# 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 June 30, 2021**

**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 | ☒ | Smaller 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 August 5, 2021, the registrant had 79,406,317 shares of common stock, par value $0.001 per share, outstanding.

**Progenity, Inc.**

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PART I—FINANCIAL INFORMATION



**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)**

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 65,991 | $ 91,520 |
| Accounts receivable, net | 5,047 | 6,634 |
| Prepaid expenses and other current assets | 13,107 | 8,107 |
| Current assets of disposal group held for sale | 30,181 | 20,077 |
| Total current assets | 114,326 | 126,338 |
| Property and equipment, net | 5,474 | 8,660 |
| Other assets | 146 | 169 |
| Long-term assets of disposal group held for sale | — | 19,273 |
| Total assets | $ 119,946 | $ 154,440 |
| **Liabilities and Stockholders' Deficit** | | |
| Current liabilities: | | |
| Accounts payable | $ 14,560 | $ 12,657 |
| Accrued expenses and other current liabilities | 58,172 | 51,206 |
| Current portion of mortgages payable | 74 | 72 |
| Current portion of capital lease obligations | 128 | 266 |
| Current liabilities of disposal group held for sale | 12,703 | 8,469 |
| Total current liabilities | 85,637 | 72,670 |
| Capital lease obligations, net of current portion | — | 42 |
| Mortgages payable, net of current portion | 1,238 | 1,275 |
| Convertible notes, net of unamortized discount of $8,767 and $9,614 as of June 30, 2021 and December 31, 2020, respectively | 157,533 | 158,886 |
| Embedded derivative liability | 388 | 18,370 |
| Other long-term liabilities | 14,759 | 8,239 |
| Long-term liabilities of disposal group held for sale | — | 1,952 |
| Total liabilities | $ 259,555 | $ 261,434 |
| Commitments and contingencies | | |
| Stockholders' deficit: | | |
| Common stock – $0.001 par value. 350,000,000 shares authorized as of June 30, 2021 and December 31, 2020; 81,995,756 and 59,287,331 shares issued as of June 30, 2021 and December 31, 2020, respectively; 78,347,655 and 55,772,303 shares outstanding as of June 30, 2021 and December 31, 2020, respectively | 82 | 59 |
| Additional paid-in capital | 531,156 | 452,992 |
| Accumulated deficit | (652,069) | (541,274) |
| Treasury stock – at cost; 3,648,101 and 3,515,028 shares of common stock as of June 30, 2021 and December 31, 2020, respectively | (18,778) | (18,771) |
| Total stockholders' deficit | (139,609) | (106,994) |
| Total liabilities and stockholders' deficit | $ 119,946 | $ 154,440 |

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 June 30, 2021 | Three Months Ended June 30, 2020 | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 |
|---|---|---|---|---|
| Revenues | $ 463 | $ — | $ 630 | $ — |
| Cost of sales | — | — | — | — |
| Gross profit | 463 | — | 630 | — |
| Operating expenses: | | | | |
| Research and development | 13,401 | 12,234 | 25,074 | 23,476 |
| Selling and marketing | 2,006 | 1,547 | 3,864 | 3,235 |
| General and administrative | 20,709 | 12,702 | 38,809 | 24,421 |
| Total operating expenses | 36,116 | 26,483 | 67,747 | 51,132 |
| Loss from operations | (35,653) | (26,483) | (67,117) | (51,132) |
| Interest expense | (3,502) | (2,489) | (7,022) | (4,771) |
| Loss on warrant liability | (5,146) | — | (2,496) | — |
| Interest and other income (expense), net | 2,901 | (3,751) | 17,774 | (3,771) |
| Loss before income taxes | (41,400) | (32,723) | (58,861) | (59,674) |
| Income tax benefit | — | — | — | (37,697) |
| Loss from continuing operations | (41,400) | (32,723) | (58,861) | (21,977) |
| Loss from discontinued operations | (37,131) | (20,060) | (51,934) | (47,958) |
| Net loss | (78,531) | (52,783) | (110,795) | (69,935) |
| Dividend paid to preferred stockholders | — | (268) | — | (268) |
| Net loss attributable to common stockholders | $ (78,531) | $ (53,051) | $ (110,795) | $ (70,203) |
| Net loss per share from continuing operations, basic and diluted | $ (0.65) | $ (3.77) | $ (0.97) | $ (3.21) |
| Net loss per share from discontinued operations, basic and diluted | $ (0.58) | $ (2.31) | $ (0.85) | $ (7.01) |
| Net loss per share, basic and diluted | $ (1.23) | $ (6.08) | $ (1.82) | $ (10.22) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (1.23) | $ (6.11) | $ (1.82) | $ (10.26) |
| Weighted average number of shares outstanding used in calculating net loss per share, basic and diluted | 63,942,298 | 8,687,250 | 60,770,246 | 6,840,321 |

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 | | Additional Paid-In | Accumulated | Treasury Stock | | Total Stockholders' |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Capital | Deficit | Shares | Amount | Deficit |
| **Balance at December 31, 2020** | **59,287,331** | **$ 59** | **$ 452,992** | **$ (541,274 )** | **(3,515,028 )** | **$ (18,771 )** | **$ (106,994 )** |
| Issuance of common stock, net | 4,370,629 | 4 | 11,258 | — | — | — | 11,262 |
| Issuance of common stock upon exercise of options | 71,284 | — | 88 | — | — | — | 88 |
| Issuance of common stock upon vesting of restricted stock unit awards | 174,730 | — | (228 ) | — | (48,581 ) | (1 ) | (229 ) |
| Stock-based compensation expense | — | — | 2,630 | — | — | — | 2,630 |
| Net loss | — | — | — | (32,264 ) | — | — | (32,264 ) |
| **Balance at March 31, 2021** | **63,903,974** | **$ 63** | **$ 466,740** | **$ (573,538 )** | **(3,563,609 )** | **$ (18,772 )** | **$ (125,507 )** |
| Issuance of common stock, net | 15,694,332 | 16 | 11,991 | — | — | — | 12,007 |
| Issuance of common stock upon exercise of options | 25,498 | — | 26 | — | (5,050 ) | (6 ) | 20 |
| Issuance of common stock under employee stock purchase plan | 254,832 | 1 | 560 | — | — | — | 561 |
| Issuance of common stock upon vesting of restricted stock unit awards | 237,388 | — | (251 ) | — | (79,442 ) | — | (251 ) |
| Issuance of stock purchase warrant | — | — | 41,926 | — | — | — | 41,926 |
| Issuance of common stock upon conversion of debt, net | 611,616 | 1 | 2,068 | — | — | — | 2,069 |
| Issuance of common stock upon conversion of interest, net | 1,268,116 | 1 | 3,626 | — | — | — | 3,627 |
| Stock-based compensation expense | — | — | 4,470 | — | — | — | 4,470 |
| Net loss | — | — | — | (78,531 ) | — | — | (78,531 ) |
| **Balance at June 30, 2021** | **81,995,756** | **$ 82** | **$ 531,156** | **$ (652,069 )** | **(3,648,101 )** | **$ (18,778 )** | **$ (139,609 )** |

**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)** |

See accompanying notes to unaudited condensed consolidated financial statements.

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

| | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 |
|---|---|---|
| **Operating Activities:** | | |
| Net loss | $ (110,795) | $ (69,935) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Loss from discontinued operations | $ 51,934 | $ 47,958 |
| Non-cash revenue reserve | 172 | 23,729 |
| Depreciation and amortization | 965 | 789 |
| Stock-based compensation expense | 5,625 | 4,285 |
| Loss on extinguishment of convertible note | 242 | 3,401 |
| Amortization of debt discount | 4,753 | 1,330 |
| Loss on disposal of property and equipment | — | 18 |
| Change in fair value of derivative liability | (17,977) | 126 |
| Change in fair value of warrant liability | 2,496 | — |
| Changes in operating assets and liabilities: | | |
| Income tax receivable | — | (14,961) |
| Prepaid expenses and other current assets | (4,888) | 762 |
| Other assets | 22 | — |
| Accounts payables | 1,683 | 707 |
| Accrued expenses and other liabilities | 7,041 | (7,519) |
| Other long-term liabilities | 6,591 | 490 |
| Net cash used in operating activities - continuing operations | (52,136) | (8,820) |
| Net cash used in operating activities - discontinued operations | (32,114) | (34,382) |
| Net cash used in operating activities | (84,250) | (43,202) |
| **Investing Activities:** | | |
| Purchases of property and equipment | (853) | (683) |
| Net cash used in investing activities - continuing operations | (853) | (683) |
| Net cash used in investing activities - discontinued operations | (168) | (944) |
| Net cash used in investing activities | (1,021) | (1,627) |
| **Financing Activities:** | | |
| Proceeds from issuance of common stock, net | 23,377 | 90,937 |
| Proceeds from issuance of Series B Preferred Stock, net | — | 21,307 |
| Proceeds from issuance of convertible note, net | — | 14,895 |
| Proceeds from issuance of common stock warrants | 39,430 | — |
| Payment of deferred offering costs | (50) | — |
| Payments for insurance financing | (2,680) | — |
| Principal payments on mortgages payable | (35) | (34) |
| Principal payments on capital lease obligations | (179) | (376) |
| Net cash provided by financing activities - continuing operations | 59,863 | 126,729 |
| Net cash used in financing activities - discontinued operations | (121) | (128) |
| Net cash provided by financing activities | 59,742 | 126,601 |
| Net (decrease) increase in cash and cash equivalents | (25,529) | 81,772 |
| Cash and cash equivalents at beginning of period | 91,520 | 31,204 |
| Cash and cash equivalents at end of period | $ 65,991 | $ 112,976 |

See accompanying notes to unaudited condensed consolidated financial statements.

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

| | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 |
|---|---|---|
| **Supplemental disclosure of cash flow information:** | | |
| Cash paid for interest | $ 3,068 | $ 1,901 |
| Cash paid for income taxes | 46 | 54 |
| | | |
| **Supplemental schedule of non-cash investing and financing activities:** | | |
| Conversion of convertible note | 2,069 | 18,750 |
| Issuance of common stock upon conversion of interest | 3,627 | — |
| Equity offering costs incurred but not paid | 2,150 | 2,133 |
| Debt offering costs incurred but not paid | 62 | — |
| Issuance of preferred stock in settlement of interest payable | — | 2,698 |
| Issuance of stock options in settlement of accrued bonuses | — | 754 |
| Purchases of property and equipment in accounts payable | 135 | 262 |

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 historical 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.

Previously, the Company’s core business was 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 also include anatomic and molecular pathology testing products in the United States.

In order to refocus efforts and resources on the Company's research and development pipeline, in June 2021, the Company announced a strategic transformation that included the closure of the Progenity genetics lab in Ann Arbor, Michigan and indicated that the Company is seeking strategic alternatives for Avero, together referred to as Laboratory Operations. The Company will continue testing out of the Avero laboratory while it continues to explore ways of monetizing this asset. The Company has excluded from continuing operations for all periods presented in this report revenues and expenses associated with its Laboratory Operations, which are reported as discontinued operations. See Note 4 for additional information on the Laboratory Operations.

#### Liquidity

As of June 30, 2021, the Company had cash and cash equivalents of $66.0 million and an accumulated deficit of $652.1 million. For the six months ended June 30, 2021, the Company reported a net loss of $110.8 million and cash used in operating activities of $52.1 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 June 30, 2021, the Company had $157.5 million of convertible senior notes ("Convertible Notes") outstanding (see Note 8), and mortgages outstanding of $1.3 million (see Note 10). 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 six months ended June 30, 2021.

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 continue operating into the fourth quarter of 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 or divestitures of the Company's assets. 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 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 consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the Securities and Exchange Commission, ("SEC"), from which management derived the Company's condensed consolidated balance sheet as of December 31, 2020. Certain amounts in prior periods have been reclassified to reflect the impact of the discontinued operations treatment of the Company's Laboratory Operations in order to conform to the current period presentation. 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.

As a result of the anticipated divestiture of the Laboratory Operations, the Company has retrospectively revised the consolidated statements of operations for the three and six months ended June 30, 2020, the cash flows for the six months ended June 30, 2020 and the consolidated balance sheet as of December 31, 2020, to reflect the operations and cash flows of the Laboratory Operations as discontinued operations and the related assets and liabilities as held for sale.

### Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of June 30, 2021, the statements of operations and the statements of stockholders' deficit for the three and six months ended June 30, 2021 and 2020 and the statements of cash flows for the six months ended June 30, 2021 and 2020 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 to present fairly the results for the interim periods presented. Results are not necessarily indicative of results to be expected for the year ending December 31, 2021, 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, 2020 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 stock options, the valuation of goodwill and intangible assets, the valuation of the derivative liability associated with the Convertible Notes, accrual for reimbursement claims and settlements, the valuation of the warrant liability, the valuation of assets held for sale, assessing future tax exposure and the realization of deferred tax assets, and 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.

**Assets Held for Sale and Discontinued Operations**

Assets and liabilities are classified as held for sale when all of the following criteria for a plan of sale have been met: (1) management, having the authority to approve the action, commits to a plan to sell the assets; (2) the assets are available for immediate sale, in their present condition, subject only to terms that are usual and customary for sales of such assets; (3) an active program to locate a buyer and other actions required to complete the plan to sell the assets have been initiated; (4) the sale of the assets is probable and is expected to be completed within one year; (5) the assets are being actively marketed for a price that is reasonable in relation to their current fair value; and (6) actions required to complete the plan indicate that it is unlikely that significant changes to the plan will be made or the plan will be withdrawn. When all of these criteria have been met, the assets and liabilities are classified as held for sale in the condensed consolidated balance sheet. Assets classified as held for sale are reported at the lower of their carrying value or fair value less costs to sell. Depreciation and amortization of assets ceases upon designation as held for sale.

Discontinued operations comprise activities that were disposed of, discontinued or held for sale at the end of the period, represent a separate major line of business that can be clearly distinguished for operational and financial reporting purposes and represent a strategic business shift having a major effect on the Company’s operations and financial results according to Accounting Standard Codification (“ASC”) Topic 205, *Presentation of Financial Statements*.

Additional details surrounding the Company's assets and liabilities held for sale and discontinued operations are included in Note 4.

**Revenue Recognition**

Revenue is recognized in accordance with the Financial Accounting Standards Board (“FASB”) 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 (“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 be 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 | |
|---|---|---|
| | June 30, 2021 | December 31, 2020 |
| Blue Shield of Texas | 18.1 % | 17.8 % |
| Government Health Benefits Programs | 26.4 % | 26.2 % |
| Aetna | 5.0 % | 4.0 % |
| Anthem | 3.0 % | 3.5 % |
| United Healthcare | 6.3 % | 6.6 % |

| | Percentage of Revenue (1) | | | |
|---|---|---|---|---|
| | Three Months Ended June 30, | | Six Months Ended June 30, | |
| | 2021 | 2020 | 2021 | 2020 |
| Blue Shield of Texas | 24.9 % | 41.9 % | 23.7 % | 42.2 % |
| Government Health Benefits Programs (2) | 25.2 % | (14.4 )% | 24.2 % | (26.6 )% |
| Aetna | 7.0 % | 13.8 % | 7.4 % | 12.9 % |
| Anthem | 5.3 % | 14.0 % | 3.2 % | 12.1 % |
| United Healthcare | 7.1 % | 4.8 % | 6.9 % | 4.4 % |

(1) Percentage of revenue table shows amounts as a percentage of total revenue, including revenue classified as discontinued operations. Refer to Note 5 for details of the breakdown of revenue.
(2) The negative amounts presented in the percentage of revenues include accruals for reimbursement claims and settlements included in the estimate of variable consideration recorded during the three and six months ended June 30, 2020. Revenues 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.

**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. Amounts included in accounts receivable consist of receivables generated from Progenity's genetics lab in Ann Arbor, Michigan. The Company plans to continue to collect these receivables and has not included these amounts as assets held for sale.

**Fair Value of Financial Instruments**

The Company's financial assets and liabilities are carried at fair value or at amounts that, because of their short-term nature, approximate current fair value, with the exception of its Convertible Notes, which are carried at amortized cost. The carrying value of the Company's accounts 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 values because the instruments bear interest at rates, and have terms that are comparable to those available to the Company for similar loan instruments at June 30, 2021 and December 31, 2020. (See Note 7).

**Embedded Derivative Related to Convertible Notes**

During 2020, the Company issued Convertible Notes with an embedded derivative that is required to be bifurcated from the host contract and remeasured to fair value at each balance sheet date. Any resulting gain or loss related to the change in the fair value of the embedded derivative is recorded to interest and other income (expense), net on the condensed consolidated statements of operations. Changes in the Company's assumptions, such as the Company's stock price and volatility of common stock, could result in material changes in the valuation in future periods.

**Stock-Based Compensation**

Stock-based compensation related to stock options, restricted stock units (“RSUs”) and the 2020 Employee Stock Purchase Plan (“ESPP”) awards granted to the Company’s employees is measured at the grant date based on the fair value of the award. The fair value is recognized as expense over the requisite service period, which is generally the vesting period of the respective awards. Compensation related to service-based awards is recognized starting on the grant date on a straight-line basis over the vesting period, which is typically four years. For the ESPP, the requisite service period is generally the period of time from the offering date to the purchase date. In addition, the Company grants stock option awards that vest upon achievement of certain performance criteria ("Performance Awards"). The fair value is recognized as expense over the requisite service period when the Company has concluded that achieving the performance criteria is probable. The probability of achieving the performance criteria is assessed each reporting period. The Company accounts for the forfeitures in the period in which they occur. The fair value of RSUs is estimated based on the closing price of the Company's common stock on the date of the grant.

The fair value of stock options, ESPP awards and Performance Awards is estimated using the option-pricing model and is affected by the Company’s assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the fair value of the common stock at the date of grant, the expected term of the awards, the expected stock price volatility over the term of the awards, risk-free interest rate, and dividend rate. The Company’s assumptions with respect to these variables are as follows:

*Fair Value of Common Stock*—Prior to the IPO, the Company’s common stock was not publicly traded, therefore the Company estimated the fair value of its common stock. Following the IPO, the fair value of the Company’s common stock for awards with service-based vesting is the closing price of its common stock on the date of grant or other relevant determination date.

*Expected Term*—The expected term represents the period that the stock-based awards are expected to be outstanding. The Company determines the expected term using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life. For stock options granted to non-employees, the expected term equals the remaining contractual term of the option from the vesting date. For the ESPP, the expected term is the period of time from the offering date to the purchase date.

*Expected Volatility*—Given the limited period of time the Company’s stock has been traded in an active market, the expected volatility is estimated by taking the average historical volatility for industry peers, consisting of several public companies in the Company’s industry that are similar in size, stage, or financial leverage, over a period of time commensurate with the expected term of the awards.

*Risk-Free Interest Rate*—The risk-free interest rate is calculated using the average of the published interest rates of U.S. Treasury zero-coupon issues with maturities that are commensurate with the expected term.

*Dividend Rate*—The dividend yield assumption is zero, as the Company has no plans to pay dividends.

**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 December 2019, FASB issued Accounting Standards Update (“ASU”) No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which simplified income tax accounting in various areas. The Company adopted this standard on January 1, 2021, 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 June 2020, the FASB issued ASU No. 2020-05, *Revenue from Contracts with Customers (Topic 606) and Leases (Topic 842): Effective Dates for Certain Entities*, which further defers the effective date for certain entities. As a result, the ASU is now effective for EGCs for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. If the Company maintains EGC status, it plans to adopt the new lease standard effective January 1, 2022, using the effective date method with the cumulative effect of the change, if any, reflected in retained earnings. 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 August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)-Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for convertible instruments, amends the guidance on derivative scope exceptions for contracts in an entity's own equity, and modifies the guidance on diluted earnings per share calculations as a result of these changes. The standard is effective for the Company for annual reporting periods beginning after December 15, 2023. The Company is currently evaluating the impact the adoption of this standard may have on its consolidated financial statements.

