UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2020

OR

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

For the transition period from to

Commission File Number: 001-39659

BIODESIX, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**20-3986492**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2970 Wilderness Place, Suite 100 Boulder, Colorado 80301	**80301**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (303) 417-0500

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	BDSX	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 X

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☒ No ☐

As of December 8, 2020, the registrant had 26,541,317 shares of common stock, $0.001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

BIODESIX, INC.

Condensed Statements of Operations (unaudited)
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues	$ 9,193	$ 3,942	$ 18,528	$ 16,281
Operating expenses				
Direct costs and expenses	3,891	1,503	7,346	4,244
Research and development	2,706	2,359	7,713	7,966
Sales, marketing, general and administrative	7,879	8,212	22,793	24,080
Accretion of contingent consideration	957	896	2,901	2,525
Change in fair value of contingent consideration	-	-	(1,944)	663
Total operating expenses	15,433	12,970	38,809	39,478
Loss from operations	(6,240)	(9,028)	(20,281)	(23,197)
Interest expense	(2,658)	(706)	(6,899)	(2,005)
Other income, net	53	133	363	1,001
Net loss	$ (8,845)	$ (9,601)	$ (26,817)	$ (24,201)
Net loss per share, basic and diluted	$ (31.93)	$ (39.35)	$ (99.69)	$ (103.87)
Weighted-average shares outstanding, basic and diluted	277	244	269	233

See notes to condensed financial statements.

BIODESIX, INC.

Condensed Balance Sheets (unaudited)
(in thousands, except share data)

	September 30, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 6,348	$ 5,286
Accounts receivable	5,396	5,292
Other current assets	6,405	2,122
Total current assets	18,149	12,700
Non-current assets		
Property and equipment, net	3,005	2,120
Intangible assets, net	13,667	15,092
Deposits	95	90
Goodwill	11,631	11,631
Total non-current assets	28,398	28,933
Total assets	$ 46,547	$ 41,633
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 3,485	$ 1,717
Accrued liabilities	6,953	4,180
Deferred revenue	5,673	1,283
Convertible notes payable	26,600	12,159
Current portion of note payable	7,202	—
Put option liability	6,650	3,261
Total current liabilities	56,563	22,600
Non-current liabilities		
Warrant liability	403	329
Other liabilities	392	358
Long-term notes payable	17,236	23,812
Paycheck protection program note payable	3,099	—
Contingent consideration	30,071	29,114
Total non-current liabilities	51,201	53,613
Total liabilities	107,764	76,213
Commitments and contingencies		
Convertible Preferred stock		
Convertible preferred stock, $0.001 par value, 185,432,719 (2020) and 174,237,067 (2019) authorized; 118,766,273 (2020 and 2019) issued and outstanding; liquidation preference of $202,582 (2020 and 2019)	193,959	193,959
Stockholders' deficit		
Common stock, $0.001 par value, 220,000,000 (2020) and 190,000,000 (2019) authorized; 289,508 (2020) and 254,918 (2019) issued and outstanding	2	1
Additional paid-in capital	2,503	2,324
Accumulated deficit	(257,681)	(230,864)
Total stockholders' deficit	(255,176)	(228,539)
Total liabilities, convertible preferred stock, and stockholders' deficit	$ 46,547	$ 41,633

See notes to condensed financial statements.

BIODESIX, INC.

Condensed Statements of Changes in Convertible Preferred Stock and Stockholders' Deficit (unaudited)
(in thousands)

	Series A-1		Series A-2		Series A-3		Series B		Series B-1	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance - December 31, 2019	700	$ 800	267	$ 400	750	$ 1,672	3,642	$ 9,907	2,999	$ 9,551
Exercise of stock options	—	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—
Balance - March 31, 2020	700	$ 800	267	$ 400	750	$ 1,672	3,642	$ 9,907	2,999	$ 9,551
Exercise of stock options	—	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—
Balance - June 30, 2020	700	$ 800	267	$ 400	750	$ 1,672	3,642	$ 9,907	2,999	$ 9,551
Exercise of stock options	—	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—
Balance - September 30, 2020	700	$ 800	267	$ 400	750	$ 1,672	3,642	$ 9,907	2,999	$ 9,551

	Series A-1		Series A-2		Series A-3		Series B		Series B-1	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance - December 31, 2018	700	$ 800	267	$ 400	750	$ 1,672	3,642	$ 9,907	2,999	$ 9,551
Exercise of stock options	—	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—
Issuance of Series H Preferred Stock, net of issuance costs of $3	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—
Balance - March 31, 2019	700	$ 800	267	$ 400	750	$ 1,672	3,642	$ 9,907	2,999	$ 9,551
Exercise of stock options	—	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—
Balance - June 30, 2019	700	$ 800	267	$ 400	750	$ 1,672	3,642	$ 9,907	2,999	$ 9,551
Exercise of stock options	—	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—
Balance - September 30, 2019	700	$ 800	267	$ 400	750	$ 1,672	3,642	$ 9,907	2,999	$ 9,551

See notes to condensed financial statements.

BIODESIX, INC.

Condensed Statements of Changes in Convertible Preferred Stock and Stockholders' Deficit (unaudited)
(in thousands)

(Continued from the previous page)

	Series C		Series D		Series E		Series F	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance - December 31, 2019	2,357	$ 7,040	10,875	$ 41,266	7,640	$ 32,736	19,468	$ 28,585
Exercise of stock options	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—
Balance - March 31, 2020	2,357	7,040	10,875	41,266	7,640	32,736	19,468	28,585
Exercise of stock options	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—
Balance - June 30, 2020	2,357	$ 7,040	10,875	$ 41,266	7,640	$ 32,736	19,468	$ 28,585
Exercise of stock options	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—
Balance - September 30, 2020	2,357	$ 7,040	10,875	$ 41,266	7,640	$ 32,736	19,468	$ 28,585

	Series C		Series D		Series E		Series F	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance - December 31, 2018	2,357	$ 7,040	10,875	$ 41,266	7,640	$ 32,736	19,468	$ 28,585
Exercise of stock options	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—
Issuance of Series H Preferred Stock, net of issuance costs of $3	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—
Balance - March 31, 2019	2,357	$ 7,040	10,875	$ 41,266	7,640	$ 32,736	19,468	$ 28,585
Exercise of stock options	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—
Balance - June 30, 2019	2,357	$ 7,040	10,875	$ 41,266	7,640	$ 32,736	19,468	$ 28,585
Exercise of stock options	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—
Balance - September 30, 2019	2,357	$ 7,040	10,875	$ 41,266	7,640	$ 32,736	19,468	$ 28,585

See notes to condensed financial statements.

BIODESIX, INC.

Condensed Statements of Changes in Convertible Preferred Stock and Stockholders' Deficit (unaudited)
(in thousands)

(Continued from the previous page)

	Series G		Series H		Total Convertible Preferred	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Stock	Shares	Amount	Capital	Deficit	Deficit
Balance - December 31, 2019	46,147	$ 34,537	23,923	$ 27,465	$ 193,959	255	$ 1	$ 2,324	$ (230,864)	$ (228,539)
Exercise of stock options	—	—	—	—	—	20	1	10	—	11
Stock-based compensation	—	—	—	—	—	-	—	—	—	—
Net loss	—	—	—	—	—	-	—	—	(9,706)	(9,706)
Balance - March 31, 2020	46,147	$ 34,537	23,923	$ 27,465	$ 193,959	275	2	$ 2,334	$ (240,570)	$ (238,234)
Exercise of stock options	—	—	—	—	—	-	—	—	—	-
Stock-based compensation	—	—	—	—	—	-	—	55	—	55
Net loss	—	—	—	—	—	-	—	—	(8,266)	(8,266)
Balance - June 30, 2020	46,147	$ 34,537	23,923	$ 27,465	$ 193,959	275	2	$ 2,389	$ (248,836)	$ (246,445)
Exercise of stock options	—	—	—	—	—	15	—	14	—	14
Stock-based compensation	—	—	—	—	—	-	—	100	—	100
Net loss	—	—	—	—	—	-	—	—	(8,845)	(8,845)
Balance - September 30, 2020	46,147	$ 34,537	23,923	$ 27,465	$ 193,959	290	2	$ 2,503	$ (257,681)	$ (255,176)

	Series G		Series H		Total Convertible Preferred	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Stock	Shares	Amount	Capital	Deficit	Deficit
Balance - December 31, 2018	46,147	$ 34,537	15,228	$ 17,468	$ 183,962	215	$ 1	$ 2,107	$ (200,138)	$ (198,030)
Exercise of stock options	—	—	—	—	—	25	—	30	—	30
Stock-based compensation	—	—	—	—	—	—	—	31	—	31
Issuance of Series H Preferred Stock, net of issuance costs of $3	—	—	8,695	9,997	9,997	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	(7,744)	(7,744)
Balance - March 31, 2019	46,147	$ 34,537	23,923	$ 27,465	$ 193,959	240	$ 1	$ 2,168	$ (207,882)	$ (205,713)
Exercise of stock options	—	—	—	—	—	3	—	1	—	1
Stock-based compensation	—	—	—	—	—	—	—	49	—	49
Net loss	—	—	—	—	—	—	—	—	(6,856)	(6,856)
Balance - June 30, 2019	46,147	$ 34,537	23,923	$ 27,465	$ 193,959	243	$ 1	$ 2,218	$ (214,738)	$ (212,519)
Exercise of stock options	—	—	—	—	—	12	—	16	—	16
Stock-based compensation	—	—	—	—	—	—	—	45	—	45
Net loss	—	—	—	—	—	—	—	—	(9,601)	(9,601)
Balance - September 30, 2019	46,147	$ 34,537	23,923	$ 27,465	$ 193,959	255	$ 1	$ 2,279	$ (224,339)	$ (222,059)

See notes to condensed financial statements.

BIODESIX, INC.

Condensed Statements of Cash Flows (unaudited)
(in thousands)

	2020	2019
Cash flows from operating activities		
Net loss	$ (26,817)	$ (24,201)
Adjustments to reconcile net loss to net cash, cash equivalents, and restricted cash used in operating activities		
Depreciation and amortization	2,174	2,080
Amortization of convertible notes debt discount	4,389	—
Stock-based compensation expense	155	125
Change in fair value of warrant liability	31	—
Change in contingent consideration	957	3,188
Accrued interest on notes payable and convertible notes payable	1,025	415
Amortization of debt issuance costs	109	109
Provision for doubtful accounts	113	—
Write off of assets	—	16
Changes in operating assets and liabilities, net of assets acquired and liabilities assumed in acquisitions:		
Accounts receivable	(217)	17
Other current assets	(4,283)	14
Other long-term assets	(5)	10
Accounts payable and other accrued liabilities	5,369	1,722
Deferred revenue	4,390	508
Net cash and cash equivalents and restricted cash used in operating activities	(12,610)	(15,997)
Cash flows from investing activities		
Purchase of property and equipment	(1,483)	(915)
Patent costs and intangible asset acquisition, net	(151)	(79)
Payments to acquire Oncimmune	(750)	—
Net cash and cash equivalents and restricted cash used in investing activities	(2,384)	(994)
Cash flows from financing activities		
Proceeds from issuance of series H preferred stock	—	10,000
Proceeds from issuance of convertible notes payable	12,955	10,000
Proceeds from exercise of common stock options	25	45
Proceeds from Paycheck protection program note payable	3,085	—
Other	(10)	(14)
Net cash and cash equivalents and restricted cash provided by financing activities	16,055	20,031
Net increase in cash and cash equivalents and restricted cash	1,061	3,040
Cash, cash equivalents, and restricted cash - beginning of period	5,469	6,094
Cash, cash equivalents, and restricted cash - end of period	$ 6,530	$ 9,134

See notes to condensed financial statements.

BIODESIX, INC.

Condensed Statements of Cash Flows (unaudited)
(in thousands)

(Continued from the previous page)

Supplemental disclosure of cash flow information:

There was no cash paid for income taxes during the nine months ended September 30, 2020 and 2019.

Cash paid for interest for the nine-months ended September 30, 2020 and 2019 was $1.4 million and $1.3 million, respectively.

Supplemental disclosure of non-cash activity (in thousands):

	September 30,	
	2020	2019
Value of put option recorded at issuance of convertible notes payable	$ 3,389	$ —

See notes to condensed financial statements.

Note 1 - Description of Business and Summary of Significant Accounting Policies

(a) Organization and Nature of Operations

Biodesix, Inc. (the "Company"), formerly Elston Technologies, Inc., was incorporated in Delaware in 2005. The Company's headquarters are in Colorado, with laboratories in Colorado, Kansas, and Washington. Biodesix is a data-driven diagnostic solutions company leveraging state of the art technologies with its proprietary artificial intelligence platform to discover, develop, and commercialize solutions for clinical unmet needs, with a primary focus in lung disease. In addition to diagnostic tests, the Company provides biopharmaceutical companies with services that include diagnostic research, clinical trial testing, and the discovery, development, and commercialization of companion diagnostics.

In March 2020, the World Health Organization declared the outbreak of COVID-19, a novel strain of coronavirus, a global pandemic. This outbreak is causing major disruptions to businesses and markets worldwide as the virus spreads. The COVID-19 pandemic has disrupted, and the Company expects will continue to disrupt, its operations. In addition, the COVID-19 pandemic also has started to negatively affect, and the Company expects will continue to negatively affect, its non-COVID-19 testing-related revenue and its clinical studies. The extent of the effect on the Company's operational and financial performance will depend on future developments, including the duration, spread and intensity of the pandemic, and governmental, regulatory and private sector responses, all of which are uncertain and difficult to predict. Although the Company is unable to estimate the financial effect of the pandemic, at this time, if the pandemic continues over a long period of time, it could have a material adverse effect on the Company's business, results of operations, financial condition, and cash flows. The condensed financial statements do not reflect any adjustments as a result of the pandemic.

