprietary information. For example, although we have a policy of requiring our consultants, advisors and collaborators to enter into confidentiality agreements and our employees to enter into invention, non-disclosure and, where lawful, noncompete agreements, we cannot assure you that such agreements will provide for a meaningful protection of our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure of information, including as a result of breaches of our physical or electronic security systems, or as a result of our employees failing to abide by their confidentiality obligations during or upon termination of their employment with us. Any action to enforce our rights is likely to be time-consuming and expensive, and may ultimately be unsuccessful, or may result in a remedy that is not commercially valuable. These risks are heightened in countries where laws or law enforcement practices may not protect proprietary rights as fully as in the United States. Any unauthorized use or disclosure of, or access to, our trade secrets, know-how or other proprietary information, whether accidentally or through willful misconduct, could have a material and adverse effect on our programs, our business strategy, and on our ability to compete effectively.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be adversely affected.

Failure to maintain our trademark registrations, or to obtain new trademark registrations in the future, could limit our ability to protect our trademarks and impede our marketing efforts in the countries in which we operate. We may not be able to protect our rights to trademarks and trade names which we may need to build name recognition with potential partners or customers in our markets of interest. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive, particularly for a company of our size, and time-consuming, and we may not be successful. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks.

Our pending trademark applications in the United States and in other foreign jurisdictions where we may file may not be allowed or may subsequently be opposed. Even if these applications result in registration of trademarks, third parties may challenge our use or registration of these trademarks in the future. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other companies in the industries in which we operate, including biotechnology or diagnostic companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or willfully used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that our employees' former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims, and if we are unsuccessful, we could be required to pay substantial damages and could lose rights to important intellectual property.

Even if we are successful, litigation could result in substantial costs to us and could divert the time and attention of our management and other employees.

Risks Related to Ownership of Our Common Stock

The market price of our common stock has fluctuated in the past, and is likely to continue to be volatile, which could subject us to litigation.

The market price of our common stock has fluctuated and is likely to be subject to further wide fluctuations in response to numerous factors, many of which are beyond our control, such as those in this "Risk Factors" section and others including:

- actual or anticipated variations in our and our competitors' operating results;
- announcements by us or our competitors of new products, product development results, significant acquisitions, strategic and commercial partnerships and relationships, joint ventures, collaborations or capital commitments;
- changes in reimbursement by current or potential payors;
- issuance of new securities analysts' reports or changed recommendations for our stock;
- periodic fluctuations in our revenue, due in part to the way in which we recognize revenue;
- actual or anticipated changes in regulatory oversight of our products;
- developments or disputes concerning our intellectual property or other proprietary rights or alleged infringement of third party's rights by our products;
- commencement of, or our involvement in, litigation or other proceedings;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- any major change in our management; and
- general economic conditions and slow or negative growth of our markets.

In addition, if the stock market experiences uneven investor confidence, the market price of our common stock could decline for reasons unrelated to our business, operating results, or financial condition. The market price of our common stock might also decline in reaction to events that affect other companies within, or outside, our industry even if these events do not directly affect us. Some companies that have experienced volatility in the trading price of their stock have been the subject of securities class action litigation. If we are the subject of such litigation, it could result in substantial costs and a diversion of our management's attention and resources.

Insiders have substantial control over us and will be able to influence corporate matters.

As of September 30, 2020, our current directors and executive officers, together with their affiliates, beneficially own, in the aggregate, a majority of our outstanding common stock. As a result, these stockholders, if they act, will be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as a merger or other sale of our company or its assets. They may have interests that differ from yours and may vote in a way with which you disagree and that may be adverse to your interests. This concentration of ownership could limit stockholders' ability to influence corporate matters and may have the effect of delaying, deterring or preventing a third party from acquiring control over us, depriving our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company, and could negatively impact the value and market price of our common stock.

We do not intend to pay dividends on our capital stock, so any returns will be limited to changes in the value of our common stock.