**3. Variable Interest Entity**

In June 2015, the Company, through a wholly-owned subsidiary, entered into a series of agreements with Avero. The subsidiary entity 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 subsidiary entity also 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's subsidiary entity 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 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's subsidiary entity 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 was paid over 24 months. The Company provided financial support to Avero in the amount of $0.8 million and $1.5 million during the three and six months ended June 30, 2020, respectively, related to the Cigna settlement obligation, which was fully settled as of December 31, 2020. The Company did not provide any additional financial support to Avero during the three and six months ended June 30, 2021 and 2020, 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 June 30, 2021 and December 31, 2020 (in thousands). All of the following is included in assets and liabilities held for sale - Avero, refer to Note 4. The creditors of Avero have no recourse to the general credit of the Company, with the exception of $1.6 million and $1.7 million in mortgages payable guaranteed by the Company as of June 30, 2021 and December 31, 2020, respectively (see Note 10). The assets and liabilities exclude intercompany balances that eliminate in consolidation:

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| Assets of Avero that can only be used to settle obligations of Avero | | |
| Cash and cash equivalents | $ 1,247 | $ 556 |
| Accounts receivable, net | 3,647 | 6,047 |
| Inventory | 2,038 | 3,382 |
| Prepaid expenses and other current assets | 2,236 | 1,254 |
| Property and equipment, net | 5,453 | 5,436 |
| Other assets | 30 | 30 |
| Goodwill | 6,219 | 6,219 |
| Other intangible assets, net | 3,384 | 3,843 |
| Total assets of Avero that can only be used to settle obligations of Avero | $ 24,254 | $ 26,767 |
| Liabilities of Avero | | |
| Accounts payable | $ 5,271 | $ 4,722 |
| Accrued expenses and other accrued liabilities | 3,590 | 3,472 |
| Current portion of capital lease obligations | 27 | 46 |
| Current portion of mortgage payable | 202 | 199 |
| Capital lease obligations, net of current portion | — | 4 |
| Mortgage payable, net of current portion | 1,418 | 1,520 |
| Other long-term liabilities | 306 | 428 |
| Total liabilities of Avero | $ 10,814 | $ 10,391 |

**4. Assets Held for Sale and Discontinued Operations**

In June 2021, the Company announced its plan to reallocate resources to research and development to better position the business for future growth. The plan includes the closure of the Progenity genetics laboratory in Ann Arbor, Michigan and the potential divestiture of Avero. The Company will continue testing out of the Avero laboratory while it continues to explore ways of monetizing this asset. This plan represents a strategic business shift having a major effect on the Company's operations and financial results. As of June 30, 2021, the Company stopped providing genetic laboratory-developed test services in its Ann Arbor, Michigan laboratory and determined that the Laboratory Operations, including Avero, met the requirements of discontinued operations. The Company has classified the results of its Laboratory Operations as discontinued operations in its condensed consolidated statements of operations and cash flows for all periods presented. The Company recognized a loss of $19.3 million for the three and six months ended June 30, 2021 related to contract terminations, severance, inventory and fixed asset write-downs in discontinued operations related to the Progenity genetics laboratory shut down. Additionally, the related assets and liabilities have been reported as assets and liabilities held for sale in the Company's condensed consolidated balance sheet as of June 30, 2021 and December 31, 2020.

The following table presents the combined results of discontinued operations of the Laboratory Operations (in thousands):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Revenues | $ 18,242 | $ 17,266 | $ 42,601 | $ 34,094 |
| Cost of sales | 26,233 | 21,835 | 48,466 | 48,405 |
| Gross loss | (7,991) | (4,569) | (5,865) | (14,311) |
| Operating expenses: | | | | |
| Research and development | 1,590 | — | 1,590 | (2) |
| Selling and marketing | 20,127 | 11,189 | 32,917 | 23,937 |
| General and administrative | 7,413 | 4,479 | 11,533 | 9,869 |
| Total operating expenses | 29,130 | 15,668 | 46,040 | 33,804 |
| Interest and other (expense) income, net | (10) | 177 | (29) | 157 |
| Net loss from discontinued operations | $ (37,131) | $ (20,060) | $ (51,934) | $ (47,958) |

The following table presents the carrying amounts of the classes of assets and liabilities held for sale related to the Laboratory Operations as of June 30, 2021 and December 31, 2020 (in thousands):

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| Carrying amounts of assets of disposal group held for sale | | |
| Current assets: | | |
| Cash and cash equivalents | $ 1,247 | $ 556 |
| Accounts receivable, net | 3,647 | 6,047 |
| Inventory | 3,686 | 12,220 |
| Prepaid expenses and other current assets | 2,236 | 1,254 |
| Total current assets of disposal group held for sale (1) | | 20,077 |
| Property and equipment, net | 9,732 | 9,181 |
| Other assets | 30 | 30 |
| Goodwill | 6,219 | 6,219 |
| Other intangible assets, net | 3,384 | 3,843 |
| Total assets of disposal group held for sale (1) | $ 30,181 | $ 39,350 |
| Carrying amounts of disposal group held for sale | | |
| Current liabilities: | | |
| Accounts payable | 5,285 | 4,722 |
| Accrued expenses and other current liabilities | 5,770 | 3,503 |
| Current portion of mortgages payable | 1,620 | 198 |
| Current portion of capital lease obligations | 28 | 46 |
| Total current liabilities of disposal group held for sale (1) | 12,703 | 8,469 |
| Capital lease obligations, net of current portion | — | 4 |
| Mortgages payable, net of current portion | — | 1,520 |
| Other long-term liabilities | — | 428 |
| Total liabilities of disposal group held for sale (1) | $ 12,703 | $ 10,421 |

(1) The assets and liabilities of the Laboratory Operations are classified as held for sale and are classified as current in the unaudited condensed consolidated balance sheet at June 30, 2021, because they are expected to be sold within one year.

### 5. Revenues

Revenues are 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.

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, 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 consolidated statements of operations as an element of variable consideration. 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. As of December 31, 2020, the Company settled all existing obligations to the relevant government programs as due and will continue to settle any future obligation as they arise.

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 $0.8 million and $3.0 million of revenue reported for the three and six months ended June 30, 2021, respectively, and a reduction of $6.1 million and $18.9 million of revenue reported for the three and six months ended June 30, 2020, 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 11.

### Disaggregation of Revenues

The following tables shows revenues disaggregated by payor type and revenue classification (in thousands):

| Payor | Three Months Ended June 30, 2021 | Three Months Ended June 30, 2020 | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 |
|---|---|---|---|---|
| Commercial third-party payors | $ 13,044 | $ 18,030 | $ 29,495 | $ 39,592 |
| Government health benefit programs(1) | 4,725 | (2,922) | 10,450 | (9,065) |
| Patient/laboratory distribution partners | 936 | 2,158 | 3,286 | 3,567 |
| Total revenues | $ 18,705 | $ 17,266 | $ 43,231 | $ 34,094 |

(1) The revenue amounts include accruals for reimbursement claims and settlements included in the estimates of variable consideration recorded during the three and six months ended June 30, 2021 and 2020. Revenues 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.

| Classification | Three Months Ended June 30, 2021 | Three Months Ended June 30, 2020 | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 |
|---|---|---|---|---|
| Revenue from continuing operations | $ 463 | $ — | $ 630 | $ — |
| Revenue reported under discontinued operations | 18,242 | 17,266 | 42,601 | 34,094 |
| Total revenues | $ 18,705 | $ 17,266 | $ 43,231 | $ 34,094 |

## 6. Balance Sheet Components

### Prepaid Expenses and Other Current Assets

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

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| Prepaid expenses | $ 12,568 | $ 7,996 |
| Other current assets | 539 | 111 |
| Total | $ 13,107 | $ 8,107 |

### Property and Equipment, Net

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

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| Computers and software | $ 5,885 | $ 8,770 |
| Building and leasehold improvements | 747 | 747 |
| Laboratory equipment | 3,569 | 3,556 |
| Furniture, fixtures, and office equipment | 1,438 | 1,438 |
| Construction in progress | 496 | 2,774 |
| Land | 346 | 346 |
| Total property and equipment | 12,481 | 17,631 |
| Less accumulated depreciation and amortization | (7,007) | (8,971) |
| Property and equipment, net | $ 5,474 | $ 8,660 |

Depreciation expense included in continuing operations was $1.0 million for both the six months ended June 30, 2021 and $0.8 million for the six months ended June 30, 2020.

**Intangible Assets, Net**

All intangible assets have been reclassified into assets held for sale, refer to Note 4. Amortization expense was $0.2 million and $0.5 million for the three and six months ended June 30, 2021 and $0.2 million and $0.5 million for the three and six months ended June 30, 2020, respectively and is included in discontinued operations.

**Accrued Expenses and Other Current Liabilities**

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

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| Accrual for reimbursement claims and settlements, current (1) | $ 27,874 | $ 30,487 |
| Commission and bonus | 3,366 | 3,934 |
| Vacation and payroll benefits | 10,347 | 7,364 |
| Accrued professional services | 1,099 | 3,142 |
| Accrued interest | 1,183 | 855 |
| Insurance financing | 9,019 | 1,799 |
| Contract liabilities | 443 | 378 |
| Other (2) | 4,841 | 3,247 |
| Total | $ 58,172 | $ 51,206 |

(1) All of the Company's revenues related to Progenity's Laboratory Operations have been discontinued, these amounts related to the revenue reserve generated from the Progenity Laboratory Operations are not included in the assets held for sale.
(2) Included in this amount are contracts that Progenity will be responsible for that can not be terminated, as there is no future benefit to the Company, they have been expensed in discontinued operations, but are not included in assets held for sale.

**Other Long-term Liabilities**

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

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| Accrual for reimbursement claims and settlements, net of current portion (1) | $ 7,053 | $ 7,053 |
| Other (2) | 7,706 | 1,186 |
| Total | $ 14,759 | $ 8,239 |

(1) All of the Company's revenues related to Progenity's Laboratory Operations have been discontinued, these amounts related to the revenue reserve generated from the Progenity Laboratory Operations are not included in the assets held for sale.
(2) Included in this amount are contracts that Progenity will be responsible for that can not be terminated, as there is no future benefit to the Company, they have been expensed in discontinued operations, but are not included in assets held for sale.

**7. Fair Value Measurements**

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 measurement 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. 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 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.

There were no significant transfers between these fair value measurement classifications during the six months ended June 30, 2021 and 2020.

**Fair Value of Financial Instruments**

The Company's Level 3 liabilities consist of the embedded derivative liability associated with the Company's Convertible Notes (See Note 8). The Company periodically assesses the fair value of the conversion feature related to the Convertible Note. The conversion feature was bifurcated and recorded as an embedded derivative liability with a corresponding discount at the date of issuance that is netted against the principal amount of the Convertible Notes. The Company utilizes a Monte Carlo simulation method to determine the fair value of the conversion feature, which utilizes inputs including the common stock price, volatility of common stock, the risk-free interest rate and the probability of conversion to common shares at the conversion rate in the event of a major transaction (e.g. a change in control). Due to the use of significant unobservable inputs, the overall fair value measurement of the conversion feature is classified as Level 3.

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):

| | Level 1 | Level 2 | Level 3 |
|---|---|---|---|
| **June 30, 2021** | | | |
| Money market funds(1) | $ 64,360 | $ — | $ — |
| Embedded derivative liability | $ — | $ — | $ 388 |
| | | | |
| **December 31, 2020** | | | |
| Money market funds(1) | $ 90,254 | $ — | $ — |
| Embedded derivative liability | $ — | $ — | $ 18,370 |

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

The carrying value of the Company's Convertible Notes does not approximate its fair value because the carrying value of the Convertible Notes reflects the balance of unamortized discount related to the derivative liability associated with the value of conversion feature assessed at inception. The carrying value of the Company's Convertible Notes, net of discount, was $157.5 million and $158.9 million at June 30, 2021 and December 31, 2020, respectively. Based on unadjusted quoted prices in active market obtained from third-party pricing services, the Company determined the fair value of the Convertible Notes was $169.0 and $250.2 million as of June 30, 2021 and December 31, 2020, respectively.

## 8. Convertible Notes

In December 2020, the Company issued a total of $168.5 million principal amount of its Convertible Notes in a private offering of the Convertible Notes pursuant to Rule 144A under the Securities Act. The Convertible Notes were issued pursuant to, and are governed by, an indenture, dated as of December 7, 2020, by and between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee (the "Indenture"). The Convertible Notes are due on December 1, 2025, unless earlier repurchased, redeemed or converted, and accrue interest at a rate per annum equal to 7.25% payable semi-annually in arrears on June 1 and December 1 of each year, with the initial payment on June 1, 2021. During the three and six months ended June 30, 2021, the Company recognized interest expense on the Convertible Notes of $3.1 million and $6.2 million, respectively.

At any time, noteholders may convert their Convertible Notes at their option into shares of the Company's common stock, together, if applicable, with cash in lieu of any fractional share, at the then-applicable conversion rate. The initial conversion rate is 278.0094 shares of common stock per $1,000 principal amount of Convertible Notes, which represents an initial conversion price of approximately $3.60 per share of common stock. Noteholders that convert their Convertible Notes before December 1, 2022 will, in certain circumstances, be entitled to an additional cash payment representing the present value of any remaining interest payments on the Convertible Notes through December 1, 2022. The conversion rate and conversion price are subject to customary adjustments upon the occurrence of certain dilutive events. In addition, if certain corporate events that constitute a "Make-Whole Fundamental Change" (as defined in the Indenture) occur, then the conversion rate will, in certain circumstances, be increased for a specified period of time.

The Convertible Notes are redeemable, in whole and not in part, at the Company's option at any time on or after December 1, 2023, at a cash redemption price equal to the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date, but only if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price on (i) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends the related redemption notice; and (ii) the trading day immediately before the date the Company sends such notice. In addition, calling the Convertible Notes will constitute a Make-Whole Fundamental Change, which will result in an increase to the conversion rate in certain circumstances for a specified period of time.

The Convertible Notes have customary provisions relating to the occurrence of "Events of Default" (as defined in the Indenture), which include the following: (i) certain payment defaults on the Convertible Notes (which, in the case of a default in the payment of interest on the Convertible Notes, will be subject to a 30-day cure period); (ii) the Company's failure to send certain notices under the Indenture within specified periods of time; (iii) the Company's failure to comply with certain covenants in the Indenture relating to the Company's ability to consolidate with or merge with or into, or sell, lease or otherwise transfer, in one transaction or a series of transactions, all or substantially all of the assets of the Company and its subsidiaries, taken as a whole, to another person; (iv) a default by the Company in its other obligations or agreements under the Indenture or the Convertible Notes if such default is not cured or waived within 60 days after notice is given in accordance with the Indenture; (v) certain defaults by the Company or any of its subsidiaries with respect to indebtedness for borrowed money of at least $7.5 million; (vi) the rendering of certain judgments against the Company or any of its subsidiaries for the payment of at least $7.5 million, where such judgments are not discharged or stayed within 60 days after the date on which the right to appeal has expired or on which all rights to appeal have been extinguished; and (vii) certain events of bankruptcy, insolvency and reorganization involving the Company or any of the Company's significant subsidiaries. As of June 30, 2021 and December 31, 2020, the Company was in compliance with all such covenants.

The Convertible Notes have a conversion option which was required to be bifurcated upon issuance and then periodically remeasured to fair value separately as an embedded derivative. The conversion option includes additional interest payments payable to the noteholders if converted prior to December 1, 2022. The conversion feature was bifurcated as recorded separately as an embedded derivative as (1) the conversion feature is not clearly and closely related to the debt instrument and is not considered to be indexed to the Company's equity, (2) the conversion feature standing alone meets the definition of a derivative, and (3) the Convertible Notes are not remeasured at fair value each reporting period with changes in fair value recorded in the consolidated statement of operations.

As of June 30, 2021 and December 31, 2020, the fair value of the derivative liability was $0.4 million and $18.4 million, respectively. The change in the fair value of the derivative liability of $18.0 million is included in interest and other income (expense), net in the condensed consolidated statements of operations for the six months ended June 30, 2021. As of June 30, 2021 and December 31, 2020, the unamortized debt discount was $8.8 million and $9.6 million, respectively. The Company amortizes the debt discount using the effective interest method over the term of the Convertible Notes, resulting in an effective interest rate of approximately 8.7%. For the three and six months ended June 30, 2021, the amortization of the Convertible Notes debt discount was $0.4 million and $0.8 million, respectively, and was included in interest expense in the condensed consolidated statements of operations.

## 9. 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 ("2017 Transaction"). The 2017 Transaction provided for the 2017 Term Loan, the issuance of Series B Preferred Stock ("Series B Preferred Stock"), and the issuance of a warrant to purchase Series B Preferred Stock ("Series B Preferred Stock Purchase Warrant"). The 2017 Term Loan accrued interest at a rate per annum equal to 9.5% and was due October 27, 2022.

The 2017 Term Loan contained customary covenants, including a requirement to maintain a minimum unrestricted cash balance at all times of at least $5.0 million, and was 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 was amortized as interest expense using the effective interest method over the term of the loan.

During the three and six months ended June 30, 2020, the Company recognized interest expense of $2.5 million and $4.7 million, inclusive of $0.7 million and $1.1 million of discount amortization, respectively. The Term Loan was discharged in December 2020 in connection with the offering of Convertible Notes.

In connection with the Company's initial public offering ("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 ("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 ("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 ("Note") with the same private equity firm 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 for the six months ended June 30, 2020. 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 same private equity firm participated in the IPO and acquired 3,333,333 shares at a price of $15.00 per share, which was at par with the price to other investors.

In December 2020, the private equity firm discharged any and all amounts owed and any obligations outstanding under the 2017 Term Loan in exchange for $78.5 million principal amount of Convertible Notes issued by the Company's. The exchange was accounted for as an extinguishment of the 2017 Term Loan and resulted in $7.6 million of loss on extinguishment, which was included in the interest and other income (expense), net in the consolidated statement of operations for the year ended December 31, 2020. This private equity firm also acquired an additional $25.0 million principal amount of the Company's Convertible Notes for cash in this private offering, which resulted in $103.5 million aggregate principal amount of the Convertible Notes acquired by this private equity firm (see Note 8). As of June 30, 2021 and December 31, 2020, the accrued interest expense related to the Convertible Notes held by this private equity firm was $0.6 million and $0.5 million, respectively. In December 2020, the same private equity firm participated in the underwritten public offering and acquired 4,128,440 shares at a price of $3.27 per share, resulting in proceeds to the Company of $13.2 million before expenses.

In June 2021, the private equity firm participated in a private placement. Refer to Note 12 for further details.

**10. 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 both June 30, 2021 and December 31, 2020, the outstanding balance of this mortgage was $1.3 million. 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, that matures in 2029 and requires monthly principal and interest payments at an interest rate of 3.25%. As of June 30, 2021 and December 31, 2020, the outstanding balance of this mortgage of $1.6 million and $1.7 million, respectively is included in assets held for sale and excluded from the table below.

As of June 30, 2021, the minimum principal payments under the mortgages payable were as follows (in thousands):

| Year ending December 31, | Minimum Mortgages Payable Payments Obligations |
|---|---|
| Remainder of 2021 | $ 37 |
| 2022 | 76 |
| 2023 | 80 |
| 2024 | 1,119 |
| 2025 and thereafter | — |
| Total future minimum payments | 1,312 |
| Less current portion of mortgages payable | (74) |
| Mortgages payable, net of current portion | $ 1,238 |

**11. 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 included in continuing operations for operating leases was $1.7 million and $3.1 million, for the three and six months ended June 30, 2021, respectively, and $0.6 million and $3.4 million for the three and six months ended June 30, 2020, respectively.

As of June 30, 2021, net minimum payments under the non-cancelable operating leases were as follows (in thousands):

| Year ending December 31, | Minimum Operating Lease Payments |
|---|---|
| Remainder of 2021 | $ 1,716 |
| 2022 | 1,929 |
| 2023 | 933 |
| 2024 | 35 |
| 2025 and thereafter | — |
| Total future minimum lease payments | $ 4,613 |

**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.

***Federal Investigations***

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.

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 U.S. Department of Justice ("DOJ") through the AUSA for SDNY, and on behalf of the Office of Inspector General of the Department of Health and Human Services ("OIG"), and with the relator named therein ("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 ("SDCA Civil Settlement Agreement");
- a non-prosecution agreement, effective July 21, 2020, with the AUSA for SDCA ("Non-Prosecution Agreement") in resolution of all criminal allegations;
- a corporate integrity agreement, effective July 21, 2020, with the OIG ("Corporate Integrity Agreement"); and
- civil settlement agreements, effective October 1, 2020, with the State Attorney Generals ("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 six months ended June 30, 2021, the Company did not make any settlement payments. The outstanding settlement amount is payable in two remaining annual installments as follows:

- 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 $4.1 million. During the year ended December 31, 2020, the Company received a tax refund of approximately $37.7 million related to the NOL carryback provisions available under the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") and made accelerated payments of approximately $4.1 million under the SDNY Civil Settlement Agreement. The Company did not receive any tax refunds during the six months ended June 30, 2021.

*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 six months ended June 30, 2021, the Company did not make any settlement payments. The outstanding settlement amount is payable in two remaining annual installments as follows:

- approximately $1.7 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 ("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, the Company 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. The Company did not receive any tax refunds during the six months ended June 30, 2021.

*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 expired on July 21, 2021.

*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 Attorney Generals 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. The outstanding settlement amount is payable in three remaining installments as follows:

- 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, 2020, the Company had accrued an aggregate of $12.1 million associated with a potential settlement with the DOJ and the participating State Attorney Generals within accrued expenses and other current liabilities and as a reduction of revenue as reflected on the consolidated balance sheets as of December 31, 2020 and consolidated statements of operations for the year ended December 31, 2020. As of June 30, 2021, the Company's accrual consists of $5.0 million in accrued expenses and other current liabilities and $7.1 million in other long-term liabilities.

***Colorado Recoupment***

On July 21, 2021, the Company received a letter from the Colorado Department of Health Care Policy and Financing, ("Department"), informing the Company that, as a result of a post-payment review of Medicaid claims from October 2014 to June 2018, the Department is seeking recoupment for historical payments in an aggregate amount of approximately $5.7 million. The historical payments for which the Department is seeking recoupment are claimed to relate to the Company's Preparent expanded carrier screening tests primarily on the basis that such tests were not medically necessary.

The State Settlement Agreements discussed above include the State of Colorado as part of the settlement with respect to certain civil claims related to its discontinued legacy billing practices for its non-invasive prenatal tests and microdeletion tests and the provision of alleged kickbacks or inducements to physicians and patients.