As of September 30, 2020, the Company has cash and cash equivalents of $6.3 million, accumulated deficit of $257.7 million, and stockholders' deficit as of $255.2 million. The Company may seek additional funding through private or public equity financings, collaborations, strategic alliances and marketing, distribution or licensing agreements. If the Company is unable to obtain additional funding, the Company will be forced to delay, reduce or eliminate some or all if its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all. The Company believes that it has sufficient cash and cash equivalents, after considering the proceeds from its initial public offering of $63.0 million in October 2020, to fund its operations at least through twelve months following the issuance of these financial statements.

The Company is subject to various risks and uncertainties frequently encountered by early stage life science companies. Such risks and uncertainties include, but are not limited to, undeveloped technology, strict regulatory requirements and approval of products, a limited operating history, competition from other service providers, dependence on key personnel, the need for ongoing capital to fund operations, and management of rapid growth. To address these risks, the Company must, among other things, successfully develop its customer base, successfully execute its business and marketing strategy, successfully develop its technology, raise capital on acceptable terms to the Company, and attract, retain, and motivate qualified personnel. There can be no guarantee that the Company will be successful in addressing these or other such risks.

(b) Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information and with the instructions of the Securities and Exchange Commission ("SEC") on Form 10-Q and Rule 10-01 of Regulation S-X. Certain information and note disclosures normally included in annual financial statements prepared in accordance with GAAP have been omitted. The accompanying unaudited condensed financial statements include all known adjustments necessary for a fair presentation of the results of interim periods as required by GAAP. These adjustments consist primarily of normal recurring accruals and estimates that impact the carrying value of assets and liabilities. Operating results for the period ended September 30, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020. Management performed an evaluation of the Company's activities through the date of the filing of this Quarterly Report on Form 10-Q.

The accompanying unaudited condensed financial statements should be read in conjunction with the audited financial statements and the related notes for the year ended December 31, 2019, which are included in the Company's final prospectus filed with the SEC pursuant to Rule 424(b)(4) on October 29, 2020 under the Securities Act of 1933, as amended (the "Securities Act").

(c) Reverse Stock Split and Initial Public Offering

On October 19, 2020, the Company obtained approval of an amended and restated certificate of incorporation effecting a 0.1684664-for-1 reverse stock split of its issued and outstanding common stock as converted. All common shares, stock options, and per share information presented in these financial statements and notes thereto have been adjusted, where applicable, to reflect the reverse stock split on a retroactive basis for all periods presented. The per share par value and authorized number of shares of the Company's common stock were not adjusted as a result of the reverse stock split.

The Company's registration statement on Form S-1 related to its initial public offering ("IPO") was declared effective by the SEC on October 27, 2020, and the Company's common stock began trading on the Nasdaq Global Market on October 28, 2020. On October 30, 2020, the Company closed its IPO, in which the Company issued and sold 4,000,000 shares of its common stock, at a price to the public of $18.00 per share. The Company received approximately $63.0 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by the Company. In connection with the IPO, all outstanding shares of the Company's convertible preferred stock and convertible notes payable converted into 21,939,025 shares of common stock. The unaudited condensed financial statements, including share and per share amounts, do not give effect to the IPO or the related conversion of securities into shares of common stock. In addition, the put option liability related to the convertible notes payable was transferred to additional paid-in capital upon the closing of the IPO.

(d) Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Areas of the financial statements where estimates have the most significant effect include the valuation of contingent consideration and purchased technology related to the Company's business acquisition, valuation of impairment of goodwill and long-lived assets, stock-based compensation, valuation of put option liabilities, and the valuation allowance related to net deferred tax assets. Actual results could differ from those estimates.

(e) Segment Information

The Company operates in one operating segment and, accordingly, no segment disclosures have been presented herein. All equipment, leasehold improvements, and other fixed assets are physically located within the United States.

(f) Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and/or circumstances from non-owner sources. If the Company had comprehensive gains (losses), they would be reflected in the statement of operations and comprehensive loss and as a separate component in the statement of stockholders' deficit. There were no elements of comprehensive loss during the nine months ended September 30, 2020 and 2019.

(g) Concentration of Risk

The Company is subject to credit risk from its accounts receivable related to services provided to its customers. Reimbursement on behalf of customers covered by Medicare accounted for 61% and 58% of the Company's non-COVID-19 diagnostic test revenue for the nine months ended September 30, 2020 and 2019, respectively and represented 17% and 18% of the Company's total accounts receivable as of September 30, 2020 and December 31, 2019, respectively. One services customer represented 10% and 44% of the Company's total accounts receivable balance as of September 30, 2020 and December 31, 2019, respectively. Two diagnostic test customers represented 35% and 0% of the Company's total accounts receivable balance as of September 30, 2020 and December 31, 2019, respectively.

(h) Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. The Company continually monitors its positions with, and the credit quality of, the financial institutions with which it invests. Periodically throughout the year, the Company has maintained balances in various operating accounts in excess of federally

insured limits. Included in cash and cash equivalents are money market funds recorded at $4.8 million at September 30, 2020 and December 31, 2019. These money market funds were measured using Level 1 inputs.

Restricted cash consists of deposits related to the Company's corporate credit card and a letter of credit related to an operating lease agreement. As of September 30, 2020 and December 31, 2019, the Company had $0.2 million in restricted cash, which was included in other current assets in the accompanying balance sheets.

The majority of the Company's cash and cash equivalents are deposited with one major financial institution in the United States. Deposits with this institution may exceed the amount of insurance provided on such deposits. The Company has not experienced any losses on its deposits of cash and cash equivalents.

(i) Accounts Receivable

The Company provides an allowance for doubtful accounts based on experience and specifically identified risks. Accounts receivable are recorded at carrying value and charged off against the allowance for doubtful accounts when it is determined that recovery is unlikely and cease collection efforts cease.

The Company analyzes trade accounts receivable quarterly and considers historic experience, customer creditworthiness, facts and circumstances specific to outstanding balances, and payment terms when evaluating the adequacy of the allowance for doubtful accounts. The Company recorded an allowance for doubtful accounts of $0.2 million as of September 30, 2020 and December 31, 2019, respectively.

(j) Inventory

Inventories are stated at the lower of cost or net realizable value on a first-in, first-out basis. Inventory consists primarily of supplies, which are consumed when processing tests. The Company does not maintain any finished goods inventory. Inventory balances were $3.2 million and $0.8 million as of September 30, 2020 and December 31, 2019, respectively, and are included in other current assets in the accompanying balance sheets.

(k) Property and Equipment

Property and equipment are stated at cost. Depreciation is provided utilizing the straight-line method over the estimated useful lives, ranging from three to five years.

(l) Intangible Assets

Intangible assets are stated at cost, net of accumulated amortization and include patents, trademarks, and acquired developed technology. Trademarks have an indefinite life and are not being amortized but are reviewed for impairment on an annual basis and more frequently if events or changes in circumstances indicate that it is more likely than not that the assets are impaired. External costs associated with patents are capitalized as long as such efforts are expected to be successful. Upon approval of the patent, the related capitalized costs are amortized over the lesser of the contractual term of the patent or the estimated useful life of 10 years. Acquired developed technology is amortized over a useful life of 9 years.

Intangible assets are reviewed for impairment whenever events or changes in circumstances may affect the recoverability of the intangible assets. Such reviews include an analysis of current results and take into consideration the undiscounted value of projected operating cash flows. See Note 2, Business Combinations, for further information.

(m) Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recovered. The Company looks primarily to the undiscounted future cash flows in its assessment of whether or not long-lived assets have been impaired. The Company has determined that no impairments are necessary for the periods presented.

(n) Deferred Rent

The Company leases office space under non-cancelable, long-term operating leases that include scheduled increases in minimum rents and renewal provisions at the option of the Company. The expense associated with leases that have escalating payment terms is recognized on a straight-line basis over the lease term. Tenant improvement allowances received from a lessor are recorded as a deferred rent liability and recognized evenly as a reduction to rent expense over the remaining lease term. The portion of the deferred rent liability that will reverse in the next 12 months is not significant to the balance sheets; therefore, the entire amount was recorded as non-current in the accompanying condensed financial statements.

(o) Goodwill

Goodwill is recorded when the purchase price paid for an acquisition exceeds the estimated fair value of the net identified tangible and intangible assets acquired. Goodwill is not amortized and is tested for impairment at the reporting unit level on an annual basis as of December 31 and between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit below its carrying value. The Company may first perform a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. If it is concluded that this is the case, it is necessary to perform a quantitative two-step goodwill impairment test. Otherwise, the two-step goodwill impairment test is not required. The quantitative two-step goodwill impairment review process compares the fair value of the reporting unit in which goodwill resides to its carrying value. Multiple valuation techniques can be used to assess the fair value of the reporting unit. All these techniques include the use of estimates and assumptions that are inherently uncertain. Changes in these estimates and assumptions could materially affect the determination of fair value or goodwill impairment, or both. The Company assessed qualitative factors to determine whether it is more likely than not that the fair value of goodwill exceeded the carrying value. Based on that assessment, there were no events or circumstances in the nine months ended September 30, 2020 and 2019 to indicate that the fair value of goodwill exceeded its carrying value, and thus a quantitative analysis was not performed.

The Company did not have any goodwill impairments for the three and nine months ended September 30, 2020 and 2019.

(p) Revenue Recognition

Revenue is recognized when control of the promised services is transferred to customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those services.

The Company's revenue is generated from the following:

- *Diagnostic tests.* These services are completed upon the delivery of test results to the prescribing physician, which is considered the performance obligation. The fees for such services are billed either to a third party such as Medicare, medical facilities, commercial insurance payers, or to the patient.

- *Services.* These services are generally completed upon the delivery of test results for assay development and testing services, which is considered the performance obligation. Customers for these services are typically large pharmaceutical companies.

For the three and nine months ended September 30, 2020 and 2019, revenue from these services consisted of the following (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Diagnostic tests	$ 8,552	$ 3,770	$ 15,798	$ 12,716
Services	641	172	2,730	3,565
Total revenue	$ 9,193	$ 3,942	$ 18,528	$ 16,281

Diagnostic test revenue that were reimbursed by Medicare comprised 63% and 57% of non-COVID-19 diagnostic test revenue for the three months ended September 30, 2020 and 2019, respectively. Diagnostic test revenue that were reimbursed by Medicare comprised 61% and 58% of non-COVID-19 diagnostic test revenue for the nine months ended September 30, 2020 and 2019, respectively. Two services customers comprised 53% and 85% of services revenue for the nine months ended September 30, 2020 and 2019, respectively. For the three and nine months ended September 30, 2020, three health care providers comprised 62% and 42% of diagnostic test revenue, respectively.

Revenue from diagnostic tests are recognized when the performance obligation is satisfied, which is when a customer receives results of the Company's tests, occurring generally upon delivery to the requesting physician. Revenue from services are recognized when the performance obligation is satisfied, which is when a customer receives results of the Company's tests, occurring generally upon the delivery of test results for assay development and testing services. The Company also provides services to patients with whom the Company does not have contracts as defined in ASC 606, *Revenue from Contracts with Customers* (ASC 606). The Company recognizes revenue for these patients when contracts as defined in ASC 606 are established at the amount of consideration to which it expects to be entitled or when the Company receives substantially all of the consideration subsequent to the performance obligations being satisfied.

The Company determines the transaction price related to its diagnostic test contracts by considering the nature of the payer and historical price concessions granted to groups of customers. For diagnostic test revenue, the Company estimates the transaction price, which is the amount of consideration it expects to be entitled to receive in exchange for providing services based on its historical collection experience, using a portfolio approach as a practical expedient to account for patient contracts as collective groups rather than individually.

(q) Deferred Revenue

Deferred revenue has historically primarily consisted of research, development, and testing services fee payments received in advance. As of September 30, 2020, deferred revenue also includes $3.5 million in a Medicare advance payment on testing services which can either be paid back or earned back starting 1 year from receipt.

(r) Research and Development Expenses and Accrued Research and Development Expenses

Expenditures made for research and development are charged to expense as incurred. External costs consist primarily payments to clinical trial sites, sample acquisition costs and laboratory supplies purchased in connection with the Company's discovery and preclinical activities, process development and clinical development activities. Internal costs consist primary of employee-related costs, facilities, depreciation and costs related to compliance with regulatory requirements.

The Company estimates and accrues its expenses resulting from its obligations under contracts with vendors and consultants in connection with conducting research and development activities. The financial terms of these contracts vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company's estimates depend on the timeliness and accuracy of the data provided by consultants and vendors regarding the status of each activity. The Company periodically evaluates the estimates to determine if adjustments are necessary or appropriate based on information received.

(s) Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees and recognizes compensation expense for stock-based awards based on the estimated fair value of the awards. Compensation expense for all employee stock-based awards is based on the estimated grant-date fair value and recognized as an expense on a straight-line basis over the requisite service period (generally the vesting period).

(t) Income Taxes

The Company recognizes deferred tax assets and liabilities based on the differences between the tax basis of assets and liabilities and their reported amounts in the financial statements and net operating loss carryforwards that will result in taxable or deductible amounts in future years. The Company establishes a valuation allowance for all deferred tax assets to the extent it is more likely than not that a deferred tax asset will not be realized.

(u) Warrant Liability

Freestanding financial instruments that permit the holder to acquire shares that are either puttable by the holder, redeemable or contingently redeemable are required to be reported as liabilities in the financial statements. The issuer must present such liabilities on the balance sheets at their estimated fair values. Changes in fair value of the liability are calculated each reporting period, and any change in value is recognized in operations. The Company has determined that certain warrants issued to investors and lenders, which are exercisable for shares of the Company's convertible preferred stock, shall be classified as liabilities due to a contingent redemption provision.

(v) Changes in Fair Value of Contingent Consideration

In connection with the purchase transaction with Integrated Diagnostics, Inc. ("Indi"), the Company recorded contingent consideration pertaining to the amounts potentially payable to Indi's shareholder pursuant to the terms of the asset purchase agreement. The fair value of contingent consideration is assessed at each balance sheet date and changes, if any, to the fair value are recognized as operating expenses within the statements of operations.

The estimated fair value of the contingent consideration is based upon significant assumptions including probabilities of successful achievement of the related milestone event ("Milestone"), the estimated timing in which the Milestone is achieved, and discount rates. The estimated fair value could materially differ from actual values or fair values determined using different assumptions.