While we have paid dividends to our stockholders in the past, we currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our ability to pay cash dividends on our capital stock may be prohibited or limited by the terms of any current or future debt financing arrangement, including our credit and security agreement with Athyrium Opportunities III Co-Invest 1 LP. Any return to stockholders may therefore be limited to the increase, if any, of the price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause the stock price of our common stock to decline.

In the future, we may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. We also expect to issue common stock to employees, directors, and consultants pursuant to our equity incentive plans. If we sell common stock, convertible securities, or other equity securities in subsequent transactions, or common stock is issued pursuant to equity incentive plans, investors may be materially diluted. New investors in such subsequent transactions could gain rights, preferences, and privileges senior to those of holders of our common stock.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

We have and will continue to incur significantly increased costs and devote substantial management time to reporting and other requirements as a result of operating as a public company.

As a public company, we have and will continue to incur significant legal, accounting, and other expenses that we did not incur as a private company. For example, we are subject to the reporting requirements of the Securities Exchange Act of 1934, or Exchange Act, and are required to comply with the applicable requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC and The Nasdaq Global Market, or Nasdaq, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. Certain members of our management and other personnel have little experience managing a public company and preparing public filings. In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act, which will increase when we are no longer an emerging growth company, as defined by the JOBS Act. We will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs. Additional compensation costs and any future equity awards will increase our compensation expense, which would increase our general and administrative expense and could adversely affect our profitability. We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance on reasonable terms. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors or our board committees or as executive officers.

We are an emerging growth company and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an emerging growth company. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption and, as a result, will not be subject to the same implementation timing for new or revised accounting standards as are required of other public companies that are not emerging growth companies, which may make comparison of our consolidated financial information to those of other public companies more difficult.

For as long as we continue to be an emerging growth company, however, we intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and experience decreases.

We will remain an emerging growth company until the earliest of (a) the end of the fiscal year (i) following the fifth anniversary of the closing of our IPO, (ii) in which the market value of our common stock that is held by non-affiliates exceeds $700 million and (iii) in which we have total annual gross revenues of $1.07 billion or more during such fiscal year, and (b) the date on which we issue more than $1 billion in non-convertible debt in a three-year period.

We have previously identified material weaknesses in our internal control over financial reporting. If additional material weaknesses or significant deficiencies in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results, which could adversely affect our stock price and result in an inability to maintain compliance with applicable stock exchange listing requirements.

We previously concluded that there were matters that constituted material weaknesses in our internal control over financial reporting that have since been remediated. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. The 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.

If additional material weaknesses or significant deficiencies in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results. If we are unable to successfully remediate any material weaknesses in our internal controls or if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected, and we may be unable to maintain compliance with applicable stock exchange listing requirements.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If few securities analysts provide coverage of us, or if industry analysts cease coverage of us, the trading price and volume for our common stock could be adversely affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

Provisions in our eighth amended and restated certificate of incorporation and amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our eighth amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay, or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- authorize the issuance of “blank check” preferred stock that our board of directors could use to implement a stockholder rights plan;
- prohibit stockholder action by written consent, which requires stockholder actions to be taken at a meeting of our stockholders, except for so long as specified current stockholders hold in excess of 50% of our outstanding common stock;
- prohibit stockholders from calling special meetings of stockholders;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings;
- provide the board of directors with sole authorization to establish the number of directors and fill director vacancies; and
- provide that the board of directors is expressly authorized to make, alter, or repeal our amended and restated bylaws.

In addition, Section 203 of the Delaware General Corporation Law may discourage, delay, or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

Our eighth amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our eighth amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent permitted by law, for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (3) any action asserting a claim against us or any director, officer or other employee arising pursuant to the Delaware General Corporation Law, (4) any action to interpret, apply, enforce or determine the validity of our eighth amended and restated certificate of incorporation or amended and restated bylaws, or (5) any other action asserting a claim that is governed by the internal affairs doctrine, shall be the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction), in all cases subject to the court's having jurisdiction over indispensable parties named as defendants. In addition, our eighth amended and restated certificate of incorporation provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the Exchange Act. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision contained in our eighth amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition, and operating results. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Use of Proceeds from IPO of Common Stock

On June 23, 2020, we completed our IPO pursuant to which we issued and sold an aggregate of 6,666,667 shares of our common stock at the IPO price of $15.00 per share.