The Company intends to dispute this claim of recoupment with the Department and seek to offset any amounts previously paid to the Department by the Company in connection with the State Settlement Agreements. As stated previously, such provider-payor disputes are not uncommon and the Company expects to approach this dispute with an aim to resolve in a mutually satisfactory manner. At this very preliminary stage, the Company is unable to predict the ultimate outcome of this action, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from this action.

***California Subpoena***

On July 19, 2021, the Company received a subpoena from the California Attorney General's Office, Division of Public Rights, requesting documents and information related to Progenity's genetic testing practices, including NIPT, particularly those with a nexus to California patients. The subpoena is captioned "In the Matter of the Investigation of: Prenatal Genetic Testing Companies." At this very preliminary stage, the Company is unable to predict the ultimate outcome of this action, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that could result from any unfavorable outcome related to this action.

***UnitedHealth Group Settlement Agreements***

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. The Aetna settlement obligation was fully settled during the first quarter of 2021.

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. As of June 30, 2021 the remaining settlement accrual related to United is $12.0 million and is included in accrued expenses and other current 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. 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 (see Note 5), 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 ultimate outcome of this action, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from this action.

***Payor Dispute***

On November 16, 2020, the Company received a letter from Anthem, Inc. ("Anthem") informing the Company that Anthem is seeking recoupment for historical payments made by Anthem in an aggregate amount of approximately $27.4 million. The historical payments for which Anthem is seeking recoupment are claimed to relate primarily to discontinued legacy billing practices for the Company's NIPT and microdeletion tests and secondarily to the implementation of the new CPT code for reimbursement for the Company's Preparent expanded carrier screening tests.

As noted above, the Company has historically negotiated and settled similar claims with third-party payors. Although the Company's practice in resolving disputes with other similar large commercial payors has generally led to agreed-upon settlement amounts substantially less than the originally claimed amount, there can be no assurance that the Company will be successful in negotiating a similar settlement amount in any ongoing or future dispute. In management's experience with negotiations with similarly situated commercial payors, a settlement may take six to twelve months to negotiate, and the time period over which a negotiated settlement payment may be paid could extend from one to two years, or longer. Historical settlement amounts and payment time periods may not be indicative of the final settlement terms with Anthem, if any. Management intends to negotiate and/or dispute this claim of recoupment with Anthem and seek to offset any amounts owed by Anthem to the Company. Such provider-payor disputes are not uncommon and the Company expects to approach this dispute with an aim to resolve in a mutually satisfactory manner. The Company has recorded an accrual for the estimated probable loss for this matter as of December 31, 2020 and June 30, 2021.

***Natera Settlement***

On June 17, 2020, Natera, Inc. 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. In August 2021, the Company and Natera entered into a settlement agreement. The agreement does not require a cash payment by the Company. The settlement agreement is subject to court approval.

***Ravgen Lawsuit***

On December 22, 2020, Ravgen, Inc. ("Ravgen") filed suit in the District of Delaware (D. Del. Civil Action No. 1:20-cv-1734) asserting the Company's infringement of two Ravgen patents. The Company responded to the complaint on March 23, 2021. Management believes the claims in Ravgen's complaint are without merit, and the Company is vigorously defending against them.

***IPO Litigation***

On June 23, 2020, the Company closed its initial public offering of common stock ("IPO"). Lawsuits were filed on August 28, 2020 and September 11, 2020 against the Company, certain of its executive officers and directors, and the underwriters of the IPO. On December 3, 2020, the U.S. District Court for the Southern District of California consolidated the two actions, appointed Lin Shen, Lingjun Lin and Fusheng Lin to serve as Lead Plaintiffs, and approved Glancy Prongay & Murray LLP to be Lead Plaintiffs' Counsel. Lead Plaintiffs filed their amended complaint on February 4, 2021. It alleges that the Company's registration statement and related prospectus for the IPO contained 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 and thus overstated its revenues for the full fiscal year 2019 and first quarter of 2020, and (ii) was allegedly suffering from material negative trends with respect to testing volumes, average selling prices for its tests, and revenues. Lead Plaintiffs seek certification as a class, unspecified compensatory damages, interest, costs and expenses including attorneys' fees, and unspecified extraordinary, equitable, and/or injunctive relief.  Together with the underwriters of the IPO, the Company moved to dismiss the amended complaint on April 5, 2021. Lead Plaintiffs' filed their opposition to the motion on June 4, 2021. Together with the underwriters of the IPO, the Company filed a reply in support of the motion to dismiss on July 19, 2021. The Company intends to continue to vigorously defend against these claims. Subject to a reservation of rights, the Company is advancing expenses subject to indemnification to the underwriters of the IPO.

On June 4, 2021, a purported shareholder filed a lawsuit in the U.S. District Court for the Southern District of California, claiming to sue derivatively on behalf of the Company.  The complaint names certain of the Company's officers and directors as defendants, and names the Company as a nominal defendant.  Premised largely on the same allegations as the above-described securities lawsuit, it alleges that the individual defendants breached their fiduciary duties to the Company, wasted corporate assets, and caused the Company to issue a misleading proxy statement in violation of the Securities Exchange Act of 1934.  The complaint seeks the award of unspecified damages to the Company, equitable and injunctive remedies, and an order directing the Company to reform and improve its internal controls and board oversight.  It also seeks the costs and disbursements associated with bringing suit, including attorneys', consultants', and experts' fees.  The case is stayed pending the outcome of the motion to dismiss in the above-described securities lawsuit.  The Company intends to vigorously defend against these claims.

Given the uncertainty of litigation, the preliminary stages of the Ravgen and IPO litigations, 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.

## 12. 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 350,000,000 shares of common stock and 10,000,000 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.

In December 2020, the Company issued and sold 8,792,047 shares of its common stock in an underwritten public offering, at a price of $3.27 per share. The Company received approximately $26.9 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

In February 2021, the Company entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors ("February Purchasers"). Pursuant to the Securities Purchase Agreement, the February Purchasers purchased an aggregate of 4,370,629 units ("February Units"), representing (i) 4,370,629 shares of the Company's common stock and (ii) warrants to purchase up to 4,370,629 shares of common stock. The purchase price for each February Unit was $5.72, for an aggregate purchase price of approximately $25.0 million. The warrants are exercisable for cash at an exercise price of $6.86 per share, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable at any time for cash and expire on the fifth anniversary of the date of issuance. If exercised for cash, the warrants would result in additional gross proceeds to the Company of approximately $30.0 million.

Pursuant to ASC 815-40, *Derivatives and Hedging – Contracts in Entity's Own Equity* ("ASC 815"), the Company deemed the warrants to be liability classified and allocated the proceeds from issuance between the warrants and common stock using the with-and-without method. $12.8 million of the proceeds, equal to the fair value of the warrants determined using the Black-Scholes Model, were allocated to the warrant liability, and the remaining proceeds of $12.2 million were allocated to the common stock. The Company incurred a total of $1.4 million in issuance costs, which were allocated between the warrants and common stock on a relative fair value basis, $0.5 million and $0.9 million, respectively. The warrant liability was remeasured at $10.2 million as of March 31, 2021 and the Company recognized a gain on warrant liability in the amount of $2.6 million associated with this transaction during the quarter ended March 31, 2021. On April 1, 2021, the registration statement to register the shares of common stock underlying the warrants was declared effective by the SEC. As a result, the warrants met the conditions to be classified in equity and the related warrant liability was reclassified from liability to equity on April 1, 2021.

In June 2021, the Company entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors ("June Purchasers"). Pursuant to the Securities Purchase Agreement, the June Purchasers purchased an aggregate of 16,194,332 units ("June Units"), representing (i) 15,694,332 shares of the Company's common stock (ii) warrants to purchase up to 16,194,332 shares of common stock and (iii) pre-funded warrants to purchase up to 500,000 shares of common stock. The purchase price for each June Unit was $2.47, for an aggregate purchase price of approximately $40.0 million. The warrants are exercisable for cash at an exercise price of $2.84 per share, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable at any time and expire on the fifth anniversary of the date of issuance. If exercised for cash, the warrants would result in additional gross proceeds to the Company of approximately $46.0 million. The pre-funded warrants are exercisable at an exercise price of $0.001 per share and have no expiration date. In July 2021, the Company issued 500,000 shares of common stock as a result of the exercise of the outstanding pre-funded warrants at an exercise price of $0.001 per share.

Pursuant to ASC 815, the Company deemed the warrants to be liability classified and allocated the proceeds from issuance between the warrants and common stock using the with-and-without method. $26.6 million of the proceeds, equal to the fair value of the warrants determined using the Black-Scholes Model, were allocated to the warrant liability, and the remaining proceeds of $13.4 million were allocated to the common stock. The Company incurred a total of $2.1 million in issuance costs, which were allocated between the warrants and common stock on a relative fair value basis, $0.7 million and $1.4 million, respectively. The warrant liability was remeasured at $31.8 million as of June 30, 2021 and the Company recognized a loss on warrant liability in the amount of $5.1 million in the condensed consolidated statements of operations during the three and six months ended June 30, 2021. On June 30, 2021, the registration statement to register the shares of common stock underlying the warrants was declared effective by the SEC. As a result, the warrants met the conditions to be classified in equity and the related warrant liability was reclassified from liability to equity on June 30, 2021.

**Convertible Preferred Stock**

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 ("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 ("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 an 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 ("November Series B Preferred Stock Purchase Agreement") with a private equity firm and received $25.0 million ("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.

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:

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| Outstanding options to purchase common stock | 11,166,946 | 4,268,945 |
| Restricted stock units outstanding | 4,377,826 | 1,468,765 |
| Available for future issuance under equity incentive plan | 4,876,797 | 2,938,616 |
| Common stock issuable upon conversion of Convertible Notes | 50,856,253 | 51,529,036 |
| Common stock warrant | 21,465,121 | 400,160 |
| Total | 92,742,943 | 60,605,522 |

## 13. Stock-Based Compensation

In February 2018, the Company adopted the 2018 Equity Incentive Plan ("2018 Plan"). The 2018 Plan is the successor to and continuation of the Second Amended and Restated 2012 Stock Plan ("2012 Plan") and the 2015 Consultant Stock Plan ("2015 Plan") and is administered with either stock options or restricted stock units. The Board of Directors administers the plans. Upon adoption of the 2018 Plan, no new stock options or awards are issuable under the 2012 Plan, as amended, or the 2015 Plan. 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 1,100,000 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 2,700,000 shares. On March 4, 2020, the Board of Directors adopted the Third Amended and Restated 2018 Equity Incentive Plan ("2018 Third Amended Plan"), which increased the number of shares available for future grant to a total of 7,615,733 shares and was approved by stockholders on March 5, 2020.

The 2018 Third Amended Plan provides for automatic annual increase in the number of shares of common stock reserved for issuance, which resulted in an additional 4,537,676 shares reserved for future issuance effective January 1, 2021. On May 5, 2021, holders of a majority of the outstanding common stock executed a written consent approving the Fourth Amended and Restated 2018 Equity Incentive Plan ("2018 Fourth Amended Plan") and an increase of 7,700,000 shares authorized for issuance, resulting in a total of 19,853,409 shares authorized for issuance under the 2018 Fourth Amended Plan. As of June 30, 2021, the number of shares available for grant under the 2018 Fourth Amended Plan was 4,876,797.

**Stock Options**

The following table summarizes stock option activity, which includes Performance Awards, under the 2012 Plan, the 2015 Plan, and the 2018 Third Amended Plan during the six months ended June 30, 2021 (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, 2020 | 4,268,945 | $ 8.14 | | |
| Options granted | 8,387,906 | 3.62 | | |
| Options exercised | (96,782) | 1.27 | | |
| Options forfeited/cancelled | (1,217,632) | 4.61 | | |
| Options expired | (175,491) | 10.72 | | |
| Balance at June 30, 2021 | 11,166,946 | $ 5.15 | 8.91 | $ 2,065 |
| Vested and expected to vest at June 30, 2021 | 11,166,946 | $ 5.15 | 8.91 | $ 2,065 |
| Vested and exercisable at June 30, 2021 | 2,225,549 | $ 7.76 | 6.21 | $ 793 |

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 six months ended June 30, 2021:

| | |
|---|---|
| Risk-free interest rate | 0.6% - 1.1% |
| Expected volatility | 52.9% - 69.9% |
| Expected dividend yield | —% |
| Expected life (years) | 3.0 - 6.3 years |

The weighted-average grant date fair value of options granted during the six months ended June 30, 2021 and 2020 was $2.13 per option and $6.78 per option, respectively.

**Restricted Stock Units**

The following table summarizes RSU activity for the six months ended June 30, 2021:

| | Number of Shares | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Balance at December 31, 2020 | 1,468,765 | $ 8.73 |
| Granted | 3,920,143 | 3.37 |
| Vested | (412,118) | 7.37 |
| Forfeited/cancelled | (598,964) | 4.84 |
| Balance at June 30, 2021 | 4,377,826 | $ 4.59 |

**2020 Employee Stock Purchase Plan**

In June 2020, the Company's board of directors adopted the ESPP. At December 31, 2020, 510,000 shares of common stock were reserved for future issuance under the ESPP. The ESPP also provides for automatic annual increases in the number of shares of common stock reserved for issuance, which resulted in an additional 557,723 shares reserved for future issuance effective January 1, 2021. As of June 30, 2021 there were 812,891 total shares of common stock reserved for future issuance.

The Company commenced a series of offerings under the ESPP on December 1, 2020. The initial offering began December 1, 2020, ends on November 30, 2022 (unless terminated earlier, as described below) and consists of four purchase periods. The purchase periods end on the last trading day of May and November of each year. Eligible employees who enroll in the initial offering or any subsequent offering will be able to purchase shares of the Company's common stock at a discount through payroll deductions, subject to certain limitations. The purchase price of the shares of common stock will be the lesser of (i) 85% of the fair market value of such shares on the offering date and (ii) 85% of the fair market value of such shares on the purchase date. Following the commencement of the initial offering, a new 24-month offering with four six-month purchase periods will automatically begin approximately every six months thereafter over the term of the ESPP. Offerings will be concurrent, but in the event the fair market value of a share of common stock on the first day of any purchase period during an offering ("New Offering") is less than or equal to the fair market value of a share of common stock on the offering date for an ongoing offering ("Ongoing Offering"), then the Ongoing Offering terminates immediately following the purchase of shares on the purchase date immediately preceding the New Offering and the participants in the terminated Ongoing Offering are automatically enrolled in the New Offering. Notwithstanding the above, the Company's board of directors (or an authorized committee thereof) may modify the terms of or suspend any future offerings prior to their commencement. The Company issues new shares for purchases of stock made pursuant to the ESPP.

**Stock-Based Compensation Expense**

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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Research and development | 1,080 | 823 | 1,675 | 1,472 |
| Selling and marketing | 310 | 511 | 660 | 882 |
| General and administrative | 2,000 | 1,240 | 3,290 | 1,931 |
| Discontinued operations | 1,080 | 450 | 1,475 | 796 |
| Total stock-based compensation expense | $ 4,470 | $ 3,024 | $ 7,100 | $ 5,081 |

At June 30, 2021 and December 31, 2020, there was $23.2 million and $12.8 million, respectively, of compensation cost related to unvested stock options expected to be recognized over a remaining weighted average vesting period of 2.82 and 2.93 years, respectively.

**14. 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 for the three and six months ended June 30, 2021. 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 10). The Company received a tax refund of $37.7 million related to the NOL carryback provisions available under the CARES Act during 2020. There is no additional carryback for the six months ended June 30, 2021.

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 ("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 year ended December 31, 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. Any future ownership changes under Section 382 and 383 could have an impact to the utilization of the net operating losses and general business credits.

## 15. 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:

| | June 30, 2021 | June 30, 2020 |
|---|---|---|
| Options to purchase common stock | 11,166,946 | 3,848,838 |
| Restricted stock units | 4,377,826 | 1,095,095 |
| Common stock warrant | 21,465,121 | 400,160 |
| Common stock issuable upon conversion of Convertible Notes | 50,856,253 | — |
| Series A Preferred Stock | — | — |
| Series B Preferred Stock | — | — |
| Series B Preferred Stock Purchase Warrant | — | — |
| Total | 87,866,146 | 5,344,093 |

**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 ("Quarterly Report") and the audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2020 included in our Annual Report on Form 10-K. 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," "target," "forecast," 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**

We are a biotechnology company innovating in the fields of women's health, gastrointestinal health and oral biotherapeutics. We apply a multi-omics approach, combining genomics, epigenomics, proteomics, and metabolomics to the development of a suite of investigational ingestible devices and drug/device combinations designed to provide precise diagnostic sampling and drug delivery solutions. Our vision is to transform healthcare to become more precise and personal by improving the diagnoses of disease and improving patient outcomes through localized treatment with targeted therapies. Our continuous pursuit of innovative solutions seeks to provide near-term commercial applications while also developing the drug delivery systems of the future, with critical near-term milestones across numerous pipeline products, including our Preecludia™ pre-eclampsia rule-out test, our Drug Delivery System (DDS) platform, and our Oral Biopharmaceutical Delivery System (OBDS).

**Strategic Transformation**

In June 2021, we announced a strategic transformation pursuant to which we are refocusing our efforts on our robust research and development pipeline to better position the business for future growth. The strategic transformation includes the closure of our genetics lab in Ann Arbor, Michigan, a reduction in force and other cost-cutting measures and operational improvements. We also continue to seek opportunities to generate non-dilutive capital through partnerships and strategic alternatives for non-core assets, including our affiliate Avero Diagnostics, the potential proceeds of which could help fund the company's research and clinical development activities, if successful.

Prior to the closure of our genetics laboratory in Ann Arbor, Michigan, we generated revenue by providing tests through our Ann Arbor laboratory, including throughout most of the second quarter of 2021. We received payments for such tests from payors, laboratory distribution partners, and self-paying individuals and more than 95% of payments for our tests we received through reimbursement. We received reimbursement from several distinct channels: commercial third-party payors, laboratory distribution partners, and government health benefits programs such as Medicare and Medicaid. Due to the typical lag in payment following performance of a test, we expect to continue to receive reimbursement payments for a period of time following the closure of the laboratory.

We continue to provide anatomic and molecular pathology tests and genetic testing through our affiliate Mattison Pathology, LLP, a Texas limited liability partnership doing business as Avero Diagnostics ("Avero"), located in Lubbock and Irving, Texas. Tests are distributed through a dedicated direct sales force, supported by a field operations team who provide 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 began offering COVID-19 testing nationally in mid-November 2020. Future demand for COVID-19 testing is becoming increasing difficult to predict due to various factors, including, but not limited to, the availability of vaccinations, the number of individuals who choose to be vaccinated, the effectiveness of the various vaccinations against variants, the rate of new cases, and evolving government directives, laws, regulations and rules related to COVID-19 testing. In the long term, we expect that the COVID-19 pandemic will eventually dissipate and, as a result, the significance of COVID-19 testing to our business and financial results will decrease. During the three months ended June 30, 2021, we accessioned approximately 12,000 COVID-19 tests.

We are engaged in research and development activities with respect to tests under development and precision medicine product candidates. Following the strategic transformation, we have begun devoting substantially all of our resources to developing and perfecting our intellectual property rights, conducting research and development activities, including undertaking preclinical and clinical studies of our precision medicine product candidates, conducting clinical trials of our most advanced precision medicine product candidates, organizing and staffing our company, business planning and raising capital. We do not have any precision medicine products approved for sale, and we have not generated any revenue from precision medicine product sales.

Our business involves significant investment in research and development activities for the development of new products. 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 precision medicine product candidates and as we seek to expand our pipeline of precision medicine product candidates. 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 candidates) is a key factor in evaluating our performance.

We expect to continue to incur significant expenses and increasing operating losses in the near term. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- continue to advance the preclinical and clinical development of our lead precision medicine product candidates;
- initiate preclinical studies and clinical trials for additional precision medicine product candidates that we may identify in the future;
- increase personnel and infrastructure to support our clinical development, research and manufacturing efforts;
- build out and expand our in-house process development and engineering and manufacturing capabilities for R&D and clinical purposes;
- continue to develop, perfect and defend our intellectual property portfolio; and
- incur additional legal, accounting or other expenses in operating our business, including the additional costs associated with operating as a public company.

We do not expect to generate significant product revenue unless and until we successfully complete development and obtain regulatory and marketing approval of, and begin to sell, one or more of our precision medicine product candidates, which we expect will take several years. We expect to spend a significant amount in development and marketing costs prior to such time. We may never succeed in achieving regulatory and marketing approval for our precision medicine product candidates. We may obtain unexpected results from our preclinical and clinical trials. We may elect to discontinue, delay or modify preclinical and clinical trials of our precision medicine product candidates. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. Accordingly, until such time as we can generate significant product revenue, if ever, we expect to continue to seek private or public equity and debt financing to meet our capital requirements. There can be no assurance that such funding may be available to us on acceptable terms, or at all, or that we will be able to commercialize our precision medicine product candidates. In addition, we may not be profitable even if we commercialize any of our precision medicine 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 Ann Arbor facilities, our preeclampsia test verification work restarted in June 2020 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.

**Key Components of Our Results of Operations**

We are providing the following summary of our revenues, research and development expenses and general and administrative expenses to supplement the more detailed discussion below. This summary excludes our revenues, research and development expenses, selling and marketing, general and administrative and other expenses associated with our Laboratory Operations, which are reported within loss from discontinued operations.