(w) Fair Value of Financial Instruments

The carrying amounts of financial instruments, including cash and cash equivalents, receivables, other current assets, accounts payable, and accrued liabilities, approximated fair value as of September 30, 2020 and December 31, 2019 because of the relatively short maturity of these instruments.

The carrying amounts of long-term notes payable and convertible notes payable issued approximated fair value as of September 30, 2020 and December 31, 2019 because interest rates on these instruments approximate market interest rates.

(x) Business Combinations

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination by assessing whether or not the Company has acquired inputs and processes that have the ability to create outputs. If determined to be a business combination, the Company accounts for business acquisitions under the acquisition method of accounting as indicated in the Financial Accounts Standards Board ("FASB") issued Accounting Standards Codification ("ASC") Topic 805, *Business Combinations* ("ASC 805"), which requires the acquiring entity in a business combination to recognize the fair value of all assets acquired and liabilities assumed and establishes the acquisition date as the fair value measurement point. Accordingly, the Company recognizes assets acquired and liabilities assumed in business combinations, including contingent assets and liabilities, and non-controlling interest in the acquiree based on the fair value estimates as of the date of acquisition. In accordance with ASC 805, the Company recognizes and measures goodwill as of the acquisition date, as the excess of the fair value of the consideration paid over the fair value of the identified net assets acquired.

(y) Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity issuances as deferred offering costs until such equity issuances are consummated. After consummation of the equity issuance, these costs are recorded as a reduction in the capitalized amount associated with the equity issuance. Should the equity issuance be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the unaudited condensed consolidated statement of operations. Upon the IPO closing in October 2020, deferred offering costs were reclassified to additional paid-in capital, representing a reduction in IPO proceeds. As of September 30, 2020 and December 31, 2019, the Company had deferred offering costs of $1.4 million and $0, respectively, which are included in other current assets in the accompanying balance sheets.

(z) Recently Issued Accounting Standards Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASC Topic 842). The new guidance maintains two classifications of leases: finance leases, which replace capital leases, and operating leases. Lessees will need to recognize a right-of-use asset and a lease liability on the statement of financial position for those leases previously classified as operating leases under the old guidance. The liability will be equal to the present value of lease payments. The asset will be based on the liability, subject to adjustment, such as for direct costs. The accounting standard will be effective for the Company beginning January 1, 2022. The Company is currently evaluating the impact of the lease guidance on the Company's financial statements.

(aa) Net loss per share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the convertible preferred stock, common stock options, restricted stock units, preferred stock warrants and convertible debt are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the convertible preferred stock is considered a participating security. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. As the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

The following table sets forth the computation of the basic and diluted net loss per share attributable to common stockholders (in thousands, except per share amounts):

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Numerator				
Net loss attributable to common stockholders	$ (8,845)	$ (9,601)	$ (26,817)	$ (24,201)
Denominator				
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	277	244	269	233
Net loss per share, basic and diluted	$ (31.93)	$ (39.35)	$ (99.69)	$ (103.87)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been anti-dilutive for the three and nine month periods ended September 30, 2020 and 2019 (in thousands):

	Nine months ended September 30,	
	2020	2019
Options to purchase common stock	2,843	2,010
Convertible preferred stock	119,257	119,257
Warrants	613	2,440
Restricted stock units	79	26
Convertible debt (1)	20,746	16,240
Total	143,538	139,973

(1) The number of common shares that convertible debt was assumed to convert to was based on the Company's estimated common stock price as of September 30, 2020, as determined by the Company's board of directors ("Board of Directors") with assistance from a valuation firm.

Note 2 – Business Combinations

Oncimmune Limited

On October 31, 2019, the Company purchased select assets and liabilities from Oncimmune Limited ("Oncimmune") for total consideration of $1.2 million payable in quarterly installments commencing 30 days following the closing of the transaction. Concurrent with the Oncimmune purchase, the Company acquired an option to license rights within the United States to an additional indication for their product for $9.0 million. This option, which is exclusive to the Company, expires on the earlier of 30 days following Food and Drug Administration approval or December 31, 2020. As of September 30, 2020, (a) the full $1.2 million has been paid-out and (b) the Company notified Oncimmune that it will not exercise this option for expansion of the field of use.

The Company accounted for the transaction as a business combination in accordance with ASC 805. As such, the assets acquired and liabilities assumed were recorded at fair value, with the remaining purchase price recorded as goodwill. The goodwill associated with the acquisition is the result of expected synergies, an increase in future revenue as a result of,the expansion of the technology into additional markets, and lower future operating expenses.

The following summarizes the aggregate consideration paid by the Company and the allocation of the purchase price (in thousands):

Cash	$	1,206
Total fair value of consideration transferred	$	1,206
Deposit	$	6
Inventory		14
Property and equipment		241
Purchase option		121
Goodwill		827
Accrued liabilities		(3)
	$	1,206

As of December 31, 2019, the Company has finalized its accounting for this business combination.

Integrated Diagnostics, Inc.

On June 30, 2018, the Company purchased select assets and liabilities from Indi for total consideration of $27.6 million, consisting of $8.0 million (10,649,604 shares) of the Company's Series G Preferred Stock and contingent consideration with an initial fair value of $19.6 million. The 10,649,904 shares issued at closing include 2,129,981 shares that were deposited in an escrow account to be used to satisfy any indemnification obligations of Indi that may arise.

The Company accounted for the transaction as a business combination in accordance with ASC 805. As such, the assets acquired and liabilities assumed were recorded at fair value, with the remaining purchase price recorded as goodwill. The estimated fair values of acquired assets and assumed liabilities were determined by management with the assistance of an independent third party. The goodwill associated with the acquisition is the result of expected synergies, an increase in future revenues as a result of the expansion of the technology into additional markets, as well as lower future operating expenses.

The following summarizes the aggregate consideration paid by the Company and the allocation of the purchase price (in thousands):

Preferred stock issued - 10,694,904 shares	$	7,987
Contingent consideration		19,600
Total fair value of consideration transferred	$	27,587
Prepaid expenses and other assets	$	50
Inventory		394
Property and equipment		316
Technology		16,900
Goodwill		10,804
Liabilities		(877)
	$	27,587

The acquisition of Indi included a contingent consideration arrangement that requires additional consideration to be paid by the Company to Indi based on the Milestone of the attainment of a three consecutive month gross margin target of $2 million within a seven-year period after the acquisition date. For the six months following the achievement of the Milestone, Indi has the option to require the Company to pay the contingent consideration in cash over eight equal installments due each calendar quarter or to require the issuance of additional shares of Series G preferred stock. The total amount of undiscounted contingent consideration which the Company may be required to pay under the arrangement is $37.0 million. If Indi elects not to exercise these options, the Company has 12 months to settle the contingent consideration in either two equal quarterly cash installments or in 14,959,114 shares of Series G Preferred Stock.

The fair value of $19.6 million contingent consideration recognized on the acquisition date was estimated by management with the assistance of an independent third party. These fair value measurements were based on significant inputs not observable in the market and thus represent Level 3 fair value measurements. See Note 3, Fair Value Accounting, for a discussion of the fair value of the contingent consideration and changes in fair value subsequent to the acquisition date.

Intangible assets acquired, amortization method and estimated useful lives as of June 30, 2018 was as follows (dollars in thousands):

	Useful Life	Amortization Method	Fair Value
Technology	9 years	Straight-line	$ 16,900

The technology acquired from Indi consisted of the technology and related know-how of the XL2 test which Indi had developed. The fair value of the technology was estimated by applying a multi-period excess earnings method. The results of this method are based on significant inputs that are not observable in the market, or Level 3 inputs (see discussion of the fair value hierarchy in Note 3). Key assumptions included (a) projected revenue and related profitable attributable to the acquired technology over the estimated life of the acquired technology and (b) a discount rate of 37.5%.

As of December 31, 2018, the Company had finalized its accounting for this business combination.

Note 3 - Fair Value Accounting

The Company accounts for certain assets and liabilities that are required to be recorded at fair value under a framework for measuring fair value that requires enhanced disclosures about fair value measurements. This framework requires disclosure about how fair value is determined for assets and liabilities and establishes a hierarchy for which these assets and liabilities must be grouped based on significant levels of inputs as follows:

Level 1: Quoted prices in active markets for identical assets or liabilities;

Level 2: Quoted prices in active markets for similar assets and liabilities and inputs that are observable for the asset or liability; or

Level 3: Unobservable inputs in which there is little or no market data, which requires the reporting entity to develop its own assumptions.

The determination of where assets and liabilities fall within this hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The following tables set forth by level, within the fair value hierarchy, the Company's liabilities measured at fair value on a recurring basis (in thousands):

September 30, 2020:

Description	Level 1	Level 2	Level 3	Total
Warrant liability	$ —	$ —	$ 403	$ 403
Contingent value rights	$ —	$ —	$ —	$ —
Contingent consideration	$ —	$ —	$ 30,071	$ 30,071
Put option liability	$ —	$ —	$ 6,650	$ 6,650

December 31, 2019:

Description	Level 1	Level 2	Level 3	Total
Warrant liability	$ —	$ —	$ 372	$ 372
Contingent value rights	$ —	$ —	$ 60	$ 60
Contingent consideration	$ —	$ —	$ 29,114	$ 29,114
Put option liability	$ —	$ —	$ 3,261	$ 3,261

Due to the unobservable inputs needed to calculate the fair value of these balances, these liabilities are classified as Level 3 liabilities. The following is a reconciliation of the beginning and ending balances for the nine-month period ended September 30, 2020 for assets measured at fair value on a recurring basis using significant unobservable inputs (in thousands):

Warrant liability		
Beginning balance	$	372
Issuances		—
Exercises		—
Change in fair value		31
Ending balance	$	403
Contingent value rights		
Beginning balance	$	60
Issuances		—
Exercises		—
Change in fair value		(60)
Ending balance	$	—
Put option liability		
Beginning balance	$	3,261
Additions		3,389
Ending balance	$	6,650
Contingent consideration		
Beginning balance	$	29,114
Additions		—
Changes in fair value		(1,944)
Accretion		2,901
Payments		—
Ending balance	$	30,071

There were no changes to the valuation methods during the months presented.

See Note 11 for further discussion of preferred stock warrants.

In addition to the shares of Series F Preferred Stock that were issued in January 2016, investors who purchased more than their pro-rata amount in the financing described above received a calculated number of contingent value rights ("CVRs"), but only to the extent that the total amount raised in the financing exceeded $20,202,323. One CVR represents 0.00375% of the Company's interest in the drug ficlatuzumab (see Note 8). In connection with the Series F financing, the Company issued 3,999 CVRs originally valued at $0.5 million. The initial estimated value of the CVRs were recorded as a liability and as a reduction to the Series F proceeds. Upon receipt by the Company or a milestone, royalty, or any other type of payment from the Company’s ownership rights in the drug, the Company will make a cash payment to the CVR holders equal to 15% of net proceeds, as defined. In addition, the CVRs will be adjusted to their estimated fair values each reporting period. In September 2020, the Company exercised its opt-out right with AVEO (as defined below) for the of payment of 50% of development and regulatory costs for ficlatuzumab which will be effective December 2, 2020. At September 30, 2020, the Company recorded a liability of $0.3 million for the remainder of these development and regulatory costs. The value of these CVRs was $0 as of September 30, 2020.

The put option liability was valued based on the calculated returns as a result of the various discounts included in the Company’s convertible notes payable and the related probability assessments of the various settlement scenarios that the discounts apply to. See Note 5 for further disclosure of the discounts and settlement scenarios.

Contingent Consideration

In connection with the transaction with Indi, the Company recorded contingent consideration pertaining to the amounts potentially payable to Indi's selling shareholders pursuant to the Asset Purchase Agreement (See Note 2). Contingent consideration is measured at fair value and is based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The valuation of contingent consideration uses assumptions the Company believes would be made by a market participant. The Company assesses these estimates on an on-going basis as additional data impacting the assumptions is obtained. Future changes in the fair value of contingent consideration related to updated assumptions and estimates are recognized within the statements of operations.

Contingent consideration may change significantly as development progresses and additional data are obtained, impacting the Company's assumptions regarding probabilities of successful achievement of related Milestone used to estimate the fair value of the liability and the timing in which they are expected to be achieved. In evaluating the fair value information, considerable judgment is required to interpret the market data used to develop the estimates. The estimates of fair value may not be indicative of the amounts that could be realized in a current market exchange. Accordingly, the use of different market assumptions and/or different valuation techniques could result in materially different fair value estimates. The fair value of the Company's contingent consideration liability was estimated using significant unobservable inputs. The fair value of $19.6 million contingent consideration recognized on the acquisition date was estimated by management with the assistance of an independent third party.

Changes in the fair value measurement each period reflect the passage of time as well as the impact of adjustments, if any, to the likelihood of achieving the specified targets. Contingent consideration is recorded in the balance sheets in long-term liabilities. The change to contingent consideration during the three and nine months ended September 30, 2020 was primarily due to $1.0 million and $2.9 million, respectively, resulting from the accretion of the liability offset by $0 and $1.9 million due to the impact of the deceleration of expected revenue and decreases in expected costs, respectively. The $3.2 million change to the contingent consideration during the nine months ended September 30, 2019 was primarily due to $0.7 million resulting from the impact of the acceleration of expected revenue and decreases in expected costs as a result of events occurring after the acquisition date, as well as $2.5 million resulting from the from the accretion of the liability. For the three months ended September 30, 2019, there was a $0.9 million change to the contingent consideration resulting from the accretion of the liability.

The significant unobservable inputs used in the measurement of fair value of the Company's contingent consideration are probabilities of successful achievement of the Milestone, the period in which the Milestone is expected to be achieved and discount rates ranging from 12.2% to 13.5%. Significant increases or decreases in any of these inputs would result in a significantly higher or lower fair value measurement.