The offer and sale of all of the shares of our common stock in the IPO were registered under the Securities Act pursuant to our Registration Statement on Form S-1, as amended (File No. 333-238738), which was declared effective on June 18, 2020.

Item 6. Exhibits.

EXHIBIT NO.	DESCRIPTION
10.1	Stipulation and Order of Settlement and Dismissal, effective July 23, 2020, among the U.S. Department of Justice through the U.S. Attorney's Office for the Southern District of New York, and on behalf of the Office of Inspector General of the Department of Health and Human Services, and with the relator named therein and Progenity, Inc. (incorporated by reference from Exhibit 10.1 to Progenity's Current Report on Form 8-K filed on July 24, 2020 (Commission File No. 001-39334))
10.2	Settlement Agreement, effective July 23, 2020, among the United States of America, acting through the U.S. Department of Justice through the U.S. Attorney's Office for the Southern District of California, and on behalf of the Defense Health Agency, the Tricare Program and the Office of Personnel Management, which administers the Federal Employees Health Benefits Program, and Progenity, Inc. (incorporated by reference from Exhibit 10.2 to Progenity's Current Report on Form 8-K filed on July 24, 2020 (Commission File No. 001-39334))
10.3	Promissory Note issued pursuant to the Settlement Agreement, dated July 21, 2020, among the United States of America, acting through the U.S. Department of Justice through the U.S. Attorney's Office for the Southern District of California, and on behalf of the Defense Health Agency, the Tricare Program and the Office of Personnel Management, which administers the Federal Employees Health Benefits Program, and Progenity, Inc. (incorporated by reference from Exhibit 10.3 to Progenity's Current Report on Form 8-K filed on July 24, 2020 (Commission File No. 001-39334))
10.4	Non-Prosecution Agreement, effective July 21, 2020, between the U.S. Attorney's Office for the Southern District of California and Progenity, Inc. (incorporated by reference from Exhibit 10.4 to Progenity's Current Report on Form 8-K filed on July 24, 2020 (Commission File No. 001-39334))
10.5	Corporate Integrity Agreement, effective July 21, 2020, between the Office of Inspector General of the Department of Health and Human Services and Progenity, Inc. (incorporated by reference from Exhibit 10.5 to Progenity's Current Report on Form 8-K filed on July 24, 2020 (Commission File No. 001-39334))
31.1	Certification of principal executive officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
31.2	Certification of principal financial officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
32.1	Certification of principal executive officer and principal financial officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date:November 9, 2020

PROGENITY, INC.

By: /s/ Harry Stylli, Ph.D.
Harry Stylli, Ph.D.
President and Chief Executive Officer
(principal executive officer)

By: /s/ Eric d'Esparbes
Eric d'Esparbes
Executive Vice President and Chief Financial Officer
(principal financial and accounting officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Harry Stylli, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Progenity, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2020

By: /s/ Harry Stylli, Ph.D.

Harry Stylli, Ph.D.
Chairman and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Eric d'Esparbes, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Progenity, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2020

By: /s/ Eric d'Esparbes

Eric d'Esparbes
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Progenity, Inc. (the "Company") for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2020

By: /s/ Harry Stylli, Ph.D.
Harry Stylli, Ph.D.
Chairman and Chief Executive Officer
(principal executive officer)

By: /s/ Eric d'Esparbes
Eric d'Esparbes
Chief Financial Officer
(principal financial and accounting officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by §906 has been provided to Progenity, Inc. and will be retained by Progenity, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.