*Revenue*

Historically, all of our revenue has been derived from molecular laboratory tests, principally from the sale of NIPT, genetic carrier screening, and pathology molecular testing. If our development efforts for our precision medicine product candidates or other products under development are successful and result in regulatory approval, we may generate revenue from future product sales. If we enter into license or collaboration agreements for any of our precision medicine product candidates, other pipeline products or intellectual property, we may generate revenue in the future from payments as a result of such license or collaboration agreements. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our precision medicine product candidates or from license or collaboration agreements. We may never succeed in obtaining regulatory approval for any of our precision medicine product candidates.

*Research and Development*

Research and development expenses consist primarily of costs associated with developing 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.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we conduct additional preclinical studies and clinical trials, including later-stage clinical trials, for our current and future product candidates and pursue regulatory approval of our product candidates. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time consuming. The actual probability of success for our product candidates may be affected by a variety of factors including:

- the safety and efficacy of our product candidates;
- early clinical data for our product candidates;
- investment in our clinical programs;
- the ability of collaborators to successfully develop our licensed product candidates;
- competition;
- manufacturing capability; and
- commercial viability.

We may never succeed in achieving regulatory approval for any of our product candidates due to the uncertainties discussed above. We are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if ever.

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 decrease due to the shut down of our Laboratory Operations and the potential divestiture of our Avero affiliate.

*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 incurred 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 will continue to incur 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 California subpoena, the Colorado recoupment, the Ravgen lawsuit and IPO related litigation described in Part II, Item 1. “Legal Proceedings” in this Quarterly Report. However, we expect the dollar amount of our general and administrative expenses to decrease for the foreseeable future as a result of the shut down of our Laboratory Operations and the potential divestiture of our Avero affiliate.

*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 changes in fair value of our embedded derivative liability related to the Convertible Notes 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 to be 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. We agreed to pay 65% of any tax refund received in excess of $5.0 million in a single year, along with other civil settlements, damages awards, and tax refunds, to accelerate payments to the government in connection with our government settlement. In 2020, we received a tax refund of $37.7 million related to the NOL carryback provisions available under the CARES Act and paid a total of $37.0 million to the government in connection with our government settlements. See Part II, Item 1. "Legal Proceedings—Federal Investigations" in this Quarterly Report.

**Results of Operations.**

***Comparison of Three Months Ended June 30, 2021 and 2020***

| | Three Months Ended June 30, | |
|---|---|---|
| | 2021 | 2020 |
| | (in thousands) (unaudited) | |
| **Statement of Operations Data:** | | |
| Revenues | $ 463 | $ — |
| Cost of sales | — | — |
| Gross profit | 463 | — |
| Operating expenses: | | |
| Research and development | 13,401 | 12,234 |
| Selling and marketing | 2,006 | 1,547 |
| General and administrative | 20,709 | 12,702 |
| Total operating expenses | 36,116 | 26,483 |
| Loss from operations | (35,653) | (26,483) |
| Interest expense | (3,502) | (2,489) |
| Loss on warrant liability | (5,146) | — |
| Interest and other income (expense), net | 2,901 | (3,751) |
| Loss from continuing operations | (41,400) | (32,723) |
| Loss from discontinued operations | (37,131) | (20,060) |
| Net loss | $ (78,531) | $ (52,783) |

*Revenue*

As a result of the classification of the Company's Laboratory Operations to discontinued operations, all revenue from Laboratory Operations has been classified as discontinued operations. The remaining revenue is related to license and collaboration agreements.

*Cost of Sales*

As a result of the classification of the Company's Laboratory Operations to discontinued operations, all cost of sales from Laboratory Operations has been classified as discontinued operations.

*Research and Development Expenses*

| | Three Months Ended June 30, | | Increase/ | |
|---|---|---|---|---|
| | 2021 | 2020 | (Decrease) | % Change |
| | (in thousands) (unaudited) | | | |
| Research and development | $ 13,401 | $ 12,234 | $ 1,167 | 9.5 % |

The increase in research and development expenses was primarily attributable to an increase in supplies costs that will be used for research and development.

*Selling and Marketing Expenses*

| | Three Months Ended June 30, 2021 | Three Months Ended June 30, 2020 | Increase/ (Decrease) | % Change |
|---|---|---|---|---|
| | (in thousands) (unaudited) | | | |
| Selling and marketing | $ 2,006 | $ 1,547 | $ 459 | 29.7% |

The increase in selling and marketing expenses was primarily attributable to an increase in consulting fees for brand development related to preeclampsia. However, we expect the dollar amount of our selling and marketing expenses to decrease going forward, as a result of the shut down of our Laboratory Operations and the potential divestiture of our Avero affiliate.

*General and Administrative Expenses*

| | Three Months Ended June 30, 2021 | Three Months Ended June 30, 2020 | Increase/ (Decrease) | % Change |
|---|---|---|---|---|
| | (in thousands) (unaudited) | | | |
| General and administrative | $ 20,709 | $ 12,702 | $ 8,007 | 63.0% |

The increase in general and administrative expenses was primarily attributable to an increase in consulting professional fees as part of the strategic transformation restructuring, salary and benefits due to new equity awards issued in April 2021 and business insurance costs related to our director and officer insurance premiums. However, we expect the dollar amount of our general and administrative expenses to decrease going forward, as a result of the shut down of our Laboratory Operations and the potential divestiture of our Avero affiliate.

*Interest Expense*

| | Three Months Ended June 30, 2021 | Three Months Ended June 30, 2020 | Increase/ (Decrease) | % Change |
|---|---|---|---|---|
| | (in thousands) (unaudited) | | | |
| Interest expense | $ 3,502 | $ 2,489 | $ 1,013 | 40.7% |

The increase in interest expense was due to the extinguishment of the Term Loan and the issuance of the Convertible Notes and amortization of the debt discount.

*Loss on Warrant Liability*

| | Three Months Ended June 30, 2021 | Three Months Ended June 30, 2020 | Increase/ (Decrease) | % Change |
|---|---|---|---|---|
| | (in thousands) (unaudited) | | | |
| Loss on warrant liability | $ 5,146 | $ - | $ 5,146 | 100.0% |

The increase in loss on warrant liability was due to the remeasurement of the warrant liability for warrants issued in June 2021 as of June 30, 2021.

*Interest and Other Income (Expense), Net*

| | Three Months Ended June 30, 2021 | Three Months Ended June 30, 2020 | Increase/ (Decrease) | % Change |
|---|---|---|---|---|
| | (in thousands) (unaudited) | | | |
| Interest and other income (expense), net | $ 2,901 | $ (3,751) | $ 6,652 | * |

* The change is more than 100%

The change in Interest and other income (expense), net, was primarily due to a $3.2 million gain related to a decrease in the fair value of our embedded derivative liability related to the Convertible Notes and 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 in June 2020.

*Discontinued Operations*

| | Three Months Ended June 30, 2021 | Three Months Ended June 30, 2020 | Increase/ (Decrease) | % Change |
|---|---|---|---|---|
| | (in thousands) (unaudited) | | | |
| Loss from discontinued operations | $ 37,131 | $ 20,060 | $ 17,071 | 85.1% |

The increase in loss from discontinued operations was due to the closure of our Laboratory Operations during the second quarter ended June 30, 2021. The increase in loss was attributable to inventory write-downs, severance, property and equipment write-downs and contract termination expenses incurred during the three months ended June 30, 2021. See Note 4 to our condensed consolidated financial statements included in this Quarterly Report for additional information regarding discontinued operations.

***Comparison of Six Months Ended June 30, 2021 and 2020***

| | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 |
|---|---|---|
| | (in thousands) (unaudited) | |
| **Statement of Operations Data:** | | |
| Revenues | $ 630 | $ — |
| Cost of sales | — | — |
| Gross profit | 630 | — |
| Operating expenses: | | |
| Research and development | 25,074 | 23,476 |
| Selling and marketing | 3,864 | 3,235 |
| General and administrative | 38,809 | 24,421 |
| Total operating expenses | 67,747 | 51,132 |
| Loss from operations | (67,117) | (51,132) |
| Interest expense | (7,022) | (4,771) |
| Loss on warrant liability | (2,496) | — |
| Interest and other income (expense), net | 17,774 | (3,771) |
| Loss before income taxes | (58,861) | (59,674) |
| Income tax benefit | — | (37,697) |
| Loss from continuing operations | (58,861) | (21,977) |
| Loss from discontinued operations | (51,934) | (47,958) |
| Net loss | $ (110,795) | $ (69,935) |

*Revenue*

As a result of the classification of the Company's Laboratory Operations to discontinued operations, all revenue from Laboratory Operations has been classified as discontinued operations. The remaining revenue is related to license and collaboration agreements.

*Cost of Sales*

As a result of the classification of the Company's Laboratory Operations to discontinued operations, all cost of sales from Laboratory Operations has been classified as discontinued operations.

*Research and Development Expenses*

| | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 | Increase/ (Decrease) | % Change |
|---|---|---|---|---|
| | (in thousands) (unaudited) | | | |
| Research and development | $ 25,074 | $ 23,476 | $ 1,598 | 6.8 % |

The increase in research and development expenses was primarily attributable to an increase in salary and benefits and an increase in professional fees related to product design, offset by a decrease in supplies costs. The increase in salary and benefits is driven by additional stock-based compensation expense and increased salaries. The increase in professional fees is driven by higher product design fees and engineering work for our precision medicine product candidates.

*Selling and Marketing Expenses*

| | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 | Increase/ (Decrease) | % Change |
|---|---|---|---|---|
| | (in thousands) (unaudited) | | | |
| Selling and marketing | $ 3,864 | $ 3,235 | $ 629 | 19.4 % |

The increase in selling and marketing expenses was primarily attributable to an increase in consulting fees for brand development related to preeclampsia. However, we expect the dollar amount of our selling and marketing expenses to decrease going forward, as a result of the shut down of our Laboratory Operations and the potential divestiture of our Avero affiliate.

*General and Administrative Expenses*

| | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 | Increase/ (Decrease) | % Change |
|---|---|---|---|---|
| | (in thousands) (unaudited) | | | |
| General and administrative | $ 38,809 | $ 24,421 | $ 14,388 | 58.9 % |

The increase in general and administrative expenses was primarily attributable to an increase in consulting professional fees as part of the strategic transformation restructuring, legal fees related to general corporate and patent litigation matters, salary and benefits due to new equity awards issued in April 2021 and business insurance costs related to our director and officer insurance premiums. However, we expect the dollar amount of our general and administrative expenses to decrease going forward, as a result of the shut down of our Laboratory Operations and the potential divestiture of our Avero affiliate.

*Interest Expense*

| | Six Months Ended June 30, 2021 | 2020 | Increase/ (Decrease) | % Change |
|---|---|---|---|---|
| | (in thousands) (unaudited) | | | |
| Interest expense | $ 7,022 | $ 4,771 | $ 2,251 | 47.2 % |

The increase in interest expense was due to the extinguishment of the Term Loan and the issuance of the Convertible Notes and amortization of the debt discount.

*Loss on Warrant Liability*

| | Six Months Ended June 30, 2021 | 2020 | Increase/ (Decrease) | % Change |
|---|---|---|---|---|
| | (in thousands) (unaudited) | | | |
| Loss on warrant liability | $ 2,496 | $ - | $ 2,496 | 100.0% |

The increase in loss on warrant liability was due to the remeasurement of the warrant liability for warrants issued in June 2021, as of June 30, 2021, offset by the remeasurement of the warrant liability for warrants issued in February 2021, as of March 31, 2021.

*Interest and Other Income (Expense), Net*

| | Six Months Ended June 30, 2021 | 2020 | Increase/ (Decrease) | % Change |
|---|---|---|---|---|
| | (in thousands) (unaudited) | | | |
| Interest and other income (expense), net | $ 17,774 | $ (3,771 ) | $ 21,545 | * |

* The change is more than 100%

The change in Interest and other income (expense), net, was primarily due to an $18.0 million gain related to a decrease in the fair value of our embedded derivative liability related to the Convertible Notes and 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 in June 2020.

*Income Tax Benefit*

| | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 | Increase/ (Decrease) | % Change |
|---|---|---|---|---|
| | (in thousands) (unaudited) | | | |
| Income tax benefit | $ — | $ 37,697 | $ (37,697) | 100.0 % |

The tax benefit during the three months ended March 31, 2020 was recorded due to the net operating loss carryback provisions available under the CARES Act legislation enacted in March 2020, which did not occur again in the first quarter of 2021. The Company 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 during the six months ended June 30, 2021.

*Discontinued Operations*

| | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 | Increase/ (Decrease) | % Change |
|---|---|---|---|---|
| | (in thousands) (unaudited) | | | |
| Loss from discontinued operations | $ 51,934 | $ 47,958 | $ 3,976 | 8.3 % |

The increase in loss from discontinued operations was due to the closure of our Laboratory Operations during the second quarter ended June 30, 2021. The increase in loss was attributable to inventory write-downs, severance, property and equipment write-downs and contract termination expenses incurred during the six months ended June 30, 2021. See Note 4 to our condensed consolidated financial statements included in this Quarterly Report for additional information regarding discontinued operations.

**Liquidity and Capital Resources.**

Since our inception, our primary sources of liquidity have been generated by our operations, sales of common stock, preferred stock, warrants to purchase common stock and preferred stock, and cash from debt financings, including Convertible Notes.

As of June 30, 2021, we had $66.0 million of cash and cash equivalents, $157.5 million of outstanding Convertible Notes, and mortgages outstanding of $1.3 million. Our accumulated deficit as of June 30, 2021, was $652.1 million. For the six months ended June 30, 2021, we had a net loss of $110.8 million and cash used in operations of $52.1 million. Our primary requirements for liquidity have been to fund our working capital needs, capital expenditures, dividends, research and development expenses, and general corporate needs.

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 six months ended June 30, 2021. 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 or divestitures of the Company's assets. 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 materially and 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 disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

*Convertible Notes*

In December 2020, in connection with a private offering of convertible notes pursuant to Rule 144A under the Securities Act, we issued a total of $168.5 million principal amount of our Convertible Notes. The Convertible Notes were issued pursuant to, and are governed by, an indenture, dated as of December 7, 2020, by and between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee ("Indenture"). The Convertible Notes are due on December 1, 2025, unless earlier repurchased, redeemed or converted, and accrue interest at a rate per annum equal to 7.25% payable semi-annually in arrears on June 1 and

December 1 of each year, with the initial payment on June 1, 2021. During the three and six months ended June 30, 2021, we recognized interest expense on the Convertible Notes of $3.1 million and $6.2 million, respectively.

The Convertible Notes are our senior, unsecured obligations and are (i) equal in right of payment with our existing and future senior, unsecured indebtedness; (ii) senior in right of payment to our existing and future indebtedness that is expressly subordinated to the Notes; (iii) effectively subordinated to our existing and future secured indebtedness, to the extent of the value of the collateral securing that indebtedness; and (iv) structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent we are not a holder thereof) preferred equity, if any, of our subsidiaries.

At any time, noteholders may convert their Convertible Notes at their option into shares of our common stock, together, if applicable, with cash in lieu of any fractional share, at the then-applicable conversion rate. The initial conversion rate is 278.0094 shares of common stock per $1,000 principal amount of Convertible Notes, which represents an initial conversion price of approximately $3.60 per share of common stock. Noteholders that convert their Notes before December 1, 2022 will, in certain circumstances, be entitled to an additional cash payment representing the present value of any remaining interest payments on the Convertible Notes through December 1, 2022. The conversion rate and conversion price are subject to customary adjustments upon the occurrence of certain events. In addition, if certain corporate events that constitute a Make-Whole Fundamental Change (as defined in the Indenture) occur, then the conversion rate will, in certain circumstances, be increased for a specified period of time.

The Convertible Notes are redeemable, in whole and not in part, at our option at any time on or after December 1, 2023, at a cash redemption price equal to the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date, but only if the last reported sale price per share of the our common stock exceeds 130% of the conversion price on (i) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date we send the related redemption notice; and (ii) the trading day immediately before the date we send such notice. In addition, calling the Convertible Notes will constitute a Make-Whole Fundamental Change, which will result in an increase to the conversion rate in certain circumstances for a specified period of time.

The Convertible Notes have customary provision relating to the occurrence of Events of Default (as defined in the Indenture), which include the following: (i) certain payment defaults on the Convertible Notes (which, in the case of a default in the payment of interest on the Convertible Notes, will be subject to a 30-day cure period); (ii) our failure to send certain notices under the Indenture within specified periods of time; (iii) our failure to comply with certain covenants in the Indenture relating to the Company’s ability to consolidate with or merge with or into, or sell, lease or otherwise transfer, in one transaction or a series of transactions, all or substantially all of our assets and assets of our subsidiaries, taken as a whole, to another person; (iv) a default by us in our other obligations or agreements under the Indenture or the Convertible Notes if such default is not cured or waived within 60 days after notice is given in accordance with the Indenture; (v) certain defaults by us or any of our subsidiaries with respect to indebtedness for borrowed money of at least $7,500,000; (vi) the rendering of certain judgments against us or any of our subsidiaries for the payment of at least $7,500,000, where such judgments are not discharged or stayed within 60 days after the date on which the right to appeal has expired or on which all rights to appeal have been extinguished; and (vii) certain events of bankruptcy, insolvency and reorganization involving us or any of our significant subsidiaries.

*PIPE Financings*

In February 2021, we entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors, pursuant to which the purchasers purchased an aggregate of 4,370,629 units representing (i) 4,370,629 shares of the Company’s common stock, par value $0.001 per share, and (ii) warrants to purchase up to 4,370,629 shares of common stock. The purchase price for each unit was $5.72, for an aggregate purchase price of approximately $25.0 million. The transaction closed on February 25, 2021. The warrants are exercisable for cash at an exercise price of $6.86 per share, subject to adjustments as provided under the terms of the warrants. The warrants are immediately exercisable for cash and expire on the fifth anniversary of the date of issuance. If exercised for cash, the warrants would result in additional gross proceeds to us of approximately $30.0 million.

In June 2021, we entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors, pursuant to which the purchasers have agreed to purchase an aggregate of 16,194,332 units representing (i) 16,194,332 shares of the Company’s common stock, par value $0.001 per share (or pre-funded warrants in lieu thereof), and (ii) warrants to purchase up to 16,194,332 shares of common stock. The purchase price for each unit was $2.47, for an aggregate purchase price of approximately $40.0 million. The transaction closed on June 14, 2021. The warrants are immediately exercisable at an exercise price of $2.84 per share, subject to adjustments as provided under the terms of the warrants, and expire on the fifth anniversary of the date of issuance. If exercised for cash, the warrants would result in additional gross proceeds to us of approximately $46 million.

*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 $1.3 million and $1.3 million as of June 30, 2021 and December 31, 2020, respectively. 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. Additionally, we 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 $1.6 million and $1.7 as of June 30, 2021 and December 31, 2020, 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 expenses will continue to increase 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. We expect selling and marketing and general and administrative expenses to decrease as a result of the shut down of our Laboratory Operations and the potential divestiture of our Avero affiliate. 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 (in thousands):

| | Six Months Ended June 30, | |
|---|---|---|
| | **2021** | **2020** |
| Cash used in operating activities | $ (84,250) | $ (43,202) |
| Cash used in investing activities | (1,021) | (1,627) |
| Cash provided by financing activities | 59,742 | 126,601 |

*Operating Activities*

Net cash used in operating activities in the six months ended June 30, 2021 was primarily attributable to a $110.8 million net loss, adjusted for $3.7 million of non-cash charges, primarily driven by $18.0 million change in fair value related to the Convertible Notes, $2.5 million of change in fair value of warrant liability, $5.6 million of stock-based compensation expense, and $1.0 million of depreciation and amortization expense. The net cash outflow from changes in operating assets and liabilities was attributable to a $4.9 million increase in prepaid expenses and other and a $7.0 million increase in accrued expenses and other liabilities, offset by a $6.6 million decrease in other long-term liabilities and a $1.7 million decrease in accounts payable. Additionally, net cash used in operating activities from discontinued operations contributed $32.1 million of outflows.

Net cash used in operating activities in the six months ended June 30, 2020 was primarily attributable to a $69.9 million net loss, adjusted for $33.7 million of non-cash charges, primarily driven by $23.7 million of non-cash revenue reserve, $4.3 million of stock-based compensation expense, $3.4 million loss on extinguishment of convertible notes and $1.3 million of amortization of debt discount. The net cash outflow from changes in operating assets and liabilities was attributable to a $15.0 million increase in income tax receivable offset by a $7.5 million decrease in accrued expenses and other current liabilities related to settlement accruals for payments due to third-party payors. Additionally, net cash used in operating activities from discontinued operations contributed $34.9 million of outflows.

*Investing Activities*

Net cash used in investing activities during the six months ended June 30, 2021 was attributable to a $0.9 million purchase of property and equipment. Net cash used in investing for the six months ended June 30, 2020 was attributable to a $0.7 million purchase of property and equipment and $0.9 million from discontinued operations.

*Financing Activities*

Net cash provided by financing activities during the six months ended June 30, 2021 was primarily attributable to $23.4 million in net proceeds from the issuance of common stock, and $39.4 million in net proceeds from the issuance of common stock warrants, partially offset by $2.7 million in payments for insurance financing, and $0.2 million in principal payments on mortgages payable and capital lease obligations. Net cash provided by financing activities during the six months ended June 30, 2020 was primarily attributable to $90.9 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.