Note 4 - Balance Sheet Disclosures

Property and equipment consist of the following (in thousands):

	September 30, 2020	December 31, 2019
Lab equipment	$ 5,741	$ 4,221
Leasehold improvements	1,778	1,894
Computer equipment	871	869
Furniture and fixtures	424	427
Software	633	503
Construction in process	40	592
	9,487	8,506
Less accumulated depreciation	(6,482)	(6,386)
Total property and equipment	$ 3,005	$ 2,120

Depreciation expense for each of the three and nine months ended September 30, 2020 and 2019 was $$0.2 million and 0.6 million, respectively.

Intangible assets consist of the following (in thousands):

	September 30, 2020	December 31, 2019
Patents	$ 1,393	$ 1,245
Less accumulated amortization	(475)	(411)
	$ 918	$ 834
Purchased technology	$ 16,900	$ 16,900
Less accumulated amortization	(4,225)	(2,817)
	$ 12,675	$ 14,083
Purchase option	—	$ 121
Less accumulated amortization	—	(17)
	$ —	$ 104
Trademarks (indefinite life)	$ 74	$ 71
Total intangible assets	$ 13,667	$ 15,092

The Company recorded amortization expense of $0.5 million and $1.6 million for the three and nine months ended September 30, 2020, respectively, and $0.5 million and $1.5 million for the three and nine months ended September 30, 2019, respectively. Amortization related to the remaining net intangible assets is scheduled to amortize as follows (in thousands):

Year Ending December 31,	
Remainder of 2020	$ 489
2021	1,944
2022	1,938
2023	1,936
2024	1,927
Thereafter	5,359
Total future amortization expense	$ 13,593

Accrued liabilities consist of the following (in thousands):

	September 30, 2020	December 31, 2019
Compensation related accruals	$ 2,688	$ 1,165
Accrued clinical trial expense	699	620
Other expenses	3,566	2,352
Warrant liability, current	—	43
Total accrued liabilities	$ 6,953	$ 4,180

Note 5 - Convertible Notes Payable

In March 2020, the Company issued $10 million of convertible notes (the “March 2020 Notes”) scheduled to mature in August 2020. In August 2020, the maturity date of this debt was extended to June 30, 2021. The March 2020 Notes were issued in two tranches of $5 million, with the first tranche funded in March 2020 and the second tranche funded in June 2020. Interest on the March 2020 Notes was 3% per annum and is payable in full upon maturity through the conversion to Series H Preferred Stock at 80% of the original issuance price of $1.15 per share. Under the terms of the March 2020 Notes, on or before the maturity date and if the March 2020 Notes are unpaid, the outstanding principal and unpaid accrued interest under the March 2020 Notes shall be automatically converted into, the earlier of, the preferred stock sold at the close of the Company’s next equity financing (“Qualified Financing”) or

common stock in an IPO. The conversion price would be equal to 80% of the price per share paid for the preferred stock in the Qualified Financing or common stock sold in an IPO. The discounts on the automatic conversions created a put option liability that was separated from the March 2020 Notes. The estimated value of the put option liability as of the issuance of the March 2020 Notes was $2.5 million. The put option liability was reflected as a debt discount on the March 2020 Notes which is being amortized over the term of the March 2020 Notes. There was no unamortized debt discount as of September 30, 2020. Following the closing of the IPO in October 2020, the March 2020 Notes automatically converted into 703,503 shares of our common stock at a conversion price of $14.40, which is equal to 80% of the price per share paid for the common stock sold in the IPO.

In December 2019, the Company issued $6 million of convertible notes (the "December 2019 Notes") that were scheduled to mature in August 2020. In August 2020, the maturity date of this debt was extended to June 30, 2021. The December 2019 Notes were issued in two tranches of $3 million, with the first tranche funded in December 2019 and the second tranche funded in February 2020. Interest on the December 2019 Notes was 3% per annum and payable in full upon maturity through the conversion to Series H Preferred Stock at 80% of the original issuance price of $1.15 per share. Under the terms of the December 2019 Notes, on or before the maturity date and if the December 2019 Notes are unpaid, the outstanding principal and unpaid accrued interest under the December 2019 Notes shall be automatically converted into, the earlier of, the preferred stock sold at the close of the Company's next Qualified Financing or common stock in an IPO. The conversion price would be equal to 80% of the price per share paid for the preferred stock in the Qualified Financing or common stock sold in an IPO. The discounts on the automatic conversions created a put option liability that was separated from the December 2019 Notes. The estimated value of the put option liability as of the issuance of the December 2019 Notes was $1.5 million for each tranche issued. The put option liability was reflected as a debt discount on the December 2019 Notes which is being amortized over the term of the December 2019 Notes. The unamortized debt discount was $0 and $0.7 million as of September 30, 2020 and December 31, 2019, respectively. Following the closing of the IPO in October 2020, the December 2019 Notes automatically converted into 426,386 shares of our common stock at a conversion price of $14.40, which is equal to 80% of the price per share paid for the common stock sold in the IPO.

In August and September 2019 (the "August 2019 Notes"), the Company issued $10 million of convertible notes that were scheduled to mature in August 2020. In August 2020, the maturity date of this debt was extended to June 30, 2021. Interest on the August 2019 Notes was 3% per annum and payable in full upon maturity through the conversion to Series H Preferred Stock at the original issuance price of $1.15 per share. Under the terms of the August 2019 Notes, on or before the maturity date and if the August 2019 Notes are unpaid, the outstanding principal and unpaid accrued interest under the August 2019 Notes shall be automatically converted into, the earlier of, the preferred stock sold at the close of the Company's next Qualified Financing or common stock sold in the event of an IPO. The conversion price would be equal to 95% of the price per share paid for the preferred stock in the Qualified Financing or common stock sold in an IPO. The discounts on the automatic conversions created a put option liability that was separated from the August 2019 Notes. The estimated value of the put option liability as of the issuance of the August 2019 Notes was $0.5 million. The put option liability was reflected as a debt discount on the August 2019 Notes which is being amortized over the term of the August 2019 Notes. The unamortized debt discount was $0 and $0.3 million as of September 30, 2020 and December 31, 2019, respectively. Following the closing of the IPO in October 2020, the August 2019 Notes automatically converted into 718,391 shares of our common stock at a conversion price of $14.40, which is equal to 80% of the price per share paid for the common stock sold in the IPO.

In connection with the issuance of the December 2019 Notes, the conversion price on the August 2019 Notes was amended to 80% of the price per share paid for the preferred stock in the Qualified Financing or common stock in an IPO. In addition, the conversion price to Series H preferred stock at the maturity date was amended to be 80% of the Series H original issuance price of $1.15 per share. The changes to the discounts on the conversions of the August 2019 Notes created an increase to the put option liability on the August 2019 Notes of $2 million to a total estimated value of $2.5 million as of December 31, 2019. The increase in the value of the put option liability was reflected as a change in put option in the 2019 statement of operations.

A summary of convertible notes payable is as follows (in thousands):

	September 30, 2020	December 31, 2019
March 2020 Notes	$ 10,000	$ —
December 2019 Notes	6,000	3,045
August 2019 Notes	10,000	10,000
Accrued interest	600	114
Unamortized debt discount	—	(1,000)
	$ 26,600	$ 12,159

Note 6 – Long-Term Debt

Paycheck Protection Program Note Payable

In April 2020, the Company entered into a loan pursuant to the Paycheck Protection Program under the CARES Act, as administered by the U.S. Small Business Administration (the "SBA"). The loan, in the principal amount of $3.1 million (the "PPP Loan"), was disbursed by JPMorgan Chase Bank ("Lender") pursuant to a Paycheck Protection Program Promissory Note and Agreement (the "Note and Agreement").

The PPP Loan matures on the two-year anniversary of the funding date and bears interest at a fixed rate of 1.00% per annum. Monthly principal and interest payments, less the amount of any potential forgiveness (as discussed below), will commence after the ten-month anniversary of the funding date. The Company did not provide any collateral or guarantees in connection with the PPP Loan, nor did the Company pay any facility charge to obtain the PPP Loan. The Note and Agreement provides for customary events of default, including those relating to failure to make payment, bankruptcy, breaches of representations and material adverse effects. The Company may prepay the principal of the PPP Loan at any time without incurring any prepayment charges.

All or a portion of the PPP Loan may be forgiven by the SBA and the Lender upon application by the Company. Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, and covered utilities during the eight-week period beginning on the approval date of the PPP Loan. For purposes of the CARES Act, payroll costs exclude compensation of an individual employee earning more than $100,000, prorated annually. Not more than 40% of the forgiven amount may be for non-payroll costs. Forgiveness is reduced if full-time headcount declines, or if salaries and wages for employees with salaries of $100,000 or less annually are reduced by more than 25%. The Company cannot assure that the PPP Loan will be forgiven, in whole or in part.

The Company accounts for the PPP Loan as debt in accordance with FASB ASC 470, *Debt* and accrues interest in accordance with the interest method. If the loan is forgiven in part or in whole, and legal release is received, the Company will reduce the liability by the amount forgiven and record a gain on extinguishment in the statement of operations.

Note Payable

In February 2018, the Company extinguished a Note that originated in 2013 (the "2013 Notes") through the issuance of new long-term debt with Innovatus Life Sciences Lending Fund ("Innovatus") (the "2018 Notes"). The lender for the 2018 Notes is also a holder of the Company's Series G preferred stock.

The initial amount borrowed under the 2018 Notes was $23 million and the maturity date is February 2023. At the time of the issuance of the 2018 Notes, the Company paid a 1% facility fee of $0.2 million and issued a warrant to the private investment company for the purchase of 613,333 shares of Series G preferred stock, which had an initial fair value of $0.3 million. The facility fee and the value of the warrants were recorded as reductions to the carrying value of the 2018 Notes and are being amortized to interest expense over the term of the 2018 Notes. The 2018 Notes bears interest at 10% with 7.5% being paid in cash and 2.5% being added to the principal value of the 2018 Notes through December 31, 2020. The Company is required to make quarterly interest payments beginning in June 2018 and outstanding principal is due in 24 equal installments commencing in March 2021. As of September 30, 2020 and December 31, 2019, the interest added to the principal value of the 2018 Notes was $1.5 million and $1.1 million, respectively.

The loan may be prepaid by the Company at any time, subject to a prepayment penalty of up to 3% of the principal amount, depending on the date of prepayment. Upon payment of the 2018 Notes at maturity or prepayment on any earlier date, unless waived, a 2% back-end facility fee will apply to the amounts paid or prepaid. The 2% fee is being recorded as additional interest expense over the term of the 2018 Notes. The 2018 Notes are senior to all of the Company's other indebtedness including any contingent consideration payable to Indi.

The 2018 Notes contain customary affirmative covenants, including covenants regarding compliance with applicable laws and regulations, payment of taxes, insurance coverage, notice of certain events, and reporting requirements. Further, the 2018 Notes contain customary negative covenants limiting the ability of the Company to, among other things, to incur future debt, transfer assets except for the ordinary course of business, make acquisitions, make certain restricted payments, and sell assets, subject to certain exceptions. In addition, the 2018 Notes require the Company to comply with a minimum daily liquidity covenant and a rolling monthly revenue requirement. Failure to comply with the covenants and loan requirements may result in early amortization of the loan in a 24- or 36-month payment schedule. As of September 30, 2020, the Company was not in default under the terms of the 2018 Notes.

In accordance with the 2018 Notes, the Company granted the lender a security interest in all of the Company's assets through a pledge and security agreement, patent security agreement and trademark security agreement, each between the Company and the lender.

Long-term notes payable as of September 30, 2020 and December 31, 2019 was as follows (in thousands):

	2020	2019
2018 Notes	$ 24,543	$ 24,088
Other	6	12
Final payment fee	238	170
Unamortized debt discount and debt issuance costs	(349)	(458)
	24,438	23,812
Less: current maturities	(7,202)	—
Long-term notes payable	$ 17,236	$ 23,812

Maturities of long-term obligations as of September 30, 2020 are as follows (in thousands):

Year Ending December 31,	
Remainder of 2020	$ —
2021	10,318
2022	12,199
2023	2,270
2024	—
Thereafter	—
	$ 24,787

In connection with entering into the 2018 Notes, the Company issued to the lender a warrant to purchase 613,333 shares of Series G convertible preferred stock, at an exercise price of $0.75 per share, subject to adjustment upon specified dilutive issuances. The warrant was immediately exercisable upon issuance and expires on February 23, 2028. The fair value of the warrant on the issuance date of $0.3 million was recorded as a debt discount and as a preferred stock warrant liability.

Note 7 - Income Taxes

Since inception, the Company has incurred net taxable losses, and accordingly, no current provision for income taxes has been recorded.

Note 8 – Commitments

Leases

The Company leases facilities under non-cancelable operating leases. Rent expense was $1.5 million and $1.6 million for the nine months ended September 30, 2020 and 2019, respectively, and was inclusive of common area maintenance charges.

Future minimum lease payments for operating lease obligations, net of sublease income are as follows as of September 30, 2020 (in thousands):

Year Ending December 31,		
Remainder of 2020	$	246
2021		828
2022		729
2023		112
2024		—
Thereafter		—
	$	1,915

Co-Development Agreement

In April 2014 and amended in October 2016, the Company entered into a worldwide agreement with AVEO Oncology ("AVEO") to develop and commercialize AVEO's hepatocyte growth factor inhibitory antibody ficlatuzumab with the Company's proprietary companion diagnostic test, BDX004, a version of the Company's serum protein test that is commercially available to help physicians guide treatment decisions for patients with advanced non-small cell lung cancer ("NSCLC"). Under the terms of the agreement, AVEO will conduct a proof-of-concept ("POC") clinical study of ficlatuzumab for NSCLC in which BDX004 will be used to select clinical trial subjects (the "NSCLC POC Trial"). The Company and AVEO will share equally in the costs of the NSCLC POC Trial, and each will be responsible for 50% of development and regulatory costs associated with all future clinical trials agreed upon by the Company and AVEO. The Company and AVEO continue to conduct POC clinical trials of ficlatuzumab in combination with BDX004 with each responsible for 50% of development and regulatory costs.