**Off-Balance Sheet Arrangements.**

As of June 30, 2021, 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.

For the Company's significant accounting policies for assets held for sale and discontinued operations, see Note 2, within the notes to the unaudited condensed consolidated financial statements. During the six months ended June 30, 2021, there were no other 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 our Form 10-K for the year ended December 31, 2020.

**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 a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934 and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

**Item 4. Controls and Procedures.**

Our management, with the participation and supervision of our Chairman 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 Chairman 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 Chairman 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.

Refer to Note 11, "Commitments and Contingencies" to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, our Annual Report and our Quarterly Reports on Form 10-Q for prior periods, for information on our historical and ongoing legal proceedings.

***Colorado Recoupment***

On July 21, 2021, we received a letter from the Colorado Department of Health Care Policy and Financing ("Department"), informing us that, as a result of a post-payment review of Medicaid claims from October 2014 to June 2018, the Department is seeking recoupment for historical payments in an aggregate amount of approximately $5.7 million. The historical payments for which the Department is seeking recoupment are claimed to relate to our Preparent expanded carrier screening tests primarily on the basis that such tests were not medically necessary.

We previously entered into settlement agreements with 45 states, including the State of Colorado as part of a settlement with respect to certain civil claims related to 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.

We intend to dispute this claim of recoupment with the Department and seek to offset any amounts previously paid to the Department in connection with the State Settlement Agreements. As stated previously, such provider-payor disputes are not uncommon and we expect to approach this dispute with an aim to resolve in a mutually satisfactory manner. At this very preliminary stage, we are unable to predict the ultimate outcome of this action, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from this action.

***California Subpoena***

On July 19, 2021, the Company received a subpoena from the California Attorney General's Office, Division of Public Rights, requesting documents and information related to Progenity's genetic testing practices, including NIPT, particularly those with a nexus to California patients. The subpoena is captioned "In the Matter of the Investigation of: Prenatal Genetic Testing Companies." At this very preliminary stage, we are unable to predict the ultimate outcome of this action, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from this action.

***Natera Settlement***

On June 17, 2020, Natera, Inc. 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. In August 2021, the Company and Natera entered into a settlement agreement. The agreement does not require us to make a cash payment. The settlement agreement is subject to court approval.

***Ravgen Lawsuit***

On December 22, 2020, Ravgen, Inc., or Ravgen, filed suit in the District of Delaware (D. Del. Civil Action No. 1:20-cv-1734) asserting our infringement of two Ravgen patents. We responded to the complaint on March 23, 2021.

We believe the claims in Ravgen's complaint 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. Lawsuits were filed on August 28, 2020 and September 11, 2020 against the Company, certain of its executive officers and directors, and the underwriters of the IPO. On December 3, 2020, the U.S. District Court for the Southern District of California consolidated the two actions, appointed Lin Shen, Lingjun Lin and Fusheng Lin to serve as Lead Plaintiffs, and approved Glancy Prongay & Murray LLP to be Lead Plaintiffs' Counsel. Lead Plaintiffs filed their amended complaint on February 4, 2021. It alleges that our registration statement and related prospectus for the IPO contained 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 and thus overstated our revenues for the full fiscal year 2019 and first quarter of 2020, and (ii) were allegedly suffering from material negative trends with respect to testing volumes, average selling prices for our tests, and revenues. Lead Plaintiffs seek certification as a class, unspecified compensatory damages, interest, costs and expenses including attorneys' fees, and unspecified extraordinary, equitable, and/or injunctive relief. Together with the underwriters of the IPO, we moved to dismiss the amended complaint on April 5, 2021. Lead Plaintiffs' filed their opposition to the motion on June 4, 2021. Together with the underwriters of the IPO, we filed a reply in support of the motion to dismiss on July 19, 2021. We intend to continue to vigorously defend against these claims. Subject to a reservation of rights, we are advancing expenses subject to indemnification to the underwriters of the IPO.

On June 4, 2021, a purported shareholder filed a lawsuit in the U.S. District Court for the Southern District of California, claiming to sue derivatively on behalf of the Company. The complaint names certain of the Company's officers and directors as defendants, and names the Company as a nominal defendant. Premised largely on the same allegations as the above-described securities lawsuit, it alleges that the individual defendants breached their fiduciary duties to the Company, wasted corporate assets, and caused the Company to issue a misleading proxy statement in violation of the Securities Exchange Act of 1934. The complaint seeks the award of unspecified damages to the Company, equitable and injunctive remedies, and an order directing the Company to reform and improve its internal controls and board oversight. It also seeks the costs and disbursements associated with bringing suit, including attorneys', consultants', and experts' fees. The case is stayed pending the outcome of the motion to dismiss in the above-described securities lawsuit. We intend to vigorously defend against these claims.

Given the uncertainty of litigation, the preliminary stages of the Ravgen and IPO litigations, 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.

## 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 the 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. In this "Risk Factors" section, unless the context requires otherwise, references to "we," "us," "our," "Progenity" or the "company" refer to Progenity, Inc. and, where also applicable, Avero Diagnostics.*

### *Risk Factor Summary*

- Beginning in the fourth quarter of 2020, we began to reallocate resources within our organization to align more closely with our business priorities. This included reducing the resources allocated to certain programs and refocusing our resources on other key areas of our business. In addition, in June 2021, we announced a strategic transformation that involves certain cost realignment measures. We may experience difficulties in managing these changes to our organization and if unsuccessful, our financial condition and operating results may be adversely affected.
- The 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 have incurred losses in the past, and we may not be able to achieve or sustain profitability in the future.
- 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 operate in a highly competitive business environment.
- Our success depends on our ability to 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 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 outstanding debt, and any new debt, may impair our financial and operating flexibility.
- Although we have implemented compliance policies and have an internal audit function, we cannot ensure that our employees will fully adhere to such policies.

- 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 on a cost-effective basis, or at all.
- If third-party payors do not adequately reimburse for the products offered by Avero Diagnostics or our product candidates, they might not be purchased or used, which may adversely affect our revenue and profitability.
- We may be unable to expand or maintain third-party payor coverage and reimbursement for the products offered by Avero Diagnostics or our future products.
- 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***

**Beginning in the fourth quarter of 2020, we began to reallocate resources within our organization to align more closely with our business priorities. This included reducing the resources allocated to certain programs and refocusing our resources on other key areas of our business. In addition, in June 2021, we announced a strategic transformation that involves certain cost realignment measures. We may experience difficulties in managing these changes to our organization and if unsuccessful, our financial condition and operating results may be adversely affected.**

As of June 30, 2021, we had 511 full-time employees worldwide. In November 2020, we approved a reduction in force that resulted in the termination of approximately 9.5% of our workforce. The reduction in force was a component of our broader efforts to materially reduce our research and development expenses by focusing on key milestones and to limit progression of other costs to track our top line performance.

In addition, on June 1, 2021, we announced a strategic transformation, or the Strategic Transformation, which involves certain cost realignment measures including the discontinuation of the provision of commercial genetic laboratory-developed test services through our Ann Arbor, Michigan CLIA-certified laboratory and the termination of approximately 374 employees across the Company and our affiliated entity, Mattison Pathology, LLP, a Texas limited liability partnership doing business as Avero Diagnostics, which represents approximately 56% of our workforce. As a result of the Strategic Transformation, our business is refocusing on our research and development pipeline, which we expect will materially reduce our operating expenditures, more effectively allocate capital and unlock the value of the our differentiated research and development pipeline.

Over the past several years, we significantly expanded the size of our organization, particularly personnel within our sales and marketing and research and development groups. As a result of the Strategic Transformation, we are reducing certain aspects of our organization, particularly personnel within our Laboratory Operations and support and sales and marketing teams. In addition, certain of our managerial, operational, research and development, financial, and other personnel will be impacted by the Strategic Transformation. Whereas, the historical addition of employees imposed significant added responsibilities on members of management, our cost realignment measures pursuant to the Strategic Transformation may impose additional obligations on existing personnel, including increased responsibilities with respect to managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties, and executing on and improving our operational, financial, and management controls, reporting systems, and procedures.

Our future financial performance, our ability to successfully develop, market, and sell our products and product candidates, including the products offered by Avero Diagnostics, and our ability to effectively implement the Strategic Transformation will each impact our needs in terms of personnel. Our management may also have to devote a substantial amount of time to implementing the Strategic Transformation or pursuing additional strategic transactions, which may divert a disproportionate amount of attention away from day-to-day activities. Further, our future success depends on our ability to effectively implement the Strategic Transformation and on the successful development and commercialization of our research and development pipeline. We cannot assure you that we will achieve the full magnitude of cost savings and reduced operating expenditures that we have disclosed that we expect the Strategic Transformation to achieve or that any of our businesses will achieve the revenues that we have disclosed that we expect them to achieve following the Strategic Transaction, as a result of unexpected costs, costs associated with the strategic transformation such as severance and contract terminations or otherwise. In addition, we cannot assure you that our efforts related to the Strategic Transformation will improve our financial condition due to necessarily decreased revenue, including as a result of the termination of testing services, or will increase stockholder value. Any inability to execute and evolve in accordance with the Strategic Transformation and our other business initiatives could adversely impact our financial condition and results of operations.

**The 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, including the ongoing COVID-19 pandemic, 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. While vaccines have proven effective against SARS CoV-2, virus variants may cause a resurgence of COVID cases and vaccination rates may be insufficient to achieve herd immunity in locations where we conduct business.

In response to public health directives and orders imposed as a result of the COVID-19 pandemic, 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 future developments related to restrictions, variants, levels of vaccination and effectiveness of various vaccines, 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 relevant laws and regulations, 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 or were 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. A future 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, our preclinical and clinical trials have been and may continue to be affected by the COVID-19 pandemic. For example, while we originally intended to commence our pilot clinical study for PIL Dx in 2020, that timeline was delayed due to circumstances and uncertainties created by the COVID-19 pandemic and we now expect to instead commence this study in the second half of 2021. If COVID-19 experiences a resurgence 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 may 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. Although vaccines are now available and are being distributed globally, we cannot predict the full scope, duration and severity of disruptions resulting from the COVID-19 pandemic. 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 have incurred losses in the past, and we may not be able to achieve or sustain profitability in the future.**

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

Other than revenues from our Avero Diagnostics laboratory testing business, we do not expect to generate significant revenues from other sources in the immediate future. We do not expect Avero Diagnostics to generate sufficient revenue to cover our costs, including research and development expenses related to furthering our product pipeline, and achieve or sustain profitability. In addition, and as previously disclosed, we are evaluating strategic opportunities for Avero Diagnostics to generate non-dilutive capital. If we dispose of Avero Diagnostics, our main source of revenue will be eliminated and we may not generate revenue in the future until we are able to achieve commercialization of our product candidates or enter into licensing or collaboration agreements with respect to such product candidates.

Since we or any collaborators or licensees may not successfully develop additional product candidates, obtain required regulatory authorizations, manufacture products at an acceptable cost or with appropriate quality, or successfully market and sell such product candidates 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.

**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 expect to incur significant costs in connection with our operations, including but not limited to the research and 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 offerings to date will not be sufficient to fully fund these activities. In addition, as a result of the Strategic Transformation, our revenue will be significantly reduced. We will need to raise additional funds through public or private equity or debt financings, collaborations, licensing arrangements or sales of assets to continue to fund or expand our operations. If we dispose of Avero Diagnostics, we will no longer generate revenue from our historical testing business, and we would dependent on such additional sources of capital, including public or private equity or debt financings, collaborations, licensing arrangements or sales of assets for all of our future capital requirements if we do not achieve commercialization of our product candidates.

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;
- potential and pending litigation, potential payor recoupments of reimbursement amounts, and other contingencies;
- the commercial success of our future products;
- the termination costs associated with our Strategic Transformation;
- 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;
- any revenues received from our ongoing commercial operations;
- any proceeds from strategic transactions; 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 minimize dilution to our equity holders, we are also exploring non-dilutive financing options, which could include licenses or collaborations and/or sales of certain assets or business lines. 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. To the extent that we raise additional funds through strategic transactions, including a sale of one of our lines of business, we may not ultimately realize the value of or synergies from such transactions and our long-term prospects could be diminished as a result of the divestiture of these assets. We may also be required to use some or all of these sale proceeds to pay down indebtedness, which would then not serve to increase our working capital.

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. If we engage in strategic transactions with respect to revenue-producing assets or business lines, our revenue may be adversely affected and such transactions could negatively affect the viability of our business. Each of the foregoing may harm our business, operating results, and financial condition, and may impact our ability to continue as a going concern.

**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.

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. For more information on our precision medicine competitors, see Part I, Item 1. “Business-Competition in Precision Medicine” in our Annual Report on Form 10-K for the year ended December 31, 2020, or the Annual Report.

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 products sold by Avero Diagnostics 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 our 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 develop 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 the products offered by Avero Diagnostics, 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 preclinical 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 localization technology enables identification of the location of our ingestible medical devices within the gastrointestinal tract as well as the function of our DDS and RSS devices.

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 product candidates 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 product candidates. 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 the products offered by Avero Diagnostics and our product candidates. Results of earlier studies may not be predictive of future clinical trial results, or the safety or efficacy profile for such products or product candidates.**

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 the tests offered by Avero Diagnostics or our 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. As a result in increased vaccination levels, the demand for such testing has decreased and may continue 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 or what future demand may be for COVID-19 tests. 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 Diagnostics 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. There is no assurance that our COVID-19 diagnostic testing program will continue to be accepted by the market or that, when compared to our COVID-19 tests, other diagnostic tests will not become more accepted, produce quicker results, or be more accurate. Further, the longevity and extent of the COVID-19 pandemic is uncertain. Demand for COVID-19 testing has decreased and future demand for COVID-19 testing is becoming increasing difficult to predict due to various factors including but not limited to the increased availability of vaccinations, the number of individuals who choose to be vaccinated, the effectiveness of the various vaccinations against variants, the rate of new cases, and evolving government directives, laws, regulations and rules related to COVID-19 testing. In the long term, we expect that the COVID-19 pandemic will eventually dissipate and, as a result, the significance of COVID-19 testing to our business and financial results will decrease. 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.

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

As of June 30, 2021, we had approximately $158.8 million of outstanding indebtedness, respectively, composed of the amount due under our convertible notes payable and mortgages payable. Certain of our debt agreements contain various restrictive covenants and our mortgages are secured by real estate assets.

The indenture for our convertible notes does not prohibit us or our subsidiaries from incurring additional indebtedness in the future, with certain exceptions. Under the convertible notes, we will not, and we will not permit any subsidiary of ours to, create, incur, assume or permit to exist any lien on any property or asset now owned or later acquired by us or any subsidiary that secures any indebtedness for borrowed money, other than (i) secured indebtedness for borrowed money in existence on the date of the indenture; (ii) permitted refinancing indebtedness incurred in exchange for, or the net proceeds of which are used to renew, refund, refinance, replace, defease or discharge any secured indebtedness for borrowed money permitted by clause (i) of this sentence; and (iii) additional secured indebtedness for borrowed money that, in an aggregate principal amount (or accredited value, as applicable), does not exceed $15 million at any time outstanding.

Accordingly, we may incur a significant amount of additional indebtedness in the future. Our current indebtedness and the incurrence of additional indebtedness could have significant negative consequences for our stockholders and our business, results of operations and financial condition by, among other things:

- making it more difficult for us to satisfy our obligations under our existing debt instruments;
- increasing our vulnerability to general adverse economic and industry conditions;
- limiting 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;
- requiring 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;
- limiting our flexibility to plan for, or react to, changes in our business and the industries in which we operate;

- further diluting our current stockholders as a result of issuing shares of our common stock upon conversion of our convertible notes; and
- placing us at a competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our ability to make principal and interest payments will depend on our ability to generate cash in the future. Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, and our cash needs may increase 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.

In addition, any future indebtedness that we may incur may contain financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and our other indebtedness becoming immediately payable in full.

**Although we have implemented compliance policies, 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 10 to the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. 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. For additional information regarding claims by and settlement agreements with commercial payors, see Part I, Item 1. “Business—Reimbursement-Payor Dispute” and “—Commercial Third-Party Payors” in the Annual Report. 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 the risk factor titled “Although we have implemented compliance policies and have an internal audit function, 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, consumer protection 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.

In addition, our direct communications with patients may be scrutinized under the laws and regulations governing such communications. The interpretation of many of these statutes, regulations and rulings is evolving in the courts and administrative agencies and an inability to comply may have an adverse impact on our business. For example, the Telephone Consumer Protection Act, or TCPA, imposes significant restrictions on utilizing text messages to mobile telephone numbers as a means of communication, when the prior express consent of the person being contacted has not been obtained or proof of such consent is not properly maintained. Our ability to communicate with patients may be affected by the TCPA, its implementing regulations and litigation pursuant to the TCPA. The determination by a court or regulatory agency that our SMS text messaging violates the TCPA could subject us to civil penalties, could require us to change some portions of our business and could otherwise harm our business.

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, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents.

**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 personnel in our industry 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, including, in the case of our LDTs under development, to conduct additional validation studies within their respective labs, 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. For example, following the discontinuation of genetic laboratory-developed test services in our Ann Arbor laboratory, we are unable to independently commercialize Preecludia™ as an LDT and will be required to partner with a third-party. Prior to marketing Preecludia™ as an LDT, any future development partner would need to validate the test within their own lab, and such third party may not be successful in validating the test in their lab on a timely basis, or at all.

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, including the business of Avero Diagnostics, 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 the products offered by Avero Diagnostics 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.

**The manufacturing of the products offered by Avero Diagnostics and 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. For additional information regarding our third-party suppliers and manufacturers, see Part I, Item 1. "Business—Laboratories-Laboratory Supplies" in the Annual Report.

**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, including the tests offered by Avero Diagnostics and our future 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, including through tests run by Avero Diagnostics. There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue. 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 preclinical 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 product candidates 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.

**The products offered by Avero Diagnostics or our 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 products offered by Avero Diagnostics 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 the products offered by Avero Diagnostics and 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 and genetic 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. For more information regarding our relationship with Avero Diagnostics, see Part I, Item 1. “Business—Government Regulation—Avero Diagnostics Relationship and the Corporate Practice of Medicine” of the Annual Report.

**Defects or failures associated with our products offered by Avero Diagnostics or our product candidates, if approved, 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 offered by Avero Diagnostics or our product candidates 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 or product candidates, if approved, 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 product candidates, 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 offered by Avero Diagnostics and our product candidates, if approved, 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 offered by Avero Diagnostics and our product candidates, if approved, 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, the NIPT test run by Avero Diagnostics 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 test result was a false negative. As another example, the genetic carrier screening test run by Avero Diagnostics 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 test 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 the NIPT and genetic carrier screen tests run by Avero Diagnostics 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, 2020, we had net operating loss, or NOL, carryforwards of approximately $271.1 million for federal income tax purposes, and $200.0 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. We agreed to pay 65% of any tax refund received in excess of $5.0 million in a single year, along with other civil settlements, damages awards, and tax refunds, to accelerate payments to the government in connection with our government settlement. During the year ended December 31, 2020, we received a tax refund of $37.7 million related to the NOL carryback provisions available under the CARES Act. As of December 31, 2020, we had paid a total of $37.0 million to the government in connection with our government settlements. See Part II, Item 1. “Legal Proceedings—Federal Investigations.”

***Reimbursement Risks Related to Our Business***

**If third-party payors do not adequately reimburse for the products offered by Avero Diagnostics or any future products, they might not be purchased or used, which may adversely affect our revenue and profitability.**

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 the products offered by Avero Diagnostics and our 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 or our commercial development partners 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 the products offered by Avero Diagnostics or our future 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 the products offered by Avero Diagnostics or our future 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 the products offered by Avero Diagnostics or our future tests or products.**

Our business depends on our ability to obtain or maintain adequate reimbursement coverage from third-party payors. Third-party reimbursement for our testing, including testing conducted by Avero Diagnostics, historically represented 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. It is to be determined whether and to what extent certain of our 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.

**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.
We have historically submitted for reimbursement using CPT codes based on the guidance of outside coding experts and legal counsel. There is a risk that the codes that we submitted 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 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. For more information on these disputes, see Part I, Item 1. “Business—Reimbursement—Commercial Third-Party Payors” in the Annual Report. 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 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. 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. For example, on November 16, 2020, we received a letter from Anthem informing us that Anthem is seeking recoupment for historical payments made by Anthem in an aggregate amount of approximately $27.4 million. The historical payments for which Anthem is seeking recoupment are claimed to relate primarily to discontinued legacy billing practices for our NIPT and microdeletion tests and secondarily to the implementation of the new CPT code for reimbursement for our Preparent expanded carrier screening tests. We can provide no assurance that we will not receive similar claims for recoupment from other third-party payors in the future. For more information on this claim, see Part I, Item 1. "Business-Reimbursement—Payor Dispute" in the Annual Report. 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. 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. 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. 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.

Where we are considered to be an out-of-network provider, 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.

**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 an example, on July 9, 2021, President Biden signed a sweeping executive order that, among other things, seeks to reduce prices of prescription drugs and device in the United States by encouraging competition from generic and biosimilar drugs and allowing Medicare to negotiate drug costs. 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.

Since its enactment, there have been multiple attempts to repeal ACA or significantly scale back its applicability, On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business. Any such reforms that result in a reduction in reimbursement for our testing or adversely affect our test volumes could adversely affect our business, operating results, and financial condition.

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 have been historically very small and were only 4.2% of our total revenues in 2020, given our historical product mix and the fact that our testing generally is not received by Medicare beneficiaries. However, our other products in development may be used by Medicare beneficiaries in the future. Medicare reimbursement can affect both Medicaid reimbursement 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 our current or 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.

**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 significant mandatory 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 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. 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 June 30, 2021, we have paid approximately $36.9 million towards this amount. We will pay the remaining portion of the settlement over an approximately three-year period, structured as follows: $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."

**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, preclinical, 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 Avero Diagnostics fails to comply with laboratory licensing requirements, it could lose the ability to perform its tests or experience disruptions to its business.**

Avero Diagnostics is required to maintain state licenses to conduct testing in its laboratories. We cannot provide assurance that state authorities will at all times in the future find Avero Diagnostics 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 Avero Diagnostics hold licenses to test samples from patients in those states. Avero Diagnostics has obtained licenses from states where it believes it is required to be licensed. From time to time, Avero Diagnostics 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 Avero Diagnostics identifies any other state with such requirements or if Avero Diagnostics is contacted by any other state advising it of such requirements, we expect it would seek to comply with such requirements. However, there is no assurance that Avero Diagnostics will be able to obtain any such required license for the particular state.

Any sanction imposed under state or foreign laws or regulations governing licensure, or Avero Diagnostics' failure to renew a state license or accreditation, could have a material and adverse effect on our business, operating results and financial condition. CMS also has the authority to impose a wide range of sanctions. If Avero Diagnostics were to lose its required licensure in the State of Texas, it would not be able to operate its clinical laboratory and conduct its 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 offered by Avero Diagnostics and our product candidates, if approved. 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, Avero Diagnostics 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 offered by Avero Diagnostics. 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 products offered by Avero Diagnostics and 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 may 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.**

Avero Diagnostics currently markets its commercial molecular tests as LDTs and we may in the future market other tests as LDTs. Under current federal policy, FDA premarket review of LDTs is not required, but laboratories may voluntarily submit 510(k) or PMA applications, or de novo classification requests, for LDTs to obtain FDA clearance or approval following a demonstration of clinical validity. If there are changes in FDA regulations, particularly under the Biden administration, 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 offered by Avero Diagnostics 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 June 2021, Congress introduced bipartisan legislation in both the House and the Senate that would include significant reforms to the agency's regulation of LDTs that would bring all in vitro clinical tests, or IVCTs, including LDTs, under a unified framework and would dramatically increase FDA oversight of LDTs. Under the bill, the regulatory framework for IVCTs would include a tiered, risk-based system for regulatory review that would require premarket review for certain tests, a "technology certification" program to permit approval or clearance of a group of tests based on the review of a representative test, IVCT-specific quality system requirements, adverse event reporting, and explicit authority for the FDA to require post-market studies.

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, including products offered by Avero Diagnostics and any future 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. Beginning in July 2020, the FDA began conducting only prioritized domestic inspections, where possible to do so safely, and, on a case-by-case basis, “mission-critical” inspections. The FDA also expanded its use of other tools, when possible, to ensure the quality and safety of products being imported into the United States. In May 2021, the FDA announced steps the agency is taking to resume standard operational levels of inspection activities, including how it intends to prioritize domestic and foreign inspections that were not performed during the pandemic. Certain regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic and it is uncertain when those restrictions will be lifted. 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 offered by Avero Diagnostics or our 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 offered by Avero Diagnostics or our product candidates.**

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 —Ravgen Lawsuit” for more information regarding a patent infringement suit filed by Ravgen, Inc.

As we move into new markets and develop enhancements to and new applications for our product candidates, 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 offered by Avero Diagnostics or our product candidates 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. See Part II, Item 1. "Legal Proceedings—Ravgen Lawsuit" for more information regarding a patent infringement suit filed by Ravgen, Inc.

**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 offered by Avero Diagnostics or any future 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—Ravgen Lawsuit" for more information regarding a patent infringement suit filed by Ravgen, Inc.

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 and thereby cause significant market entry delay, defeat our ability to market our products offered by Avero Diagnostics or our product candidates or cause us to abandon development and/or commercialization of a product candidate.

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 or divestitures, 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 offered by Avero Diagnostics or our product candidates;
- developments or disputes concerning our intellectual property or other proprietary rights or alleged infringement of third party's rights by our products offered by Avero Diagnostics or our product candidates;
- 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.

**The issuance of shares of our common stock upon conversion of the convertible notes will dilute the ownership interests of our stockholders and could depress the trading price of our common stock.**

We must settle conversions of our outstanding convertible notes in shares of our common stock, together with cash in lieu of issuing any fractional share. The issuance of shares of our common stock upon conversion of the convertible notes will dilute the ownership interests of our stockholders, which could depress the trading price of our common stock. In addition, the market's expectation that conversions may occur could depress the trading price of our common stock even in the absence of actual conversions. Moreover, the expectation of conversions could encourage the short selling of our common stock, which could place further downward pressure on the trading price of our common stock.

**Hedging activity by investors in the convertible notes could depress the trading price of our common stock.**

We expect that many investors in our outstanding convertible notes will seek to employ a convertible note arbitrage strategy. Under this strategy, investors typically short sell a certain number of shares of our common stock and adjust their short position over time while they continue to hold the convertible notes. Investors may also implement this type of strategy by entering into swaps on our common stock in lieu of, or in addition to, short selling shares of our common stock. This market activity, or the market's perception that it will occur, could depress the trading price of our common stock.

**Provisions in the indenture governing our outstanding convertible notes could delay or prevent an otherwise beneficial takeover of us.**

Certain provisions in our convertible notes and the indenture governing the convertible notes could make a third party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a "fundamental change" (which is defined in the indenture to include certain change-of-control events and the delisting of our common stock), then noteholders will have the right to require us to repurchase their convertible notes for cash. In addition, if a takeover constitutes a "make-whole fundamental change" (which is defined in the indenture to include, among other events, fundamental changes and certain additional business combination transactions), then we may be required to temporarily increase the conversion rate for the convertible notes. In either case, and in other cases, our obligations under the convertible notes and the indenture could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that holders of our common stock may view as favorable.

**We may be unable to raise the funds necessary to repurchase the convertible notes for cash following a fundamental change or to pay any cash amounts due upon conversion, and our other indebtedness may limit our ability to repurchase our outstanding convertible notes.**

Noteholders may require us to repurchase their convertible notes following a "fundamental change" (which is defined in the indenture governing the convertible notes to include certain change-of-control events and the delisting of our common stock) at a cash repurchase price generally equal to the principal amount of the convertible notes to be repurchased, plus accrued and unpaid interest, if any. In addition, noteholders that convert their convertible notes before December 1, 2022 will, in certain circumstances, be entitled to an additional cash payment representing the present value of any remaining interest payments on the convertible notes through December 1, 2022. Furthermore, additional cash amounts may be due upon conversion in certain circumstances if the number of shares that we deliver upon conversion of the convertible notes is limited by the listing standards of The Nasdaq Global Market, or Nasdaq. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the convertible notes or pay these cash amounts upon their conversion. In addition, applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to repurchase the convertible notes or pay these cash amounts upon their conversion. Our failure to repurchase convertible notes when required or pay these cash amounts upon their conversion will constitute a default under the indenture governing the convertible notes. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our other indebtedness, which may result in that other indebtedness becoming immediately payable in full. We may not have sufficient funds to satisfy all amounts due under the other indebtedness and the convertible notes.

**The accounting method for the convertible notes could adversely affect our reported financial results.**

The accounting method for reflecting the underlying shares of our common stock in our reported diluted earnings per share may adversely affect our reported earnings and financial condition. We expect that, under applicable accounting principles, the shares underlying our convertible notes will be reflected in our diluted earnings per share using the "if-converted" method. Under that method, diluted earnings per share would generally be calculated assuming that all the convertible notes were converted into shares of common stock at the beginning of the reporting period, unless the result would be anti-dilutive. The application of the if-converted method may reduce our reported diluted earnings per share.
Furthermore, the conversion features in our convertible notes are accounted for as a free-standing embedded derivative bifurcated from the principal balance of the convertible notes. The embedded derivative liability is remeasured at fair value each reporting period with positive or negative changes in fair value recorded in our consolidated statement of operations, which may adversely affect our reported earnings and financial condition and result in significant fluctuations in our future financial performance.

***General Risk Factors***

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

As of June 30, 2021, 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.

**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 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 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 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 6. Exhibits.**

| EXHIBIT NO. | DESCRIPTION |
|---|---|
| 4.1 | Form of Warrant (filed with the SEC as Exhibit 4.1 to registrant's Form 8-K filed on June 14, 2021). |
| 4.2 | Form of Pre-Funded Warrant (filed with the SEC as Exhibit 4.2 to registrant's Form 8-K filed on June 14, 2021). |
| 4.3* | Amendment No. 3 to Fourth Amended and Restated Investors' Rights Agreement, dated as of May 31, 2021, by and among Progenity, Inc., and certain of its stockholders. |
| 4.4 | Form of Warrant (filed with the SEC as Exhibit 4.1 to registrant's Form 8-K filed on February 25, 2021). |
| 10.1 | Securities Purchase Agreement, dated June 9, 2021, by and between the Company and the Purchasers signatory therein (filed with the SEC as Exhibit 10.1 to the registrant's Form 8-K filed on June 14, 2021). |
| 10.2* | Fourth Amended and Restated Progenity, Inc. 2018 Equity Incentive Plan dated May 5, 2021. |
| 10.3 | Securities Purchase Agreement, dated February 22, 2021, by and between the Company and the Purchasers signatory therein (filed with the SEC as Exhibit 10.1 to the registrant's Form 8-K filed on February 25, 2021). |
| 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 | Inline XBRL Instance Document |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

* Filed herewith.

**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: August 12, 2021 | PROGENITY, INC. |
| | By: /s/ Harry Stylli, Ph.D.<br>Harry Stylli, Ph.D.<br>Chairman and Chief Executive Officer<br>(principal executive officer) |
| | By: /s/ Eric d'Esparbes<br>Eric d’Esparbes<br>Executive Vice President and Chief Financial Officer<br>(principal financial and accounting officer) |

**Exhibit 4.3**

**PROGENITY, INC.**

**AMENDMENT NO. 3 TO**
**FOURTH AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT**

**May 31, 2021**

This Amendment No. 3 (this "**Amendment**") to that certain Fourth Amended and Restated Investors' Rights Agreement, dated as of August 27, 2019 (the "**Agreement**"), by and among Progenity, Inc., a Delaware corporation (the "**Company**"), the investors listed on Exhibit A thereto (each, an "**Investor**" and collectively, the "**Investors**"), and the holders of Common Stock listed on Exhibit B thereto, as previously amended by Amendment No. 1 to the Agreement, dated November 10, 2020 and Amendment No. 2 to the Agreement, dated December 7, 2021. Capitalized terms used in this Amendment that are not otherwise defined herein shall have the respective meanings assigned to them in the Agreement.

**RECITALS**

**WHEREAS**, the Company and the Investors desire to amend the Agreement as set forth below;

**WHEREAS**, the undersigned Investors represent the holders of a majority of the Registrable Securities outstanding on the date of this Amendment and, as such, together with the Company, have the right, power and authority pursuant to Section 4.4 of the Agreement to execute and deliver this Amendment and amend the Agreement in the manner provided herein.

**NOW, THEREFORE**, in consideration of the mutual promises and covenants contained in this Amendment and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the parties hereto agree as follows:

**AGREEMENT**

1. The following defined term on Section 1(a)(xv) of the Agreement is hereby deleted in its entirety and replaced with the following:

> "**Registrable Securities**" means (i) the shares of Common Stock issuable or issued upon conversion of the Preferred Stock, including any shares of Common Stock issued on or before the date hereof, upon conversion of preferred stock of the Company outstanding at any time, other than shares for which registration rights have terminated pursuant to Section 2.15 hereof, (ii) the shares of Common Stock issued pursuant to the Common Stock Purchase Agreement, dated as of August 8, 2016, by and between the Company and BCI, other than shares for which registration rights have terminated pursuant to Section 2.15 hereof, (iii) the shares of Common Stock issuable or issued upon conversion of the Warrant Shares (or, following a Qualified IPO, issuable upon exercise of the Warrant), other than shares for which registration rights have terminated pursuant to Section 2.15 hereof; (iv) shares of Common Stock issuable or issued upon the conversion of the Unsecured Convertible Promissory Note dated May 8, 2020, issued to Athyrium Opportunities 2020 LP; (v) the shares of Common Stock issuable or issued upon exercise of the Convertible Notes, other than shares for which registration rights have terminated pursuant to Section 2.15 hereof; (vi) the shares of Common Stock issued pursuant to the Stock Purchase Agreement, dated as of May 31, 2021, by and between the Company, Athyrium Opportunities III Acquisition LP, and Athyrium Opportunities III Co-Invest 1 LP, other than shares for which registration rights have terminated pursuant to Section 2.15 hereof; and (vii) any other shares of Common Stock issued as (or issuable upon the conversion or exercise of any warrant, right or other security which is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the shares listed in clauses (i) through (vi); provided, however, that the foregoing definition shall exclude in all cases any Registrable Securities sold by a Person in a transaction in which such Person's rights under this

Agreement are not assigned. Notwithstanding the foregoing, such shares of Common Stock shall only be treated as Registrable Securities if and so long as (A) they have not been sold to or through a broker or dealer or underwriter in a public distribution or a public securities transaction, (B) they have not been sold in a transaction exempt from the registration and prospectus delivery requirements of the Securities Act under Section 4(a)(1) or Rule 144 thereof so that all transfer restrictions, and restrictive legends with respect thereto, if any, are removed upon the consummation of such sale, and (C) the Holder thereof is entitled to exercise any right provided in Section 2 in accordance with Section 2.15 below.

2. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

3. This Amendment and the rights and obligations of the parties hereunder shall be governed, construed and interpreted in accordance with the laws of the State of Delaware, without giving effect to principles of conflicts of law.

4. Except as expressly provided in this Amendment, all terms and provisions of the Agreement shall remain unmodified and in full force and effect.

(*Signature Page Follows*)

IN WITNESS WHEREOF, the parties have executed this Amendment to the Agreement as of the date first written above.

**COMPANY:**

**PROGENITY, INC.**

By: /s/ Harry Stylli
Name: Harry Stylli
Title: Chief Executive Officer

IN WITNESS WHEREOF, the parties have executed this Amendment to the Agreement as of the date first written above.

**INVESTORS:**

/s/ Harry Stylli

Name: Harry Stylli

IN WITNESS WHEREOF, the parties have executed this Amendment to the Agreement as of the date first written above.

**INVESTORS:**

**ATHYRIUM OPPORTUNITIES FUND (A) LP**

By: Athyrium Opportunities Associates LP,
its General Partner

By: Athyrium Opportunities Associates GP LLC,
the General Partner of Athyrium Opportunities Associates LP

By /s/ Andrew C. Hyman

Name: Andrew C. Hyman

Title: Authorized Signatory

**ATHYRIUM OPPORTUNITIES FUND (B) LP**

By: Athyrium Opportunities Associates LP,
its General Partner

By: Athyrium Opportunities Associates GP LLC,
the General Partner of Athyrium Opportunities Associates LP

By /s/ Andrew C. Hyman

Name: Andrew C. Hyman

Title: Authorized Signatory

**ATHYRIUM OPPORTUNITIES III ACQUISITION 2 LP**

By: Athyrium Opportunities Associates III LP,
its General Partner

By: Athyrium Opportunities Associates III GP LLC,
the General Partner of Athyrium Opportunities Associates III LP

By /s/ Rashida Adams

Name: Rashida Adams

Title: Authorized Signatory

**ATHYRIUM OPPORTUNITIES III CO-INVEST 1 LP**

By: Athyrium Opportunities Associates Co-Invest LLC,
its General Partner

By /s/ Rashida Adams

Name: Rashida Adams

Title: Authorized Signatory

**ATHYRIUM OPPORTUNITIES 2020 LP**

By: Athyrium Opportunities Associates III LP,
its General Partner

By: Athyrium Opportunities Associates III GP LLC,
the General Partner of Athyrium Opportunities Associates III LP

By /s/ Rashida Adams

Name: Rashida Adams

Title: Authorized Signatory

**Exhibit 10.2**

**PROGENITY, INC.**

**2018 EQUITY INCENTIVE PLAN (FOURTH AMENDED & RESTATED)**

**ADOPTED BY THE BOARD: FEBRUARY 22, 2018 (FIRST AMENDMENT MARCH 6, 2019, SECOND AMENDMENT DECEMBER 5, 2019, THIRD AMENDMENT MARCH 4, 2020, FOURTH AMENDMENT MAY 5, 2021)**

**APPROVED BY THE STOCKHOLDERS: FEBRUARY 22, 2018 (FIRST AMENDMENT MARCH 6, 2019, SECOND AMENDMENT DECEMBER 5, 2019, THIRD AMENDMENT MARCH 4, 2020, FOURTH AMENDMENT MAY 5, 2021)**

**1. GENERAL.**

(a) **Successor to and Continuation of Prior Plans**. The Plan is the successor to and continuation of the Company's Amended and Restated 2012 Stock Plan, as amended, and the Company's 2015 Consultant Stock Plan (each a "**Prior Plan**"). From and after 11:59 p.m. Pacific time on February 22, 2018 (the "**Effective Date**"), no additional stock awards will be granted under a Prior Plan. All stock awards granted under a Prior Plan remain subject to the terms of that Prior Plan. All Awards granted on or after 11:59 p.m. Pacific Time on the Effective Date shall be subject to the terms of the Plan.

(b) **Eligible Award Recipients**. Employees, Directors and Consultants are eligible to receive Awards.

(c) **Available Awards**. The Plan provides for the grant of the following Awards: (i) Incentive Stock Options; (ii) Nonstatutory Stock Options; (iii) Stock Appreciation Rights; (iv) Restricted Stock Awards; (v) Restricted Stock Unit Awards; (vi) Performance Stock Awards; (vii) Performance Cash Awards; and (viii) Other Stock Awards.

(d) **Purpose**. The Plan, through the granting of Awards, is intended to help the Company secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate and provide a means by which the eligible recipients may benefit from increases in the value of the Common Stock.

**2. ADMINISTRATION.**

(a) **Administration by Board**. The Board will administer the Plan. The Board may delegate administration of the Plan to a Committee or Committees, as provided in Section 2(c).

(b) **Powers of Board**. The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine: (A) who will be granted Awards; (B) when and how each Award will be granted; (C) what type of Award will be granted; (D) the provisions of each Award (which need not be identical), including when a person will be permitted to exercise or otherwise receive cash or Common Stock under the Award; (E) the number of shares of Common Stock subject to, or the cash value of, an Award; and (F) the Fair Market Value applicable to a Stock Award.

(ii) To construe and interpret the Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for administration of the Plan and Awards. The Board, in the exercise of these powers, may correct any defect, omission or inconsistency in the Plan or in any Award Document or in the written terms of a

Performance Cash Award, in a manner and to the extent it will deem necessary or expedient to make the Plan or Award fully effective.

(iii) To settle all controversies regarding the Plan and Awards granted under it.

(iv) To accelerate, in whole or in part, or to extend, in whole or in part, the time during which an Award may be exercised or vest, or at which cash or shares of Common Stock may be issued.

(v) To suspend or terminate the Plan at any time. Except as otherwise provided in the Plan or an Award Document, suspension or termination of the Plan will not materially impair a Participant's rights under his or her then-outstanding Award without his or her written consent, except as provided in subsection (viii) below.

(vi) To amend the Plan in any respect the Board deems necessary or advisable, including, without limitation, adopting amendments relating to Incentive Stock Options and nonqualified deferred compensation under Section 409A of the Code and/or making the Plan or Awards granted under the Plan exempt from or compliant with the requirements for Incentive Stock Options or exempt from or compliant with the requirements for nonqualified deferred compensation under Section 409A of the Code, subject to the limitations, if any, of applicable law. If required by applicable law or listing requirements, and except as provided in Section 9(a) relating to Capitalization Adjustments, the Company will seek stockholder approval of any amendment of the Plan that (A) increases the number of shares of Common Stock available for issuance under the Plan, (B) materially expands the class of individuals eligible to receive Awards under the Plan, (C) materially increases the benefits accruing to Participants under the Plan, (D) materially reduces the price at which shares of Common Stock may be issued or purchased under the Plan, (E) materially extends the term of the Plan, or (F) materially expands the types of Awards available for issuance under the Plan. Except as otherwise provided in the Plan (including subsection (viii) below) or an Award Document, no amendment of the Plan will materially impair a Participant's rights under a then-outstanding Award without the Participant's written consent.

(vii) To submit any amendment to the Plan for stockholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of (A) Section 422 of the Code regarding "incentive stock options" or (B) Rule 16b-3 of Exchange Act or any successor rule, if applicable.