In September 2020, the Company exercised its opt-out right with AVEO for the payment of 50% of development and regulatory costs for ficlatuzumab which will be effective December 2, 2020. The Company estimates it has $0.3 million in remaining obligations related to the AVEO agreement as of the opt-out date. Following the effective date, the Company will be entitled to a 10% royalty of net sales of ficlatuzumab and 25% of license income generated from the licensing of ficlatuzumab from AVEO.

Expenses related to this agreement for the three and nine months ended September 30, 2020 and 2019 were approximately $0.3 million and $1.0 million, and $0.7 million and $0.9 million, respectively.

License Agreement

In August 2019, we entered into a non-exclusive license agreement with Bio-Rad Laboratories, Inc. ("Bio-Rad") ("the Bio-Rad License"). Under the terms of the Bio-Rad License, the Company received a non-exclusive license, without the right to grant sublicenses, to utilize certain of Bio-Rad's intellectual property, machinery, materials, reagents, supplies and know-how necessary for the performance of Droplet Digital PCR (ddPCR) in cancer detection testing for third parties in the United States. The Company also agreed to purchase all of the necessary supplies and reagents for such testing exclusively from Bio-Rad, pursuant to a separately executed supply agreement (the "Supply Agreement") with Bio-Rad. As further consideration for the non-exclusive license, the Company agreed to pay a royalty of 2.5% on the net revenue received for the performance of such ddPCR testing collected from third parties. The Bio-Rad License expires in August 2024. Either party may terminate for the other's uncured material breach or bankruptcy events. Bio-Rad may terminate the Bio-Rad License if the Company does not purchase licensed products under the Supply Agreement for a consecutive twelve-month period or for any material breach by us of the Supply Agreement. The Company incurred royalty expense of $0.1 million and $0 for the nine months ended September 30, 2020 and 2019, respectively, under the Bio-Rad License.

Revenue Share Agreement

As part of the acquisition of Oncimunne, the Company entered into several agreements to govern the relationship between the parties. The Company agreed to a revenue share payment related to an acquired diagnostic test of 8% of recognized revenue for non-screening tests up to an annual minimum volume and 5% thereafter, with an escalating minimum through the first four years of sales. Revenue share expenses of $0 and $0.2 million were incurred for the three and nine months ended September 30, 2020, respectively.

Note 9 - Convertible Preferred Stock

The following table details, by series, the Company's convertible preferred stock at September 30, 2020 (in thousands, except shares and original issue price):

Series	Shares Authorized	Shares Issued and Outstanding	Defined Original Issue Price	Liquidation Preference
Series H	53,031,883	23,923,188	$ 1.15	$ 27,512
Series G	76,464,035	46,146,517	0.75	34,610
Series F	19,468,203	19,468,203	1.50	29,202
Series E	13,972,954	7,639,556	5.00	38,198
Series D	11,781,710	10,874,876	4.00	43,499
Series C	2,356,597	2,356,596	3.00	7,070
Series B-1	2,998,852	2,998,852	3.20	9,596
Series B	3,641,817	3,641,817	2.75	10,015
Series A-3	750,000	750,000	2.24	1,680
Series A-2	266,668	266,668	1.50	400
Series A-1	700,000	700,000	1.14	800
	185,432,719	118,766,273		$ 202,582

Series H

In February and March 2019, the Company issued 8,695,621 shares of Series H Preferred Stock at $1.15 per share for total cash proceeds of $10.0 million.

The Company’s convertible preferred stock has been classified as temporary equity in the accompanying balance sheets given that a majority of the Company’s Board of Directors seats are held by convertible preferred stock holders and could cause certain events to occur that are outside of the Company’s control whereby the Company could be obligated to redeem the convertible preferred stock. The Company has not adjusted the carrying values of the convertible preferred stock to the respective liquidation preferences of such shares as the instruments are currently not redeemable and the Company believes it is not probable that the instruments will become redeemable at this point in time. Adjustments to increase the carrying values to the respective liquidation preferences will be made if and when it becomes probable that an event would occur obligating the Company to pay such amounts.

Conversion Rights

The holders of Series A-1, Series A-2, and Series A-3 (collectively, “Series A”); Series B and Series B-1 (collectively, “Combined Series B”); Series C; Series D; Series E; Series F, Series G, and Series H are entitled to convert their shares into common stock at the option of the holder, at any time, into fully paid and non-assessable shares of common stock. The number of shares of common stock to which a holder of the Series A, Combined Series B, Series C, Series D, Series E, Series F, Series G, and Series H (collectively, “Series Preferred”) can convert is obtained by multiplying the conversion rate that is in effect by the number of shares of Series Preferred being converted. The conversion rate is determined by dividing the original issue price by the applicable conversion price (initially the original issue price for all classes of Series Preferred except Series B-1, for which the conversion price is initially $2.75). As a result of the reverse stock split effected in October 2020, the conversion rate for the Series Preferred is 0.1684664 per

share. Following the closing of the IPO in October 2020, each share of Series Preferred automatically converted into shares of common stock (based on the then-effective Series Preferred conversion price).

Dividend Rights

The Series Preferred holders are entitled to receive non-cumulative cash dividends. The dividends are required to be declared by the Board of Directors and are calculated at an annual rate of 8% of the original issue price of the respective Series Preferred shares. Series Preferred holders have the following order of preference on dividends: Series H holders, Series G holders, Series F holders, Series E holders, Series D holders, Series C holders, Combined Series B holders, Series A holders. The Series A holders have preference over the common stockholders. In the event that dividends are paid on any class of Series Preferred, the Company shall pay an additional dividend on all outstanding shares of a higher preference in a per-share amount on an as-if-converted-to-common-stock basis. In the event dividends are paid on any common stock, the Company shall pay an additional dividend on all outstanding shares of Series Preferred stock in a per-share amount on an as-if-converted-to-common-stock basis.

Voting Rights

The holders of each share of Series Preferred stock have the right to one vote for each share of common stock on an as-if-converted basis. When converted, the common stock and Series Preferred stockholders have equal voting and power rights.

As long as any Series Preferred stock remains outstanding, a majority vote of the respective class of holders would be required to amend any provisions of the Company's articles of incorporation or bylaws that would adversely affect them.

Redemption

Series Preferred stockholders are subject to automatic redemption in the consolidation or merger of the Company or sale of all or substantially all of the Company's assets in which the stockholders of the Company immediately prior to the transaction hold less than 50% of the outstanding securities of the surviving entity. Proceeds available for distribution from such transaction will be distributed consistent with a liquidation event.

Liquidation

In accordance with the articles of incorporation, upon a defined event of acquisition or asset transfer, liquidation, dissolution, or winding up of the Company, any amounts that are available for distribution are to be paid out to its stockholders in the following order of preference, in an amount equal to the per-share original issue price, plus any accrued, declared, and unpaid dividends: Series H holders, Series G holders, Series F holders, Series E holders, Series D holders, Series C holders, Combined Series B holders, Series A holders. If the assets of the Company are insufficient to make payments in full to a class of holders of preferred stock, in the order of preference previously described, then remaining assets shall be distributed among the holders of that class of preferred stock ratably in proportion to the full amounts to which they would otherwise be respectively entitled and the holders of lower preference shares will receive nothing. Upon payment of all preferential amounts required to be paid to the Series Preferred, the holders of common stock and Series Preferred shall be entitled to receive a ratable portion, calculated on an as-if-converted basis, of the remaining assets of the Company available for distribution to its stockholders.

Note 10 – Stock Options

In May 2006, the Company adopted the 2006 Employee, Director, and Consultant Stock Plan (the “2006 Plan’) under which the Company is authorized to grant stock awards to employees, directors, and consultants of the Company. The Company is authorized to grant incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, and stock appreciation rights up to 831,389 total shares of stock awards. The award price and vesting terms are determined by the Board of Directors of the Company and evidenced in the award agreement extended to the employee, director, or consultant. The options granted generally terminate ten years from the date of grant and vest over various periods as determined by the Board of Directors of the Company.

In February 2016, the Company adopted the 2016 Equity Incentive Plan (“2016 Plan’) as a successor to and continuation of the 2006 Plan. As of February 2016, no additional stock awards may be granted under the 2006 Plan and any unallocated shares remaining available for issuance pursuant to the exercise of options or issuance or settlement of stock awards not previously granted under the 2006 Plan will cease to be available under the 2006 Plan and will be added to the share reserve of the 2016 Plan and be

immediately available for issuance pursuant to the stock awards granted in the 2016 Plan. In addition, all outstanding stock awards granted under the 2006 Plan will remain subject to the terms of the 2006 Plan unless they expire, terminate or are forfeited, cancelled or otherwise returned to the Company and will immediately be added to the share reserve and become available for issuance under the 2016 Plan.

Under the 2016 Plan, the Company is authorized to grant stock awards to employees, directors, and consultants of the Company. The Company is authorized to grant incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, and stock appreciation rights up to 1,431,964 total shares, plus any shares subject to outstanding stock awards granted under the 2006 Plan. The award price and vesting terms are determined by the Board of Directors of the Company and evidenced in the award agreement extended to the employee, director, or consultant. The options granted generally terminate 10 years from the date of grant and vest over various periods as determined by the Board of Directors of the Company.

The following table presents the activity for options and restricted stock units (RSUs) outstanding (in thousands, except for weighted average exercise price and weighted average grant date value per share):

	Stock Options	Weighted Average Exercise Price	RSUs	Weighted Average Grant Date Value Per Share
Outstanding - December 31, 2019	1,916	$ 1.73	26	$ 0.78
Granted	829	2.67	53	0.78
Forfeited/canceled	(40)	0.83	—	—
Exercised	(35)	0.53	—	—
Outstanding - September 30, 2020	2,670	$ 2.05	79	$ 0.78

The following table presents the composition of options outstanding and exercisable as of September 30, 2020 (in thousands, except price and life):

	Options Outstanding			Options Exercisable	
Exercise Prices	Number	Price*	Life (years)*	Number	Price*
$0.42 - $0.83	1,922	$ 0.65	7.9	711	$ 0.65
$2.61 - $3.74	157	3.15	2.7	136	3.38
$4.39 - $4.45	113	4.39	4.0	113	4.39
$6.83	478	6.83	9.2	307	6.83
Total - September 30, 2020	2,670	$ 2.05	7.7	1,267	$ 2.79

* Price and Life reflect the weighted average exercise price and weighted average remaining contractual life, respectively.

There were 79,000 and 26,000 restricted stock units outstanding at September 30, 2020 and December 31, 2019, respectively, none of which had vested as of September 30, 2020.

Fair Value of Common Stock

Prior to the Company's IPO, the fair value of the Company's common stock underlying the stock options was determined by the Board of Directors with assistance from management and, in part, on input from an independent third-party valuation firm. The Board of Directors determines the fair value of common stock by considering a number of objective and subjective factors, including valuations of comparable companies, sales of convertible preferred stock, operating and financial performance, the lack of liquidity of the Company's common stock and the general and industry-specific economic outlook. Subsequent to the Company's IPO, the fair value of the Company's common stock is determined based on its closing market price.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions for the nine months ended September 30, 2020 (dollars in thousands):

Approximate risk-free rate		0.50%
Average expected life		5.63
Dividend yield		—%
Volatility		77%
Estimated fair value of total options granted	$	362

The Company estimates volatility based on the historical volatility of its peer group and average expected life based on the review of historical exercise behavior of option grants with similar vesting periods. The expense recorded for options granted under the 2016 Plan is net of estimated forfeitures of 10%.

The following table presents the impact of employee stock-based compensation expense on statements of income line items for the periods indicated (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Research and development	$ 10	$ 10	$ 20	$ 25
Sales, marketing, general and administrative	90	35	135	100
Total stock-based compensation expense	$ 100	$ 45	$ 155	$ 125

The unrecognized remaining stock-based compensation balance for shares issued inside of the 2016 Plan was approximately $0.5 million as of September 30, 2020 which will be amortized over the next three years.

As of September 30, 2020, the Company has issued a total of 205,199 stock options outside the 2006 Plan to employees of the Company. These options are issued at the discretion of the Board of Directors of the Company to the Chief Executive Officer and their direct reports who wish to convert all or a portion of their incentive compensation to options. The value of the options at the date of grant was calculated using the Black-Scholes option pricing model using approximately the same assumptions as in the previous table other than the term, which is approximately five years. As of September 30, 2020, 173,233 options outside of the 2006 Plan are outstanding and exercisable and have a weighted average exercise price of $11.11, a weighted average remaining life of six years, and were fully vested on the grant date. There was no unrecognized remaining stock-based compensation balance for shares issued outside of the 2006 Plan as of September 30, 2020.

Note 11 – Warrants for Convertible Preferred Stock

The Company has issued warrants to purchase shares of preferred stock in conjunction with the sale of certain preferred shares and certain debt issuances. The grant date fair value and fair value at each reporting date of the warrants was determined using the Black-Scholes option pricing model with weighted average assumptions relatively consistent with those disclosed for stock options above, other than term, which is the contractual term of the warrant and the use of the exercise price and current estimated fair value of the respective series of preferred stock. The preferred warrants are classified as liabilities on the accompanying balance sheets as the underlying preferred stock has a contingent redemption feature. As these warrants are classified as a liability, they are revalued on each reporting date or exercise date, and any change in value is recorded to change in fair value of the warrant liability in the accompanying statements of operations.

The following table presents the activity for convertible preferred stock warrants outstanding (in thousands, except weighted average exercise price):

	Series E		Series G	
	Warrants	Weighted Average Exercise price	Warrants	Weighted Average Exercise price
Outstanding - December 31, 2019	925	$ 5.00	613	$ 0.75
Granted	—	—	—	—
Forfeited/canceled	(925)	(5.00)	—	—
Exercised	—	—	—	—
Outstanding - September 30, 2020	—	$ —	613	$ 0.75
Weighted average remaining contractual life at September 30, 2020			7.5 years	

Note 12 - Subsequent Events

In October 2020, the Company closed its IPO. See Note 1 (c) for further disclosure.