(viii) To approve forms of Award Documents for use under the Plan and to amend the terms of any one or more outstanding Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Award Documents for such Awards, subject to any specified limits in the Plan that are not subject to Board discretion. A Participant's rights under any Award will not be impaired by any such amendment unless the Company requests the consent of the affected Participant, and the Participant consents in writing. However, a Participant's rights will not be deemed to have been impaired by any such amendment if the Board, in its sole discretion, determines that the amendment, taken as a whole, does not materially impair the Participant's rights. In addition, subject to the limitations of applicable law, if any, the Board may amend the terms of any one or more Awards without the affected Participant's consent (A) to maintain the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code, (B) to change the terms of an Incentive Stock Option, if such change results in impairment of the Award solely because it impairs the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code, (C) to clarify the manner of exemption from, or to bring the Award into compliance with, Section 409A of the Code, or (D) to comply with other applicable laws or listing requirements.

(ix) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan and/or Award Documents.

(x) To adopt such procedures and sub-plans as are necessary or appropriate (A) to permit or facilitate participation in the Plan by persons eligible to receive Awards under the Plan who are foreign nationals or employed outside the United States or (B) allow Awards to qualify for special tax treatment in a foreign jurisdiction; provided that Board approval will not be necessary for immaterial modifications to the Plan or any Award Document that are required for compliance with the laws of a foreign jurisdiction.

(c) **Delegation to Committee**. The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in the Plan to the Board will thereafter be to the Committee or subcommittee). Any delegation of administrative powers will be reflected in the charter of the Committee to which the delegation is made, or resolutions, not inconsistent with the provisions of the Plan, adopted from time to time by the Board or Committee (as applicable). The Committee may, at any time, abolish the subcommittee and/or revest in the Committee any powers delegated to any subcommittee. Unless otherwise provided by the Board, delegation of authority by the Board to a Committee, or to an Officer pursuant to Section 2(d), does not limit the authority of the Board, which may continue to exercise any authority so delegated and may concurrently administer the Plan with the Committee and may, at any time, revest in the Board some or all of the powers previously delegated.

(d) **Delegation to an Officer**. The Board may delegate to one (1) or more Officers the authority to do one or both of the following: (i) designate Employees who are not Officers to be recipients of Options and SARs (and, to the extent permitted by applicable law, other Stock Awards) and, to the extent permitted by applicable law, the terms of such Awards; and (ii) determine the number of shares of Common Stock to be subject to such Stock Awards granted to such Employees; provided, however, that the Board resolutions regarding such delegation will specify the total number of shares of Common Stock that may be subject to the Stock Awards granted by such Officer and that such Officer may not grant a Stock Award to himself or herself. Any such Stock Awards will be granted on the form of Stock Award Document approved by the Committee or the Board for use in connection with such Stock Awards, unless otherwise provided for in the resolutions approving the delegation authority.

(e) **Effect of Board's Decision**. All determinations, interpretations and constructions made by the Board (or a duly authorized Committee, subcommittee or Officer exercising powers delegated by the Board under this Section 2) in good faith will not be subject to review by any Person and will be final, binding and conclusive on all Persons, unless found by a court of competent jurisdiction to have been either (i) arbitrary and capricious or (ii) made in bad faith.

**3. SHARES SUBJECT TO THE PLAN.**

(a) **Share Reserve**.

(i) Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate maximum number of shares of Common Stock that may be issued pursuant to Stock Awards from and after the date of adoption of the Plan by the Board, as aggregated from time to time, will be Nineteen Million Eight Hundred Fifty-Three Thousand Four Hundred Nine (19,853,409) shares of Common Stock (the "**Share Reserve**").

(ii) The Share Reserve will automatically increase on January 1st of each year, during the term of the Plan, commencing on January 1, 2022 and ending with a final increase on January 1, 2030, in an amount equal to four percent (4%) of the total number of shares of Capital Stock outstanding on December 31st of the preceding calendar year, calculated on a fully diluted, fully converted basis. The Board may provide that there will be no January 1st increase in the Share Reserve for such year or that the increase in the Share Reserve for such year will be a smaller number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence.

(iii) For clarity, the Share Reserve is a limitation on the number of shares of Common Stock that may be issued under to the Plan. As a single share may be subject to grant more than once (e.g., if a share subject to a Stock Award is forfeited, it may be made subject to grant again as provided in Section 3(b) below), the Share Reserve is not a limit on the number of Stock Awards that can be granted.

(iv) Shares may be issued under the terms of the Plan in connection with a merger or acquisition as permitted by NASDAQ Listing Rule 5635(c), NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

(b) **Reversion of Shares to the Share Reserve**. If a Stock Award or any portion of a Stock Award (i) expires, is canceled, forfeited or otherwise terminates without all of the shares covered by the Stock Award having been issued or (ii) is settled in cash (i.e., the Participant receives cash rather than stock), such expiration, cancelation, forfeiture, termination or settlement will not reduce (or otherwise offset) the number of shares of Common Stock that are available for issuance under the Plan. If any shares of Common Stock issued under a Stock Award are forfeited back to or repurchased or otherwise reacquired by the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares that are forfeited, repurchased or reacquired will revert to and again become available for issuance under the Plan. Any shares retained or reacquired by the Company in satisfaction of tax withholding obligations on a Stock Award, as consideration for the exercise or purchase price of a Stock Award, or with the proceeds paid by the Participant under the terms of a Stock Award, will again become available for issuance under the Plan. If the Company repurchases shares of Common Stock with stock option exercise or stock purchase proceeds, such shares shall be added to the Share Reserve. For any Stock Award with respect to which a net number of shares of Common Stock are issued, whether in satisfaction of tax withholding obligations, exercise or purchase prices or otherwise, only the net number of shares shall reduce the Share Reserve.

(c) **Incentive Stock Option Limit**. Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate maximum number of shares of Common Stock that may be issued on the exercise of Incentive Stock Options will be Nineteen Million Eight Hundred Fifty-Three Thousand Four Hundred Nine (19,853,409) shares of Common Stock.

(d) **Non-Employee Director Limit**. The aggregate dollar value of Stock Awards (based on the grant date fair value of the Stock Awards) granted under this Plan during any calendar year to any one non-employee Director shall not exceed $750,000.

(e) **Source of Shares**. The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock and may include shares repurchased by the Company on the open market or otherwise or shares classified as treasury shares.

**4. ELIGIBILITY.**

(a) **Eligibility for Specific Stock Awards**. Incentive Stock Options may be granted only to employees of the Company or a “parent corporation” or “subsidiary corporation” thereof (as such terms are defined in Sections 424(e) and 424(f) of the Code). Stock Awards other than Incentive Stock Options may be granted to Employees, Directors and Consultants; provided, however, that Stock Awards may not be granted to Employees, Directors and Consultants who are providing Continuous Service only to any “parent” of the Company, as such term is defined in Rule 405 of the Securities Act, unless (i) the stock underlying such Stock Awards is treated as “service recipient stock” under Section 409A of the Code (for example, because the Stock Awards are granted pursuant to a corporate transaction such as a spin off transaction), or (ii) the Company, in consultation with its legal counsel, has determined that such Stock Awards are otherwise exempt from or comply with the requirements of Section 409A of the Code.

(b) **Ten Percent Stockholders**. A Ten Percent Stockholder will not be granted an Incentive Stock Option unless the exercise price of such Option is at least 110% of the Fair Market Value on the date of grant and the Option is not exercisable after the expiration of five (5) years from the date of grant.

**5. PROVISIONS RELATING TO OPTIONS AND STOCK APPRECIATION RIGHTS.**

Each Option or SAR will be in such form and will contain such terms and conditions as the Board deems appropriate. All Options will be separately designated Incentive Stock Options or Nonstatutory Stock Options at the time of grant, and, if certificates are issued, a separate certificate or certificates will be issued for shares of Common Stock purchased on exercise of each type of Option. If an Option is not specifically designated as an Incentive Stock Option, or if an Option is designated as an Incentive Stock Option but some portion or all of the Option fails to qualify as an Incentive Stock Option under the applicable rules, then the Option (or portion thereof) will be a Nonstatutory Stock Option. The provisions of separate Options or SARs need not be identical; provided, however, that each Award Document will conform to (through incorporation of provisions hereof by reference in the applicable Award Document or otherwise) the substance of each of the following provisions:

(a) **Term**. Subject to Section 4(b) regarding Ten Percent Stockholders, no Option or SAR will be exercisable after the expiration of 10 years from the date of its grant or such shorter period specified in the Award Document.

(b) **Exercise Price**. Subject to Section 4(b) regarding Ten Percent Stockholders, the exercise price of each Option or SAR will be not less than 100% of the Fair Market Value of the Common Stock subject to the Option or SAR on the date the Award is granted. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise price lower than 100% of the Fair Market Value of the Common Stock subject to the Award if such Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a corporate transaction and in a manner consistent with the provisions of Section 409A of the Code and, if applicable, Section 424(a) of the Code. Each SAR will be denominated in shares of Common Stock equivalents.

(c) **Purchase Price for Options**. The purchase price of shares of Common Stock acquired pursuant to the exercise of an Option may be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any combination of the methods of payment set forth below. The Board will have the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to use a particular method of payment. The permitted methods of payment are as follows:

(i) by cash, check, bank draft or money order payable to the Company;

(ii) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board or a successor regulation, or a similar rule in a foreign jurisdiction of domicile of a Participant, that, prior to or contemporaneously with the issuance of shares of Common Stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the proceeds of sale of such stock;

(iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock;

(iv) if an Option is a Nonstatutory Stock Option, by a “net exercise” arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; provided, however, that the Company will accept cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued. Shares of Common Stock will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are used to pay the exercise price pursuant to the “net exercise,” (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations; or

(v) in any other form of legal consideration that the Board determines is a benefit to the Company and specified in the applicable Award Document.

(d) **Exercise and Payment of a SAR**. To exercise any outstanding SAR, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Appreciation Right Award Document evidencing such SAR. The appreciation distribution payable on the exercise of a SAR will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the SAR) of a number of shares of Common Stock equal to the number of Common Stock equivalents in which the Participant is vested under such SAR (with respect to which the Participant is exercising the SAR on such date), over (B) the aggregate exercise price of the number of Common Stock equivalents with respect to which the Participant is exercising the SAR on such date. The appreciation distribution may be paid in Common Stock, in cash, in any combination of the two or in any other form of consideration, as determined by the Board and contained in the Award Document evidencing such SAR.

(e) **Transferability of Options and SARs**. The Board may, in its sole discretion, impose such limitations on the transferability of Options and SARs as the Board determines. In the absence of such a determination by the Board to the contrary, the following restrictions on the transferability of Options and SARs will apply:

(i) Restrictions on Transfer. An Option or SAR will not be transferable except by will or by the laws of descent and distribution (or pursuant to subsections (ii) and (iii) below), and will be exercisable during the lifetime of the Participant only by the Participant. The Board may permit transfer of the Option or SAR in a manner that is not prohibited by applicable tax and securities laws. Except as explicitly provided herein, neither an Option nor a SAR may be transferred for consideration.

(ii) Domestic Relations Orders. Subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument as permitted by U.S. Treasury Regulation 1.421-1(b)(2). If an Option is an Incentive Stock Option, such Option may be deemed to be a Nonstatutory Stock Option as a result of such transfer.

(iii) Beneficiary Designation. Subject to the approval of the Board or a duly authorized Officer, a Participant may, by delivering written notice to the Company, in a form approved by the Company (or the designated broker), designate a third party who, on the death of the Participant, will thereafter be entitled to exercise the Option or SAR and receive shares of Common Stock or other consideration resulting from such exercise. In the absence of such a designation, the executor or administrator of the Participant's estate will be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. However, the Company may prohibit designation of a beneficiary at any time, including due to any conclusion by the Company that such designation would be inconsistent with the provisions of applicable laws.

(f) **Vesting Generally**. The total number of shares of Common Stock subject to an Option or SAR may vest and therefore become exercisable in periodic installments based on completion of specified periods of Continuous Service that may or may not be equal. The Option or SAR may be subject to such other terms and conditions with respect to the time or times when it may or may not be exercised (which may be based on the satisfaction of performance goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options or SARs may vary. The provisions of this Section 5(f) are subject to any Option or SAR provisions governing the minimum number of shares of Common Stock as to which an Option or SAR may be exercised.

(g) **Termination of Continuous Service**. Except as otherwise provided in the applicable Award Document, or other agreement between the Participant and the Company or any Affiliate, if a Participant's Continuous Service terminates (other than for Cause and other than upon the Participant's death or Disability), the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Award as of the date of termination of Continuous Service) within the period of time ending on the earlier of (i) the date three (3) months following the termination of the Participant's Continuous Service and (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Document. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR will terminate.

(h) **Extension of Termination Date**. Except as otherwise provided in the applicable Award Document, or other agreement between the Participant and the Company or any Affiliate, if the exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause and other than upon the Participant's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate any provisions of the Securities Act, then the Option or SAR will terminate on the earlier of (i) the expiration of a total period of three (3) months (that need not be consecutive) after the termination of the Participant's Continuous Service during which the exercise of the Option or SAR would not be in violation of such provisions, and (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Document. In addition, unless otherwise provided in a Participant's applicable Award Document, or other agreement between the Participant and the Company or any Affiliate, if the sale of any Common Stock received upon exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause) would violate the Company's Insider Trading Policy (the "**Insider Trading Policy**"), and the Company does not waive the potential violation of the policy or otherwise permit the sale, or allow the Participant to surrender shares of Common Stock to the Company in satisfaction of any exercise price and/or any withholding obligations under Section 8(h), then the Option or SAR will terminate on the earlier of (i) the expiration of a period of months (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the sale of the Common Stock received upon exercise of the Option or SAR would not be in violation of the Insider Trading Policy, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Document.

(i) **Disability of Participant**. Except as otherwise provided in the applicable Award Document, or other agreement between the Participant and the Company or any Affiliate, if a Participant's Continuous Service terminates as a result of the Participant's Disability, the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date 12 months following such termination of Continuous Service, and (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Document. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR (as applicable) will terminate.

(j) **Death of Participant**. Except as otherwise provided in the applicable Award Document, or other agreement between the Participant and the Company or any Affiliate, if (i) a Participant's Continuous Service terminates as a result of the Participant's death, or (ii) the Participant dies within the period (if any) specified in the Plan or the applicable Award Document, or other agreement between the Participant and the Company or any Affiliate, for exercisability after the termination of the Participant's Continuous Service (for a reason other than death), then the Option or SAR may be exercised (to the extent the Participant was entitled to exercise such Option or SAR as of the date of death) by the Participant's estate, by a person who acquired the right to exercise the Option or SAR by bequest or inheritance or by a person designated to exercise the Option or SAR upon the Participant's death, but only within the period ending on the earlier of (i) the date 18 months following the date of death, and (ii) the expiration of the term of such Option or SAR as set forth in the applicable Award Document. If, after the Participant's death, the Option or SAR is not exercised within the applicable time frame, the Option or SAR will terminate.

(k) **Termination for Cause**. Except as explicitly provided otherwise in a Participant's Award Document or other individual written agreement between the Company or any Affiliate and the Participant, if a Participant's Continuous Service is terminated for Cause, the Option or SAR will terminate upon the date on which the event giving rise to the termination for Cause first occurred, and the Participant will be prohibited from exercising his or her Option or SAR from and after the date on which the event giving rise to the termination for Cause first occurred (or, if required by law, the date of termination of Continuous Service). If a Participant's Continuous Service is suspended pending an investigation of the existence of Cause, all of the Participant's rights under the Option or SAR will also be suspended during the investigation period.

(l) **Non-Exempt Employees**. If an Option or SAR is granted to an Employee who is a non-exempt employee for purposes of the U.S. Fair Labor Standards Act of 1938, as amended, the Option or SAR will not be first exercisable for any shares of Common Stock until at least 6 months following the date of grant of the Option or SAR (although the Award may vest prior to such date). Consistent with the provisions of the U.S. Worker Economic Opportunity Act, (i) if such non-exempt Employee dies or suffers a Disability, (ii) upon a Corporate Transaction in which such Option or SAR is not assumed, continued, or substituted, (iii) upon a Change in Control, or (iv) upon the non-exempt Employee's retirement (as such term may be defined in the non-exempt Employee's applicable Award Document, in another agreement between the non-exempt Employee and the Company or any Affiliate, or, if no such definition, in accordance with the Company's then current employment policies and guidelines), the vested portion of any Options and SARs may be exercised earlier than 6 months following the date of grant. The foregoing provision is intended to operate so that any income derived by a non-exempt Employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay. To the extent permitted and/or required for compliance with the U.S. Worker Economic Opportunity Act to ensure that any income derived by a non-exempt Employee in connection with the exercise, vesting or issuance of any shares of Common Stock under any other Stock Award will be exempt from such employee's regular rate of pay, the provisions of this paragraph will apply to all Stock Awards and are hereby incorporated by reference into such Stock Award Documents.

**6. PROVISIONS OF STOCK AWARDS OTHER THAN OPTIONS AND SARS.**

(a) **Restricted Stock Awards**. Each Restricted Stock Award Document will be in such form and will contain such terms and conditions as the Board deems appropriate. To the extent consistent with the Company's bylaws, at the Board's election, shares of Common Stock may be (x) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse, or (y) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Board. The terms and conditions of Restricted Stock Award Documents may change from time to time, and the terms and conditions of separate Restricted Stock Award Documents need not be identical. Each Restricted Stock Award Document will conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of legal consideration (including future services) that the Board determines is a benefit to the Company, in its sole discretion, and permissible under applicable law.

(ii) Vesting. Shares of Common Stock awarded under the Restricted Stock Award Document may be subject to forfeiture to the Company in accordance with a vesting schedule and subject to such conditions as may be determined by the Board.

(iii) Termination of Participant's Continuous Service. If a Participant's Continuous Service terminates, the Company may receive through a forfeiture condition or a repurchase right, any or all of the shares of Common Stock held by the Participant that have not vested as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Document.

(iv) Transferability. Shares of Common Stock issued pursuant to an Award, and rights to acquire shares of Common Stock under the Restricted Stock Award Document, will be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Document, as the Board determines in its sole discretion, so long as such shares of Common Stock remains subject to the terms of the Restricted Stock Award Document.

(v) Dividends. A Restricted Stock Award Document may provide that any dividends paid on Restricted Stock will be subject to the same vesting and forfeiture restrictions as apply to the shares of Common Stock subject to the Restricted Stock Award to which they relate.

(b) **Restricted Stock Unit Awards**. Each Restricted Stock Unit Award Document will be in such form and will contain such terms and conditions as the Board deems appropriate. The terms and conditions of Restricted Stock Unit Award Documents may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Documents need not be identical. Each Restricted Stock Unit Award Document will conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that the Board determines is a benefit to the Company, in its sole discretion, and permissible under applicable law.

(ii) Vesting. At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(iii) Payment. A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Document.

(iv) Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(v) Dividend Equivalents. Dividend equivalents may be credited in respect of shares of Common Stock covered by a Restricted Stock Unit Award, as determined by the Board and contained in the Restricted Stock Unit Award Document. At the sole discretion of the Board, such dividend equivalents may be converted into additional shares of Common Stock covered by the Restricted Stock Unit Award in such manner as determined by the Board. The Restricted Stock Unit Award Document may provide that any additional shares of Common Stock covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will be subject to all of the same terms and conditions of the underlying Restricted Stock Unit Award Document to which they relate.

(vi) Termination of Participant's Continuous Service. Except as otherwise provided in the applicable Restricted Stock Unit Award Document, or other agreement between the Participant and the Company or any Affiliate, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

(c) **Performance Awards.**

(i) Performance Stock Awards. A Performance Stock Award is a Stock Award that is payable (including that may be granted, vest or exercised) contingent upon the attainment during a Performance Period of the achievement of certain performance goals. A Performance Stock Award may, but need not, require the completion of a specified period of Continuous Service. The length of any Performance Period, the performance goals to be achieved during the Performance Period, and the measure of whether and to what degree such performance goals have been attained will be conclusively determined by the Committee or the Board, in its sole discretion. In addition, to the extent permitted by applicable law and the applicable Award Document, the Board may determine that a Performance Stock Award may be payable in cash.

(ii) Performance Cash Awards. A Performance Cash Award is a cash award that is granted and/or becomes payable contingent upon the attainment during a Performance Period of the achievement of certain performance goals. A Performance Cash Award may also require the completion of a specified period of Continuous Service. At the time of grant of a Performance Cash Award, the length of any Performance Period, the performance goals to be achieved during the Performance Period, and the measure of whether and to what degree such performance goals have been attained will be conclusively determined by the Committee or the Board, in its sole discretion. The Board may specify the form of payment of Performance Cash Awards, which may be cash or other property, or may provide for a Participant to have the option for his or her Performance Cash Award, or such portion thereof as the Board may specify, to be paid in whole or in part in cash or other property.

(iii) Board Discretion. The Committee or the Board, retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of performance goals and to define the manner of calculating the performance criteria it selects to use for a Performance Period.

(d) **Other Stock Awards**. Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, shares of Common Stock, including the appreciation in value thereof (e.g., options or stock rights with an exercise price or purchase price less than 100% of the Fair Market Value of shares of Common Stock at the time of grant) may be granted either alone or in addition to Stock Awards provided for under Section 5 and the preceding provisions of this Section 6. Subject to the provisions of the Plan, the Board will have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards.