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

The following discussion of our financial condition and results of operations should be read together with our unaudited condensed financial statements and related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto and the related Management's Discussion and Analysis of Financial Condition and Results of Operations included in our final prospectus dated October 29, 2020 that forms a part of our Registration Statement on Form S-1 (File No. 333-249260), as filed with the Securities and Exchange Commission (SEC) pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the "Securities Act"), on October 29, 2020 (Prospectus).

In addition to historical financial information, this discussion and other parts of this report contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, based upon current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" under Part II, Item 1A below. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ from those anticipated. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

The following Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A), is provided to supplement the financial statements and the related notes in Item 1 of this Quarterly Report on Form10-Q. We intend for this discussion to provide you with information that will assist you in understanding our financial statements, the changes in key items in those financial statements from year to year and the primary factors that accounted for those changes.

Data for the three months ended September 30, and 2019 and for the nine months ended September 30, 2020 and 2019 has been derived from our unaudited condensed financial statements for the three months ended September 30, 2020 and 2019 and for the nine months ended September 30, 2020 and 2019 included in Item 1 of this Quarterly Report on Form 10-Q.

Overview

We are a leading data-driven diagnostic solutions company leveraging state of the art technologies with our proprietary AI platform to discover, develop, and commercialize solutions for clinical unmet needs, with a primary focus in lung disease. By combining a technology agnostic approach with a holistic view of the patient's disease state, we believe our solutions provide physicians with greater insights to help personalize their patient's care and meaningfully improve disease detection, evaluation, and treatment. Our unique approach to precision medicine provides timely and actionable clinical information, which we believe helps improve overall patient outcomes and lowers the overall healthcare cost by reducing the use of ineffective and unnecessary treatments and procedures. In addition to our diagnostic tests, we provide biopharmaceutical companies with services that include diagnostic research, clinical trial testing, and the discovery, development, and commercialization of companion diagnostics.

Our core belief is that no single technology will answer all clinical questions that we encounter. Therefore, we employ multiple technologies, including genomics, transcriptomics, proteomics, and radiomics, and leverage our proprietary AI platform, the Diagnostic Cortex, to discover innovative diagnostic tests for clinical use. The Diagnostic Cortex is an extensively validated deep learning platform optimized for the discovery of diagnostic tests, which we believe overcomes standard machine learning challenges faced in life sciences research. Our data-driven and technology agnostic approach is designed to enable us to discover diagnostic tests that answer critical clinical questions faced by physicians, researchers, and biopharmaceutical companies.

We continuously incorporate new market insights and patient data to enhance our platform through a data-driven learning loop. We regularly engage with our customers, key opinion leaders, and scientific experts to stay ahead of the rapidly evolving diagnostic and therapeutic landscape to identify additional clinical unmet needs where a diagnostic test could help improve patient care. Additionally, we incorporate clinical and molecular profiling data from our commercial clinical testing, research studies, clinical trials, and biopharmaceutical customers or academic partnerships, to continue to advance our platform. We have over 140,000 samples and data in our biobank, including tumor profiles and immune profiles, which are used for both internal and external R&D initiatives.

We have commercialized six diagnostic tests which are currently available for use by physicians. Our Nodify XL2 and Nodify CDT tests, marketed as part of our Nodify Lung Nodule Risk Assessment testing strategy, assess the risk of lung cancer to help identify the most appropriate treatment pathway. We believe we are the only company to offer two commercial blood-based tests to help physicians reclassify risk of malignancy in patients with suspicious lung nodules. Our GeneStrat and VeriStrat tests, marketed as part of our Biodesix Lung Reflex testing strategy, are used following diagnosis of lung cancer to measure the presence of mutations in

the tumor and the state of the patient's immune system to establish the patient's prognosis and help guide treatment decisions. The GeneStrat tumor profiling test and the VeriStrat immune profiling test have a three-day average turnaround time, providing physicians with timely results to facilitate treatment decisions. In response to the COVID-19 pandemic, through our partnership with Bio-Rad, we commercialized the Biodesix WorkSafe testing program. Our scientific diagnostic expertise, technologies, and existing commercial infrastructure enabled us to rapidly commercialize two FDA EUA-authorized tests, a part of our customizable program. Both diagnostic tests are owned and were developed by Bio-Rad and Bio-Rad has granted us permission to utilize both tests for commercial diagnostic services. HHS Secretary Azar declared a public health emergency for COVID-19 in February 2020 which justified the authorization of emergency use of diagnostic tests for the detection and/or diagnosis of COVID-19. The Bio-Rad SARS-CoV-2 ddPCR test and the Platelia SARS-CoV-2 Total Ab test have been granted FDA EUA pursuant to the current emergency declaration. The Bio-Rad SARS-CoV-2 ddPCR test was FDA EUA authorized on May 1, 2020, authorizing performance of the test in laboratories certified under Clinical Laboratory Improvement Amendments ("CLIA") to perform high complexity tests. The second test is the Platelia SARS-CoV-2 Total Ab test, which is an antibody assay intended for detecting a B-cell immune response to SARS-CoV-2, indicating recent or prior infection. The Platelia SARS-CoV-2 Total Ab test was FDA EUA authorized on April 29, 2020. Medical products that are granted an EUA are only permitted to commercialize their products under the terms and conditions provided in the authorization. The FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, if the conditions for the issuance of the EUA are no longer met, or if other circumstances make revocation appropriate to protect the public health or safety, and we cannot predict how long the EUAs for the SARS-CoV-2 tests will remain in place. Using the Bio-Rad SARS-CoV-2 ddPCR test and the Platelia SARS-CoV-2 Total Ab test, we operate and have commercialized the Biodesix WorkSafe testing program.

Prior to using the Bio-Rad tests as part of our testing program, we performed feasibility, verification, and validation studies, including developing software for process automation, sample accessioning, data management and reporting, all required to demonstrate the test operated as claimed by the manufacturer and as required by our certifying regulatory agencies for high complexity laboratory testing. We secured independent reference specimens run with EUA tests to validate these tests as fit for diagnostic use in our laboratories. Post-launch development support for these tests have included improvements in on-boarding new personnel, logistics of sample collection, sample receipt and data reporting, all required to support our testing program. Additional releases of the laboratory data management software are ongoing and planned for the foreseeable future.

These tests are utilized by healthcare providers, including hospitals and nursing homes, and are also offered to businesses and educational systems to assist in their back-to-work or back-to-school strategies. Recently we announced multiple partnerships for COVID-19 testing, and have entered into an agreement with the State of Colorado to be one of the diagnostic companies to support widespread COVID-19 testing for the State. Additionally, we recently announced that we will oversee and manage onsite testing and validating testing for the Big Ten Conference athletic competitions. To date, we have not derived significant revenues from these partnerships.

In addition to the six diagnostic tests currently on the market, we perform over 30 assays for research use as part of our laboratory services that have been used by over 50 biopharmaceutical customers and academic partners. All of our diagnostic testing is performed at one of our two certified, high-complexity clinical laboratories in Boulder, Colorado and De Soto, Kansas.

Since our inception, we have performed over 245,000 tests and continue to generate a large and growing body of clinical evidence consisting of over 275 clinical and scientific peer-reviewed publications and presentations. Through ongoing study of each of our tests, we continue to grow our depth of understanding of disease biology and the broad utility of each of our tests. We believe we are poised for rapid growth by leveraging our scientific development and laboratory operations expertise along with our commercial infrastructure which includes sales, marketing, reimbursement, and regulatory affairs.

In the United States, we market our tests to clinical customers through our targeted sales organization, which includes sales representatives that are engaged in sales efforts and promotional activities primarily to pulmonologists, oncologists, cancer centers and nodule clinics. We market our tests and services to biopharmaceutical customers globally through our targeted business development team, which promotes the broad utility of our tests and testing capabilities throughout drug development and commercialization which is of value to pharmaceutical companies and their drug-development process.

We have funded our operations to date principally from net proceeds from the sale of convertible preferred stock, revenue from diagnostic testing and services, and the incurrence of indebtedness. We had cash and cash equivalents of $6.3 million as of September 30, 2020 and $5.3 million as of December 31, 2019.

Factors Affecting Our Performance

We believe there are several important factors that have impacted our operating performance and results of operations, including:

- **Testing volume and customer mix.** Our revenues and costs are affected by the volume of testing and mix of customers from period to period. We evaluate both the volume of our commercial tests, or the number of tests that we perform for patients on behalf of clinicians, as well as tests for biopharmaceutical companies. Our performance depends on our ability to retain and broaden adoption with existing customers, as well as attract new customers. We believe that the test volume we receive from clinicians and biopharmaceutical companies are indicators of growth in each of these customer verticals. Customer mix for our tests has the potential to significantly impact our results of operations, as the average selling price for biopharmaceutical sample testing is currently significantly greater than our average selling price for clinical tests since we are not a contracted provider for, or our tests are not covered by all clinical patients' insurance. We evaluate our average selling price for tests that are covered by Medicare, Medicare Advantage and commercial payers to understand the trends in reimbursement and apply those trends to our revenue recognition policies. We expect our costs to significantly increase in 2020 and the beginning of 2021 due to a significant increase in demand for COVID-19 diagnostic testing and we expect our related revenues from such tests to also increase.

- **Reimbursement for clinical diagnostic testing.** Our revenue depends on achieving broad coverage and reimbursement for our tests from third-party payers, including both commercial and government payers. Payment from third-party payers differs depending on whether we have entered into a contract with the payers as a "participating provider" or do not have a contract and are considered a "non-participating provider." Payers will often reimburse non-participating providers, if at all, at a lower rate than participating providers.

  Historically, we have experienced situations where commercial payers proactively reduced the amounts they were willing to reimburse for our tests, and in other situations, commercial payers have determined that the amounts they previously paid were too high and have sought to recover those perceived excess payments by deducting such amounts from payments otherwise being made. When we contract to serve as a participating provider, reimbursements are made pursuant to a negotiated fee schedule and are limited to only covered indications. Becoming a participating provider generally results in higher reimbursement for covered indications and lack of reimbursement for non-covered indications. As a result, the impact of becoming a participating provider with a specific payer will vary. If we are not able to obtain or maintain coverage and adequate reimbursement from third-party payers, we may not be able to effectively increase our testing volume and revenue as expected. Additionally, retrospective reimbursement adjustments can negatively impact our revenue and cause our financial results to fluctuate.

- **Investment in clinical studies and product innovation to support growth.** A significant aspect of our business is our investment in research and development, including the development of new products and our investments in clinical utility studies. We have invested heavily in clinical studies for our on market and pipeline products. Our studies focus primarily on the clinical utility of our tests including the ongoing INSIGHT study which seeks to enroll up to 5,000 patients to continue our clinical understanding of the predictive and prognostic value of the VeriStrat test. Our recently launched ALTITUDE study seeks to further demonstrate the efficacy of the Nodify XL2 and Nodify CDT test. A secondary focus of our studies is understanding the economic impact of our tests in guiding treatment choices and the potential impact of our tests in reducing overall healthcare costs.

  Our clinical research has resulted in over 80 peer-reviewed publications for our tests. In addition to clinical studies, we are collaborating with investigators from multiple academic cancer centers. We believe these studies are critical to gaining physician adoption and driving favorable coverage decisions by payers and expect our investments in research and development to increase. Further we also expect to increase our research and development expenses to fund further innovation and develop new clinically relevant tests.

- **Ability to attract new biopharmaceutical customers and maintain and expand relationships with existing customers.** Our business development team promotes the broad utility of our products for biopharmaceutical companies in the United States and internationally. Our revenue, business opportunities and growth depend in part on our ability to attract new biopharmaceutical customers and to maintain and expand relationships with existing biopharmaceutical customers. We expect to increase our sales and marketing expenses in furtherance of this goal. As we continue to develop

these relationships, we expect to support a growing number of investigations and clinical trials. If our relationships expand, we believe we may have opportunities to offer our platform for companion diagnostic development, novel target discovery and validation efforts, and to grow into other commercial opportunities. For example, we believe our multi-omic data including genomic and proteomic data, in combination with clinical outcomes or claims data, has revenue-generating potential, including for novel target identification and companion diagnostic discovery and development.

- **Motivating and expanding our field sales force and customer support team.** Our field sales force is the primary point of contact in the clinical setting. These representatives of the company must cover expansive geographic regions which limits their time for interaction and education of our products in the clinical setting. We plan to invest heavily in the field sales force to increase the total number of sales representatives and thereby reduce the geographic footprint each representative must cover. This investment will allow the larger sales force to maximize their education and selling efforts and achieve greater returns. Additionally, we plan to invest in the Boulder-based marketing and customer support teams to continue to provide the field team with the resources to be successful in the field. Furthermore, as we increase testing volume for our COVID-19 diagnostic testing program, we plan to hire additional project support members to assist us in expanding testing capacity.

While each of these areas present significant opportunities for us, they also pose significant risks and challenges that we must address. See Part II, Item 1A. “Risk Factors” for more information.

COVID-19 Pandemic

The COVID-19 pandemic has disrupted, and we expect will continue to disrupt, our operations. To protect the health and well-being of our workforce, partners, vendors and customers, we provide voluntary COVID-19 testing for employees working on-site, implemented social distance and building entry policies at work, restricted travel and facility visits, and followed the States of Colorado and Kansas’ public health orders and the guidance from the Centers for Disease Control and Prevention. Employees who can perform their duties remotely are asked to work from home and those on site are asked to follow our social distance guidelines. Our sales, marketing and business development efforts have also been constrained by our operational response to the COVID-19 pandemic due to travel restrictions. We expect to continue to adjust our operational norms in an effort to help slow the spread of COVID-19 in the coming months, including complying with government directives and guidelines as they are modified and supplemented.