**7. COVENANTS OF THE COMPANY.**

(a) **Availability of Shares**. The Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy then-outstanding Stock Awards.

(b) **Securities Law Compliance**. No Award may be exercised or shares of Common Stock issued pursuant to an Award unless (a) a registration statement under the Securities Act shall at the time of such exercise or issuance be in effect with respect to the shares issuable pursuant to the Award or (b) in the opinion of legal counsel to the Company , the shares of Common Stock issuable pursuant to the Award may be issued in accordance with the terms of an applicable exemption from the registration requirements of the Securities Act. The Company will seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; provided, however, that this undertaking will not require the Company to register under the Securities Act the Plan, any Stock Award or any shares of Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of shares of Common Stock under the Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained. A Participant will not be eligible for the grant of an Award or the subsequent issuance of cash or shares of Common Stock pursuant to the Award if such grant or issuance would be in violation of any applicable securities law.

(c) **No Obligation to Notify or Minimize Taxes**. The Company will have no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company will have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of an Award or a possible period in which the Award may not be exercised. The Company has no duty or obligation to, and does not undertake to, provide tax advice or to minimize the tax consequences of an Award to the holder of such Award.

**8. MISCELLANEOUS.**

(a) **Repurchase Rights**. Prior to the Initial Public Offering Date, shares of Common Stock issued under the Plan may be subject to a right of first refusal, one or more repurchase options or reacquisition rights, drag-along rights, or other conditions and restrictions as determined by the Board in its discretion at the time the Award is granted. The Company shall have the right to assign at any time any repurchase right or other right that it may have with respect to a share of Common Stock issued under the Plan, whether or not such right is then exercisable, to one or more Persons as may be selected by the Company. Upon request by the Company, each Participant shall execute any agreement evidencing such transfer restrictions prior to the issuance of shares of Common Stock hereunder and shall promptly present to the Company any certificates representing shares of Common Stock acquired hereunder for the placement on such certificates of appropriate legends evidencing any such transfer restrictions. To the extent required by any agreement of stockholders or other agreement to which the Company is or may become subject, persons acquiring shares of Common Stock issued under the Plan will be required to enter into such agreement upon acquiring such shares of Common Stock as a condition of acquiring such shares of Common Stock.

(b) **Provision of Information**. To the extent required by applicable law, the Company will provide information to Participants regarding the Company.

(c) **Use of Proceeds from Sales of Common Stock**. Proceeds from the sale of shares of Common Stock pursuant to Stock Awards will constitute general funds of the Company.

(d) **Corporate Action Constituting Grant of Awards**. Corporate action constituting a grant by the Company of an Award to any Participant will be deemed completed as of the latest date that all necessary corporate action has occurred and all material terms of the Award (including, in the case of stock options, the exercise price thereof) are fixed, unless otherwise determined by the Board, regardless of when the documentation evidencing the Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (e.g., Board consents, resolutions or minutes) documenting the corporate action constituting the grant contain terms (e.g., exercise price, vesting schedule or number of shares) that are inconsistent with those in the

Award Document as a result of a clerical error in the papering of the Award Document, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Document.

(e) **Stockholder Rights**. No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to a Stock Award unless and until (i) such Participant has satisfied all requirements for exercise of, or the issuance of shares of Common Stock under, the Stock Award pursuant to its terms, and (ii) the issuance of the shares of Common Stock subject to such Stock Award has been entered into the books and records of the Company.

(f) **No Employment or Other Service Rights**. Nothing in the Plan, any Award Document or any other instrument executed thereunder or in connection with any Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or any other capacity or will affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee for any reason or no reason, with or without notice and with or without cause, including, but not limited to, Cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the organizational documents of the Company or an Affiliate (including the certificate of incorporation and bylaws), and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

(g) **Change in Time Commitment**. If after the date of grant of any Award to the Participant, the Participant's regular level of time commitment in the performance of his or her services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee or takes an extended leave of absence), or the Participant's role or primary responsibilities are changed to a level that, in the good faith determination by the Board does not justify the Participant's unvested Awards, the Board has the unilateral right, which right shall be exercised in its sole discretion, to (i) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Award that is scheduled to vest or become payable after the date of such change in time commitment, and (ii) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Award that is so reduced or extended.

(h) **Incentive Stock Option Limitations**. To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any calendar year (under all plans of the Company and any Affiliates) exceeds $100,000 (or such other limit established in the Code) or otherwise does not comply with the rules governing Incentive Stock Options, the Options or portions thereof that exceed such limit (according to the order in which they were granted) or otherwise do not comply with such rules will be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

(i) **Investment Assurances**. The Company may require a Participant, as a condition of exercising or acquiring shares of Common Stock under any Stock Award, (i) to give written assurances satisfactory to the Company (A) as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and (B) that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Stock Award, and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring the shares of Common Stock subject to the Stock Award for the Participant's own account and not with any present intention of selling or otherwise distributing the shares of Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, will be inoperative if (x) the issuance of the shares of Common Stock upon the exercise of a Stock Award or acquisition of shares of Common Stock under the Stock Award has been registered under a then currently effective registration statement under the Securities Act, or (y) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the shares of Common Stock.

(j) **Withholding Obligations**. Unless prohibited by the terms of an Award Document, the Company may, in its sole discretion, satisfy any U.S. federal, state, local, foreign or other tax withholding obligation relating to an Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Award (only up to the amount permitted that will not cause an adverse accounting consequence or cost); (iii) withholding cash from an Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant, including proceeds from the sale of shares of Common Stock issued pursuant to a Stock Award; or (v) by such other method as may be set forth in the Award Document.

(k) **Electronic Delivery**. Any reference herein to a "written" agreement or document will include any agreement or document delivered electronically, filed publicly at www.sec.gov (or any successor website thereto), or posted on the Company's intranet (or other shared electronic medium controlled by the Company to which the Participant has access).

(l) **Deferrals**. To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of shares of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code (to the extent applicable to a Participant). Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee or otherwise providing services to the Company. The Board is authorized to make deferrals of Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant's termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

(m) **Compliance with Section 409A**. Unless otherwise expressly provided for in an Award Document, or other agreement between the Participant and the Company or any Affiliate, the Plan and Award Documents will be interpreted to the greatest extent possible in a manner that makes the Plan and the Awards granted hereunder exempt from Section 409A of the Code, and, to the extent not so exempt, in compliance with Section 409A of the Code. If the Board determines that any Award granted hereunder is not exempt from and is therefore subject to Section 409A of the Code, the Award Document evidencing such Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent an Award Document is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Award Document. Notwithstanding anything to the contrary in the Plan (and unless the Award Document specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a Participant holding an Award that constitutes "deferred compensation" under Section 409A of the Code is a "specified employee" for purposes of Section 409A of the Code, no distribution or payment of any amount that is due because of a "separation from service" (as defined in Section 409A of the Code without regard to alternative definitions thereunder) will be issued or paid before the date that is six (6) months following the date of such Participant's "separation from service" or, if earlier, the date of the Participant's death, unless such distribution or payment can be made in a manner that complies with Section 409A of the Code, and any amounts so deferred will be paid in a lump sum on the day after such six (6) month period elapses, with the balance paid thereafter on the original schedule.

(n) **Clawback/Recovery**. All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Document as the Board determines necessary or appropriate, including, but not limited to, a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or "constructive termination" (or similar term) under any agreement with the Company or an Affiliate.

**9. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; OTHER CORPORATE EVENTS.**

(a) **Capitalization Adjustments**. In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a); (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section 3(c); and (iii) the class(es) and number of securities or other property and value (including price per share of stock) subject to outstanding Stock Awards. The Board will make such adjustments, and its determination will be final, binding and conclusive.

(b) **Dissolution or Liquidation**. Except as otherwise provided in the Stock Award Document, or other agreement between the Participant and the Company or any Affiliate, in the event of a dissolution or liquidation of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service; provided, however, that the Board may, in its sole discretion, cause some or all Stock Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Stock Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

(c) **Corporate Transaction**. The following provisions will apply to Stock Awards in the event of a Corporate Transaction unless otherwise provided in the instrument evidencing the Stock Award or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Board at the time of grant of a Stock Award. In the event of a Corporate Transaction, then, notwithstanding any other provision of the Plan, the Board will take one or more of the following actions with respect to each outstanding Stock Award, contingent upon the closing or completion of the Corporate Transaction:

(i) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the Stock Award or to substitute a similar stock award for the Stock Award (including, but not limited to, an award to acquire the same consideration per share paid to the stockholders of the Company pursuant to the Corporate Transaction);

(ii) arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of shares of Common Stock issued pursuant to the Stock Award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company);

(iii) accelerate the vesting, in whole or in part, of the Stock Award (and, if applicable, the time at which the Stock Award may be exercised) to a date prior to the effective time of such Corporate Transaction as the Board will determine, with such Stock Award terminating if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction, and with such accelerated vesting (and if applicable, such exercise) reversed if the Corporate Transaction does not become effective;

(iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the Company with respect to the Stock Award;

(v) cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for such cash consideration, if any, as the Board, in its reasonable determination, may consider appropriate as an approximation of the value of the canceled Stock Award, taking into account the value of the shares of Common Stock subject to the canceled Stock Award, the possibility that the Stock Award might not otherwise vest in full, and such other factors as the Board deems relevant;

(vi) cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for a payment, in such form as may be determined by the Board equal to the excess, if any, of (A) the value in the Corporate Transaction of the property the Participant would have received upon the exercise of the Stock Award immediately prior to the effective time of the Corporate Transaction, over (B) any exercise price payable by such holder in connection with such exercise; and

(vii) continuation of the Stock Award.

The Board need not take the same action or actions with respect to all Stock Awards or portions thereof or with respect to all Participants. The Board may take different actions with respect to the vested and unvested portions of a Stock Award.

In the absence of any affirmative determination by the Board at the time of a Corporate Transaction, each outstanding Stock Award will be assumed or an equivalent Stock Award will be substituted by such successor corporation or a parent or subsidiary of such successor corporation (the "**Successor Corporation**"), unless the Successor Corporation does not agree to assume the Stock Award or to substitute an equivalent Stock Award, in which case the vesting of such Stock Award will accelerate in its entirety (along with, if applicable, the time at which the Stock Award may be exercised) to a date prior to the effective time of such Corporate Transaction as the Board will determine (or, if the Board will not determine such a date, to the date that is 5 days prior to the effective date of the Corporate Transaction), with such Stock Award terminating if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction, and with such exercise reversed if the Corporate Transaction does not become effective.

(d) **Change in Control**. A Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Stock Award Document for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration will occur.

**10. TERMINATION OR SUSPENSION OF THE PLAN.**

The Board may suspend or terminate the Plan at any time. No Awards may be granted after the tenth (10th) anniversary of the earlier of (i) the date the Board adopts the Plan, or (ii) the date the stockholders approve the Plan. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

**11. EFFECTIVE DATE OF PLAN**

The Plan came into existence on the Effective Date and no Award shall be granted hereunder prior to such date.

**12. CHOICE OF LAW.**

The laws of the State of Delaware will govern all questions concerning the construction, validity and interpretation of the Plan, without regard to that state's conflict of laws rules.

**13. DEFINITIONS**. As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

(a) "**Affiliate**" means, at the time of determination, any direct or indirect "parent" or "subsidiary" of the Company, as such terms are defined in Rule 405 of the Securities Act. The Board will have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

(b) "**Award**" means a Stock Award or a Performance Cash Award.

(c) "**Award Document**" means a written agreement between the Company and a Participant, or a written notice issued by the Company to a Participant, evidencing the terms and conditions of an Award.

(d) "**Board**" means the Board of Directors of the Company.

(e) “**Capital Stock**” means each and every class and series of common stock and preferred stock of the Company, regardless of the number of votes per share.

(f) “**Capitalization Adjustment**” means any change that is made in, or other events that occur with respect to, shares of Common Stock subject to the Plan or subject to any Stock Award after the Effective Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or other similar equity restructuring transaction, as that term is used in Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(g) “**Cause**” will have the meaning ascribed to such term in any written agreement between the Participant and the Company or any Affiliate defining such term and, in the absence of such agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) Participant’s failure substantially to perform his or her duties and responsibilities to the Company or any Affiliate or violation of a policy of the Company or any Affiliate; (ii) Participant’s commission of any act of fraud, embezzlement, dishonesty or any other misconduct that has caused or is reasonably expected to result in injury to the Company or any Affiliate; (iii) unauthorized use or disclosure by Participant of any proprietary information or trade secrets of the Company or any other Person to whom the Participant owes an obligation of nondisclosure as a result of his or her relationship with the Company or any Affiliate; or (iv) Participant’s breach of any of his or her obligations under any written agreement or covenant with the Company or any Affiliate. The determination as to whether a Participant is being terminated for Cause will be made in good faith by the Company and will be final and binding on the Participant. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Awards held by such Participant will have no effect upon any determination of the rights or obligations of the Company, any Affiliate or such Participant for any other purpose.

(h) “**Change in Control**” means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company’s then outstanding securities. Notwithstanding the foregoing, a Change in Control will not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company’s securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities, or (C) solely because the level of Ownership held by any Exchange Act Person (the “**Subject Person**”) exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control will be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than 50% of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than 50% of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

(iv) individuals who, on the date on which the Board adopts the Plan, are members of the Board (the "**Incumbent Board**") cease for any reason to constitute at least a majority of the members of the Board; provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of the Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing definition or any other provision of the Plan, (A) the term Change in Control will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, and (B) the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant will supersede the foregoing definition with respect to Awards subject to such agreement; provided, however, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition will apply.

If required for compliance with Section 409A of the Code, in no event will a Change in Control be deemed to have occurred if such transaction is not also a "change in the ownership or effective control of" the Company or "a change in the ownership of a substantial portion of the assets of" the Company as determined under U.S. Treasury Regulation Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder). The Board may, in its sole discretion and without a Participant's consent, amend the definition of "Change in Control" to conform to the definition of "Change in Control" under Section 409A of the Code, and the regulations thereunder.

(i) "**Code**" means the U.S. Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(j) "**Committee**" means a committee of one (1) or more Directors to whom authority has been delegated by the Board in accordance with Section 2(c).

(k) "**Common Stock**" means the common stock of the Company.

(l) "**Company**" means Progenity, Inc., a Delaware corporation.

(m) "**Consultant**" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a "Consultant" for purposes of the Plan. Notwithstanding the foregoing, from and after the Initial Public Offering Date, a person is treated as a Consultant under the Plan only if a Form Registration Statement on Form S-8 or a successor form under the Securities Act is available to register either the offer or the sale of the Company's securities to such person.

(n) "**Continuous Service**" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the Entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, will not terminate a Participant's Continuous Service. For example, a change in status from an Employee of the Company to a Consultant of an Affiliate or to a Director will not constitute an interruption of Continuous Service. If the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board in its sole discretion, such Participant's Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or

(ii) transfers between the Company, an Affiliate, or their successors. In addition, if required for exemption from or compliance with Section 409A of the Code, the determination of whether there has been a termination of Continuous Service will be made, and such term will be construed, in a manner that is consistent with the definition of "separation from service" as defined under U.S. Treasury Regulation Section 1.409A-1(h) (without regard to any alternative definition thereunder). A leave of absence will be treated as Continuous Service for purposes of vesting in a Stock Award only to such extent as may be provided in the applicable Award Document, the Company's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law.

(o) "**Corporate Transaction**" means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of at least 90% of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

To the extent required for compliance with Section 409A of the Code, in no event will an event be deemed a Corporate Transaction if such transaction is not also a "change in the ownership or effective control of" the Company or "a change in the ownership of a substantial portion of the assets of" the Company as determined under U.S. Treasury Regulation Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder).

(p) "**Director**" means a member of the Board.

(q) "**Disability**" means, with respect to a Participant, the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than 12 months as provided in Sections 22(e)(3) and 409A(a)(2)(C)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(r) "**Effective Date**" means February 22, 2018.

(s) "**Employee**" means any person providing services as an employee of the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of the Plan.

(t) "**Entity**" means a corporation, partnership, limited liability company or other entity.

(u) "**Exchange Act**" means the U.S. Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(v) "**Exchange Act Person**" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company, (v) any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the date of adoption by the Board of the Plan, is the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities, (vi) Harry Stylli, or any trust or Entity wholly owned by him or as to which he is the trustee and beneficiary, or (vii) Athyrium Capital Management, LP, or any fund managed by Athyrium Capital Management, LP.

(w) "**Fair Market Value**" means, as of any date, the value of a share of Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock as of any date of determination will be, unless otherwise determined by the Board, the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

(ii) Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

The Board shall make a good faith determination of the Fair Market Value of any securities or derivative securities (including options) of the Company. For any options granted after the Initial Public Offering Date, the Board shall base the Fair Market Value of any options on the "fair value" determined for financial accounting purposes under Accounting Standards Codification 718.

(x) "**Incentive Stock Option**" means an option granted pursuant to Section 5 of the Plan that is intended to be, and that qualifies as, an "incentive stock option" within the meaning of Section 422 of the Code.

(y) "**Initial Public Offering**" means the initial underwritten public offering of shares of Common Stock pursuant to a registration statement filed and declared effective pursuant to the Securities Act.

(z) "**Initial Public Offering Date**" means the date of the underwriting agreement between the Company and the underwriters(s) managing the Initial Public Offering, pursuant to which shares of Common Stock are priced for the Initial Public Offering; provided that the Initial Public Offering contemplated by such underwriting agreement occurs.

(aa) "**Nonstatutory Stock Option**" means any option granted pursuant to Section 5 of the Plan that does not qualify as an Incentive Stock Option.

(bb) "**Officer**" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act (whether or not shares of Common Stock are publicly traded).

(cc) "**Option**" means an Incentive Stock Option or a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

(dd) "**Option Agreement**" means an Award Document evidencing the terms and conditions of an Option grant. Each Option Agreement will be subject to the terms and conditions of the Plan.

(ee) "**Optionholder**" means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(ff) “**Other Stock Award**” means an award based in whole or in part by reference to shares of Common Stock that is granted pursuant to the terms and conditions of Section 6(d).

(gg) “**Other Stock Award Document**” means an Award Document evidencing the terms and conditions of an Other Stock Award grant. Each Other Stock Award Document will be subject to the terms and conditions of the Plan.

(hh) “**Own**,” “**Owned**,” “**Owner**,” “**Ownership**”, a Person will be deemed to “Own,” to have “Owned,” to be the “Owner” of, or to have acquired “Ownership” of securities if such Person, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(ii) “**Participant**” means a person to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.

(jj) “**Performance Cash Award**” means an award of cash granted pursuant to the terms and conditions of Section 6(c)(ii).

(kk) “**Performance Period**” means the period of time selected by the Board over which the attainment of one or more performance goals will be measured for the purpose of determining a Participant’s right to and the payment of a Stock Award or a Performance Cash Award. Performance Periods may be of varying and overlapping duration, at the sole discretion of the Board.

(ll) “**Performance Stock Award**” means a Stock Award granted under the terms and conditions of Section 6(c)(i).

(mm) “**Person**” means a “person” as defined in Section 3(a)(9) of the Exchange Act and used in Section 13(d) and 14(d) thereof, including a “group” as defined in Section 13(d) thereof.

(nn) “**Plan**” means this 2018 Equity Incentive Plan of Progenity, Inc. (Fourth Amended and Restated).

(oo) “**Restricted Stock Award**” means an award of shares of Common Stock that is granted pursuant to the terms and conditions of Section 6(a).

(pp) “**Restricted Stock Award Document**” means an Award Document evidencing the terms and conditions of a Restricted Stock Award grant. Each Restricted Stock Award Document will be subject to the terms and conditions of the Plan.

(qq) “**Restricted Stock Unit Award**” means a right to receive shares of Common Stock that is granted pursuant to the terms and conditions of Section 6(b).

(rr) “**Restricted Stock Unit Award Document**” means an Award Document evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Document will be subject to the terms and conditions of the Plan.

(ss) “**Securities Act**” means the U.S. Securities Act of 1933, as amended.

(tt) “**Stock Appreciation Right**” or “**SAR**” means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 5.

(uu) “**Stock Appreciation Right Award Document**” means an Award Document evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Award Document will be subject to the terms and conditions of the Plan.

(vv) “**Stock Award**” means any right to receive shares of Common Stock granted under the Plan, including an Incentive Stock Option, a Nonstatutory Stock Option, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Appreciation Right, a Performance Stock Award, or any Other Stock Award. The right to receive cash under the terms of a Stock Award that is actually settled in shares of Common Stock shall not disqualify such award from satisfying the definition of a “Stock Award”.

(ww) “**Stock Award Document**” means an Award Document evidencing the terms and conditions of a Stock Award grant. Each Stock Award Document will be subject to the terms and conditions of the Plan.

(xx) “**Subsidiary**” means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other Entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

(yy) “**Ten Percent Stockholder**” means a Person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) stock possessing more than 10% of the total combined voting power of all classes of stock of the Company or any Affiliate.

END OF DOCUMENT

**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: August 12, 2021

By: /s/ Harry Stylli

**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: August 12, 2021

By: /s/ Eric d’Esparbes
**Eric d’Esparbes, Executive Vice President and 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 June 30, 2021 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:

(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: August 12, 2021 | By: | /s/ Harry Stylli |
| | | **Harry Stylli, Ph.D., Chairman 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)** |

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.