The COVID-19 pandemic also has started to negatively affect, and we expect will continue to negatively affect, our non-COVID-19 testing-related revenue and our clinical studies. For example, cancer patients may have more limited access to hospitals, healthcare providers and medical resources as they take steps to control the spread of COVID-19. Our biopharmaceutical customers are facing challenges in recruiting patients and in conducting clinical trials to advance their pipelines, for which our tests could be utilized. As a result of the COVID-19 pandemic, beginning in the latter half of March 2020, we have received fewer samples for non-COVID-19 testing on a daily average basis from our clinical and biopharmaceutical customers than before the outbreak of the COVID-19 pandemic. Further, our clinical studies, such as our ongoing INSIGHT study and our recently launched ALTITUDE study, as well as our arrangements with our biopharmaceutical customers, are expected to take longer to complete than what we expected before the outbreak of the COVID-19 pandemic.

We are also experiencing an increase in revenues related to an increase in the demand for our Biodesix WorkSafe testing program. We expect that our costs to expand capacity for COVID-19 testing will increase for the remainder of 2020 and the first quarter of 2021 and we expect that the revenue that we generate from this expansion will comprise a significant portion of our revenue for these periods. However, there is no assurance that our COVID-19 testing program will continue to be accepted by the market or that other diagnostic tests will become more accepted, produce quicker results or are more accurate. Further, the longevity and extent of the COVID-19 pandemic is uncertain. If the pandemic were to dissipate, whether due to a significant decrease in new infections, due to the availability and rapid distribution of vaccines, or otherwise, the need for a COVID-19 diagnostic test could decrease significantly and this could have an adverse effect on our results of operations and profitability. As a result, the increase in revenue due to any increase in demand for these diagnostic tests may not be indicative of our future revenue.

See Part II., Item 1A. “Risk Factors” for a description of how the COVID-19 pandemic may adversely affect our business, financial condition and results of operations.

Components of Operating Results

Revenues

We derive our revenue from two sources: (i) providing diagnostic testing in the clinical setting (“Diagnostic Tests”); and (ii) providing biopharmaceutical companies with services that include diagnostic research, clinical research, clinical trial testing,

development and testing services generally provided outside the clinical setting and governed by individual contracts with third parties as well as development and commercialization of companion diagnostics ("Services").

Diagnostic Tests

Diagnostic test revenue is generated from delivery of results from our diagnostic tests. In the United States, we performed tests as both an in-network and out-of-network service provider depending on the test performed and the contracted status of the insurer.

We consider diagnostic testing to be completed upon the delivery of test results to the prescribing physician, which is considered the performance obligation. The fees for such services are billed either to a third party such as Medicare, medical facilities, commercial insurance payers, or to the patient. We determine the transaction price related to our contracts by considering the nature of the payer, the historical amount of time until payment by a payer and historical price concessions granted to groups of customers.

Services

Services revenue is generated from the delivery of our on-market tests, pipeline tests, custom diagnostic testing, and other scientific services for a purpose as defined by any individual customer. At times we collaborate with large biopharmaceutical companies in an attempt to discover biomarkers that would be helpful in their drug development or marketing. The performance obligations and related revenue for these sales is defined by a written agreement between us and our customer. These services are generally completed upon the delivery of testing results, or other contractually defined milestone(s), to the customer, which is considered the performance obligation. Customers for these services are typically large pharmaceutical companies where collectability is reasonably assured and therefore revenue is accrued upon completion of the performance obligations. Revenue derived from services is often unpredictable and can cause dramatic swings in our overall net revenue line from quarter to quarter.

Operating Expenses

Direct costs and expenses

Cost of diagnostic testing generally consists of cost of materials, direct labor, including bonus, benefit and stock-based compensation, equipment and infrastructure expenses associated with acquiring and processing test samples, including sample accessioning, test performance, quality control analyses, charges to collect and transport samples; curation of test results for physicians; and in some cases, license or royalty fees due to third parties. Costs associated with performing our tests are recorded as the tests are processed regardless of whether revenue was recognized with respect to the tests. Infrastructure expenses include depreciation of laboratory equipment, rent costs, amortization of leasehold improvements and information technology costs. Royalties for licensed technology are calculated as a percentage of revenues generated using the associated technology and recorded as expense at the time the related revenue is recognized. One-time royalty payments related to signing of license agreements or other milestones, such as issuance of new patents, are amortized to expense over the expected useful life of the patents. While we do not believe the technologies underlying these licenses are necessary to permit us to provide our tests, we do believe these technologies are potentially valuable and of possible strategic importance to us or our competitors. Under these license agreements, we are obligated to pay aggregate royalties ranging from 1% to 8% of sales in which the patents or know-how are used in the product or service sold, sometimes subject to minimum annual royalties or fees in certain agreements.

We expect the aggregate cost of diagnostic testing to increase in line with the increase in the number of tests we perform, but the cost per test to decrease modestly over time due to the efficiencies we may gain as test volume increases, and from automation and other cost reductions.

Cost of services includes costs incurred for the performance of development services requested by our customers. Cost of development services will vary depending on the nature, timing and scope of customer projects.

Research and development

Research and development expenses consist of costs incurred to develop technology and include salaries and benefits, reagents and supplies used in research and development laboratory work, infrastructure expenses, including allocated facility occupancy and information technology costs, contract services, clinical studies, other outside costs and costs to develop our technology capabilities. Research and development costs are expensed as incurred. Payments made prior to the receipt of goods or services to be used in research and development are deferred and recognized as expense in the period in which the related goods are received or services are rendered. Costs to develop our technology capabilities are recorded as research and development.

We expect our research and development expenses to increase in absolute dollars as we continue to innovate and develop additional products and expand our data management resources. As our services revenue grows, an increasing portion of research and development dollars are expected to be allocated to cost of goods for biopharma service contracts. This expense, though expected to increase in absolute dollars, is expected to decrease as a percentage of revenue in the long term, though it may fluctuate as a percentage of our revenues from period to period due to the timing and extent of these expenses.

Sales, marketing, general and administrative

Our sales and marketing expenses are expensed as incurred and include costs associated with our sales organization, including our direct sales force and sales management, client services, marketing and reimbursement, as well as business development personnel who are focused on our biopharmaceutical customers. These expenses consist primarily of salaries, commissions, bonuses, employee benefits, travel and stock-based compensation, as well as marketing and educational activities and allocated overhead expenses. We expect our sales and marketing expenses to increase in absolute dollars as we expand our sales force, increase our presence within the United States, and increase our marketing activities to drive further awareness and adoption of our tests and our future products. These expenses, though expected to increase in absolute dollars, are expected to decrease as a percentage of revenue in the long term, though they may fluctuate as a percentage of our revenues from period to period due to the timing and extent of these expenses.

Our general and administrative expenses include costs for our executive, accounting, finance, legal and human resources functions. These expenses consist principally of salaries, bonuses, employee benefits, travel and stock-based compensation, as well as professional services fees such as consulting, audit, tax and legal fees, and general corporate costs and allocated overhead expenses. We expect that our general and administrative expenses will continue to increase in absolute dollars, primarily due to increased headcount and costs associated with operating as a public company, including expenses related to legal, accounting, regulatory, maintaining compliance with exchange listing and requirements of the SEC, director and officer insurance premiums and investor relations. These expenses, though expected to increase in absolute dollars, are expected to decrease as a percentage of revenue in the long term, though they may fluctuate as a percentage from period to period due to the timing and extent of these expenses.

Accretion and Change in Fair Value of Contingent Consideration

In connection with the purchase transaction of Indi, we recorded contingent consideration pertaining to the amounts potentially payable to Indi shareholder pursuant to the terms of the asset purchase agreement. The fair value of contingent consideration is assessed at each balance sheet date and changes, if any, to the fair value are recognized as operating expenses within the statement of operations. The estimated fair value of the contingent consideration is based upon significant assumptions including probability of successful achievement of that Milestone, the estimated timing in which the Milestone is achieved, and discount rates. The estimated fair value could materially differ from actual values or fair values determined using different assumptions.

Interest Expense and Interest Income

Interest expense consists of interest from our term loan and convertible debt, and interest income consists of income earned on our cash and cash equivalents. Our term loan does not begin principal payments until March 2021. Our interest income has not been significant to date, but we expect our interest income to increase primarily as we invest the net proceeds from our recent offering.

Results of Operations

The following table sets forth the significant components of our results of operations for the periods presented (in thousands, except percentages).

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2020	2019	$	%	2020	2019	$	%
	(unaudited)				(unaudited)			
Revenues	$ 9,193	$ 3,942	$ 5,251	133	$ 18,528	$ 16,281	$ 2,247	14
Operating expenses								
Direct costs and expenses	3,891	1,503	2,388	159	7,346	4,244	3,102	73
Research and development	2,706	2,359	347	15	7,713	7,966	(253)	(3)
Sales, marketing, general and administrative	7,879	8,212	(333)	(4)	22,793	24,080	(1,287)	(5)
Accretion of contingent consideration	957	896	61	7	2,901	2,525	376	15
Change in fair value of contingent consideration	—	—	—	—	(1,944)	663	(2,607)	(393)
Total operating expenses	15,433	12,970	2,463	19	38,809	39,478	(669)	(2)
Loss from operations	(6,240)	(9,028)	2,788	31	(20,281)	(23,197)	2,916	13
Other income (expense)								
Interest expense	(2,658)	(706)	(1,952)	(276)	(6,899)	(2,005)	(4,894)	(244)
Other, net	53	133	(80)	(60)	363	1,001	(638)	(64)
Total other expense	(2,605)	(573)	(2,032)	(355)	(6,536)	(1,004)	(5,532)	(551)
Net loss	$ (8,845)	$ (9,601)	$ 756	8	$ (26,817)	$ (24,201)	$ (2,616)	(11)

Revenue

We generate revenue from our diagnostic tests and services that we provide (in thousands, except percentages).

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2020	2019	$	%	2020	2019	$	%
	(unaudited)				(unaudited)			
Diagnostic revenue	$ 8,552	$ 3,770	$ 4,782	127%	$ 15,798	$ 12,716	$ 3,082	24%
Services revenue	641	172	469	273%	2,730	3,565	(835)	(23)%
Total revenue	$ 9,193	$ 3,942	$ 5,251	133%	$ 18,528	$ 16,281	$ 2,247	14%

Total revenue was $9.2 million for the three months ended September 30, 2020 compared to $3.9 million for the three months ended September 30, 2019, an increase of $5.3 million, or 133%.

Diagnostic test revenue increased to $8.6 million for the three months ended September 30, 2020 compared to $3.8 million for the three months ended September 30, 2019, a net increase of $4.8 million or 127%. This increase was due to $5.5 million of revenue from our two COVID-19 diagnostic tests, partially offset by a modest decline in our non-COVID-19 diagnostic test volumes of $0.7 million as health care practitioners, including pulmonologists, were increasingly diverted to pandemic-related care. In addition, company sales efforts continued to be impacted by travel and other COVID-19 pandemic related restrictions.

Services revenue increased to $0.6 million for the three months ended September 30, 2020 compared to $0.2 million for the three months ended September 30, 2019, an increase of $0.5 million or 273%.

Total revenue was $18.5 million for the nine months ended September 30, 2020 compared to $16.3 million for the nine months ended September 30, 2019, an increase of $2.2 million, or 14%.

Diagnostic test revenue increased to $15.8 million for the nine months ended September 30, 2020 compared to $12.7 million for the nine months ended September 30, 2019, a net increase of $3.1 million or 24%. This increase was due to $6.9 million of revenue from our two new COVID-19 diagnostic tests. Offsetting this increase was a decline in our non-COVID-19 diagnostic tests of

$3.8 million because COVID-19 caused our primary pulmonology call point to be diverted to pandemic-related care and our sales force being quarantined, and in many cases being locked out of call points due to the pandemic.

Services revenue decreased to $2.7 million for the nine months ended September 30, 2020 compared to $3.6 million for the nine months ended September 30, 2019, a decrease of $0.8 million or 23%. The decrease was partially attributed to the completion of a contract in the first half of 2019 for which we did not have a comparable contract in 2020.

Costs and Operating Expenses

Direct Cost and Expenses

Cost of revenue was $3.9 million for the three months ended September 30, 2020 compared to $1.5 million for the three months ended September 30, 2019, an increase of $2.4 million, or 159%. The increase in costs were primarily driven by the release of our CDT test and our COVID-19 testing program in 2020 offset by reductions in costs related to our non-COVID-19 tests.

Cost of revenue was $7.3 million for the nine months ended September 30, 2020 compared to $4.2 million for the nine months ended September 30, 2019, an increase of $3.1 million, or 73%. The increase in costs were primarily driven by the release of our CDT test and our COVID-19 testing program in 2020 offset by reductions in costs related to our non-COVID-19 tests.

Research and Development

Research and development expenses were $2.7 million for the three months ended September 30, 2020 compared to $2.4 million for the three months ended September 30, 2019, an increase of $0.3 million, or 15%. This increase was primarily related to an increase in clinical trial costs related to existing trials partially offset by a reduction in travel costs and spend on development and pipeline projects primarily due to the COVID-19 pandemic.

Research and development expenses were $7.7 million for the nine months ended September 30, 2020 compared to $8.0 million for the nine months ended September 30, 2019, a decrease of $0.3 million, or 3%. This decrease was primarily related to a reduction in external costs related to the studies and development efforts for pipeline products, partially driven by slowdowns related to the COVID-19 pandemic and partially offset by an increased spend on clinical trials

The following table summarizes our external and internal costs for the three and nine months ended September 30, 2020 and 2019 (in thousands, except percentages).

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2020	2019	$	%	2020	2019	$	%
(in thousands)								
External expenses:								
Clinical trials and associated costs	$ 729	$ 167	$ 562	337%	$ 2,021	$ 1,241	$ 780	63%
Other external costs	758	997	(239)	(24%)	2,002	2,891	(889)	(31)%
Total external costs	1,487	1,164	323	28%	4,023	4,132	(109)	(3)%
Internal expenses	1,219	1,195	24	2%	3,690	3,834	(144)	(4)%
Total research and development expenses	$ 2,706	$ 2,359	$ 347	15%	$ 7,713	$ 7,966	$ (253)	(3)%

Research and development expenses account for a significant portion of our operating expenses and consist primarily of external and internal costs incurred in connection with the discovery and development of our product candidates.

External expenses include:

- payments to third parties in connection with the clinical development of our product candidates, including contract research organizations and consultants;
- the cost of manufacturing products for use in our preclinical studies and clinical trials, including payments to contract manufacturing organizations (“CMOs”) and consultants;

- payments to third parties in connection with the preclinical development of our product candidates, including outsourced professional scientific development services, consulting research fees and for sponsored research arrangements with third parties;
- laboratory supplies; and
- allocated facilities, depreciation and other expenses, which include direct or allocated expenses for IT, rent and maintenance of facilities.

Internal expenses include employee-related costs, including salaries, related benefits and stock-based compensation expense for employees engaged in research and development functions.

We expense research and development costs in the periods in which they are incurred. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. We track external costs by the stage of program, clinical or preclinical. We do not track internal costs by product candidate because these costs are deployed across multiple programs and, as such, are not separately classified.

Sales, Marketing, General and Administrative

Sales, marketing, general and administrative expenses were $7.9 million for the three months ended September 30, 2020 compared to $8.2 million for the three months ended September 30, 2019, a decrease of $0.3 million, or 4%. This reduction was driven by reductions in the travel and related expenses as the COVID-19 pandemic reduced or eliminated the travel and related expenses.

Sales, marketing, general and administrative expenses were $22.3 million for the nine months ended September 30, 2020 compared to $24.1 million for the nine months ended September 30, 2019, a decrease of $1.3 million, or 5%. This reduction was driven by reductions in the travel and related expenses as the COVID-19 pandemic reduced or eliminated the travel and related expenses.

Accretion of and Change in Fair Value of Contingent Consideration

The amounts recorded for accretion and change in fair value reflect the passage of time as well as estimates in when the milestones that trigger the payment of contingent consideration will be achieved.

Accretion of and change in fair value of contingent consideration netted to $1.0 million and $0.9 million for the three months ended September 30, 2020 and 2019, respectively, resulting from the accretion of the liability.

Accretion of and change in fair value of contingent consideration netted to $1.0 million and $3.2 million for the nine months ended September 30, 2020 and 2019, respectively. The change to contingent consideration during the nine months ended September 30, 2020 was primarily due to $2.9 million resulting from the accretion of the liability offset by $1.9 million due to the impact of the deceleration of expected revenue and decreases in expected costs. The $3.2 million change to the contingent consideration during the nine months ended September 30, 2019 was primarily due to $0.7 million resulting from the impact of the acceleration of expected revenue and decreases in expected costs as a result of events occurring after the acquisition date, as well as $2.5 million resulting from the from the accretion of the liability.

Interest Expense

Interest expense was $2.7 million for the three months ended September 30, 2020 compared to $0.7 million for the three months ended September 30, 2019, an increase of $2.0 million. This increase was due to the addition of interest expense related to convertible notes issued to certain shareholders from August 2019 through March 2020.

Interest expense was $6.9 million for the nine months ended September 30, 2020 compared to $2.0 million for the nine months ended September 30, 2019, an increase of $4.9 million, or 244%. This increase was primarily due to payment in kind interest accruing

to principal on our existing term loan as well as addition of interest expense related to convertible notes issued to certain shareholders from August 2019 through March 2020.

Other Income and Expense

Other income and expense was $0.1 million both for the three months ended September 30, 2020 and 2019.

Other income and expense was $0.4 million for the nine months ended September 30, 2020 compared to $1.0 million for the nine months ended September 30, 2019, an increase of $0.6 million, which was primarily proceeds related to a non-recurring legal settlement in our favor.

Liquidity and Capital Resources

We have funded our activities primarily through private equity placement offerings, convertible debt, long-term debt and most recently, our IPO. Based on cash and cash equivalents on hand as of September 30, 2020 and the proceeds of $63.0 million from our recent offering, we believe that our existing cash, cash equivalents, and cash generated from sales of our products, will be sufficient to meet our anticipated needs for at least the next 12 months from the issuance of these unaudited interim condensed financial statements.

We expect to continue to incur significant expenses for the foreseeable future and to incur operating losses through at least December 2021 while we make investments to support our anticipated growth. We may raise additional capital through the issuance of additional equity financing, debt financings or other sources. If this financing is not available to us at adequate levels, we may need to reevaluate our operating plans. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Cash Flows

The following is a summary of our cash flows for the nine months ended September 30, 2020 and 2019:

	Nine months ended September 30	
	2020	2019
	(unaudited – in thousands)	
Net cash flows (used in) provided by:		
Operating activities	$ (12,610)	$ (15,997)
Investing activities	(2,384)	(994)
Financing activities	16,055	20,031
Net increase in cash and cash equivalents and restricted cash	$ 1,061	$ 3,040

Our cash flows resulted in a net increase in cash of $1.1 million and $3.0 million during the nine months ended September 30, 2020 and 2019, respectively. The net cash used in operating activities decreased primarily due to a $2.6 million increase in net losses, offset by an increase in non-cash charges of $3.0 million and an increase in cash provided by working capital items of $3.0 million.

Net cash used in investing activities during the nine months ended September 30, 2020 totaled $2.4 million, a decrease of $1.4 million compared to the same period in 2019. A decrease in net cash used in investing activities was primarily due to a decrease of $0.6 million in the purchase of research equipment and patent costs and a $0.7 million payment for our Oncimmune acquisition.

Net cash provided by financing activities during the nine months ended September 30, 2020 totaled $16.1 million, a decrease of $4.0 million compared to the same period in 2019. The net cash provided by financing activities for the nine months ended September 30, 2020 primarily resulted from $13.0 million in proceeds from the issuance of convertible notes payable and $3.1 from proceeds from our Paycheck Protection Program note payable. The net cash provided by financing activities for the nine month period ended September 30, 2019 primarily resulted from $10.0 million in proceeds from the issuance of Series H preferred stock and $10.0 million in proceeds from the issuance of convertible notes payable.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of September 30, 2020 (in thousands):

	Payments due by period(5)				
	Total	Less than 1 year	1 to 3 years	4 to 5 years	More than 5 years
Operating lease obligations(4)	$ 1,915	$ 1,074	$ 841	$ —	$ —
Term loan(1)(3)	24,781	7,203	17,578	—	—
Convertible debt(1)(2)	26,600	26,600	—	—	—
	$ 53,296	$ 34,877	$ 18,419	$ —	$ —

(1) Reflected in accompanying balance sheets.
(2) Convertible debt was converted to common stock at the completion of our IPO.
(3) The term loan is subject to a 3% prepayment penalty. In addition, upon maturity, a 2% back-end facility fee of $460,000 is due to the lender.
(4) We are obligated under non-cancellable operating leases for all of our facilities. Lease terms for our facilities in effect as of September 30, 2020, ranged from less than one to three years and generally require us to pay the real estate taxes, certain insurance and operating costs.
(5) Royalty payments that we may owe are not included as the timing of such payments is uncertain.

In February 2018, we entered into the 2018 Notes with Innovatus to refinance long-term debt carried over from earlier loan agreements. The initial amount borrowed under the 2018 Notes was $23 million and the maturity date is February 2023. We are required to make quarterly interest payments that began in June 2018 and outstanding principal is due in 24 equal installments commencing in March 2021. The agreement has been amended multiple times to adjust terms to account for our acquisitions and growth. Further, we granted the lender a security interest in all of our assets through a pledge and security agreement, patent security agreement and trademark security agreement, each between us and the lender. The loan may be prepaid by us at any time, subject to a prepayment penalty of up to 3% of the principal amount, depending on the date of prepayment. Upon payment of the 2018 Notes at maturity or prepayment on any earlier date, unless waived, a 2% back-end facility fee will apply to the amounts paid or prepaid. The 2% fee is being recorded as additional interest expense over the term of the 2018 Notes.

The 2018 Notes contain customary affirmative and negative covenants for a loan, requires us to comply with a minimum daily liquidity covenant, and has a rolling monthly revenue requirement. Failure to comply with the covenants and loan requirements may result in early amortization of the loan in a 24- or 36-month payment schedule. The 2018 Notes also contain certain covenants that prevent us from making acquisitions, incurring additional indebtedness, or making or terminating any agreement valued above a certain dollar threshold without the prior written consent of the lender. These covenants may restrict our ability to pursue new business opportunities and access additional capital.

In connection with the purchase transaction of Indi, we recorded contingent consideration pertaining to the amounts potentially payable to Indi's shareholder pursuant to the terms of the asset purchase agreement. The fair value of contingent consideration is assessed at each balance sheet date and changes, if any, to the fair value are recognized as operating expenses within the statement of operations. The estimated fair value of the contingent consideration is based upon significant assumptions including probability of successful achievement of the Milestone, the estimated timing in which the Milestone is achieved, and discount rates. The estimated fair value could materially differ from actual values or fair values determined using different assumptions. At September 30, 2020, the amount that would be due in cash at the option of the seller at the time the Milestone is met would be approximately $37 million.

For a description of our other indebtedness, please see Notes 6 and 7 in the Notes to Condensed Financial Statements in Item 1 of this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

As of September 30, 2020, we have not entered into any off-balance sheet arrangements.

Critical Accounting Policies and Significant Judgments and Estimates

In accordance with accounting principles generally accepted in the United States, we are required to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Certain of these estimates significantly influence the portrayal of our financial condition and results of operations and require us to make difficult, subjective or

complex judgments. Our critical accounting policies primarily relate to our fair value estimates, and are described in greater detail in Note 1 to our condensed financial statements in Part 1 of this Quarterly Report on Form 10-Q.

Revenue Recognition

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers", and has subsequently issued several supplemental and/or clarifying ASUs (collectively, ASC 606). ASC 606 prescribes a single common revenue standard that replaces most existing U.S. GAAP revenue recognition guidance. ASC 606 is intended to provide a more consistent interpretation and application of the principles outlined in the standard across filers in multiple industries and within the same industries compared to current practices, which should improve comparability. We adopted the new standard using the modified retrospective method on January 1, 2018 for contracts that are not completed as of the adoption date.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. ASC 606 also impacts certain other areas, such as the accounting for costs to obtain or fulfill a contract. The standard also requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

We examined our revenue recognition policies specific to revenue streams for the provisioning of services and providing research and development services to third parties and came to conclusions on the impact of the new standard using the 5-step process prescribed by ASC 606. As noted above, we used the modified retrospective method to adopt the new standard which means we did not restate previously issued financial statements but recorded a one-time adjustment to accumulated deficit and accounts receivable of $0.4 million. This adjustment reflected our ability to establish a transaction price for our non-Medicare pay arrangements as of January 1, 2018 as a result of having sufficient history to determine the transaction price under these contracts. ASC 606 did not have an aggregate impact our net cash provided by operating activities but resulted in offsetting changes in certain assets and liabilities presented within net cash used in operating activities in the accompanying statement of cash flows, as noted above.

Diagnostic service revenues are generally completed upon the delivery of test results to the prescribing physicians, which is considered the performance obligation. Testing services are generally completed upon the delivery of testing results for assay development and testing services, which is considered the performance obligation.

Change in fair value of contingent consideration

In connection with the purchase transaction with Indi, we recorded contingent consideration pertaining to the amounts potentially payable to Indi's shareholder pursuant to the terms of the asset purchase agreement. The fair value of contingent consideration is assessed at each balance sheet date and changes, if any, to the fair value are recognized as operating expenses within the statements of operations.

The estimated fair value of the contingent consideration is based upon significant assumptions including probabilities of successful achievement of the related Milestone, the estimated timing in which the Milestone is achieved, and discount rates. The estimated fair value could materially differ from actual values or fair values determined using different assumptions.

Accounting for convertible debt

During 2020 and 2019, we issued $26.0 million in convertible debt that are now scheduled to mature on June 30, 2021. The terms of the convertible debt provided discounts upon conversion to the note holders in certain situations, including upon the completion of this offering. The discounts included in the convertible debt created a put option liability that was separated from the convertible debt and reflected as a liability in our balance sheet. Subsequent to the creation of the put options, changes in the fair value of the put options will be reflected as other income or expense in the statement of operations. During the nine months ended September 30, 2019, we recorded a $2 million increase in the fair value of the put options as other expense due to the increase in the conversion discount rate provided to note holders resulting from an amendment to terms of the convertible debt issued in August and September 2019. We will estimate the fair value of the put options until they are exercised or expire. The fair value of put options are based on the value of the discounts embedded in the convertible debt and the probability of various settlement scenarios.

Stock-based compensation and common stock valuation

Stock-based compensation related to stock options granted to our employees, directors and nonemployees 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 expense for stock options with performance metrics is calculated based upon expected achievement of the metrics specified in the grant.

Starting January 1, 2019, upon adoption of Accounting Standards Update (ASU) 2018-07, Compensation—Stock Compensation (Topic 718), *Improvements to Nonemployee Share-Based Payment Accounting,* the fair value of stock options issued to nonemployee consultants is determined as of the grant date, and compensation expense is being recognized over the period that the related services are rendered.

We use the Black-Scholes option-pricing model to estimate the fair value of our stock options and stock purchase rights under our 2016 Incentive Plan. The Black-Scholes option-pricing model requires assumptions to be made related to expected term of an award, expected volatility, risk-free rate and expected dividend yield. Starting January 1, 2017, forfeitures were accounted for as they occur.

We account for restricted stock units issued to employees based on the grant date fair value which is determined based on the closing market price of the common stock on the date of grant. The expense is recognized in our statement of operations on a straight-line basis over the requisite vesting period.

In the absence of an active market for our common stock, the fair value of our common stock was determined by our Board of Directors in accordance with the methodologies outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation Practice Aid ("Practice Aid"). In doing so, our Board of Directors determined the best estimate of fair value of our common stock, exercising reasonable judgment and considering numerous objective and subjective factors, including:

- valuations of our common stock performed by independent third-party valuation specialists;
- our stage of development and business strategy, including the status of research and development efforts, of our products and product candidates, and the material risks related to our business and industry;
- our results of operations and financial position, including our levels of available capital resources;
- the valuation of publicly traded companies in the life sciences and diagnostic testing sectors, as well as recently completed mergers and acquisitions of peer companies;
- the lack of marketability of our common stock as a private company;
- the prices of our convertible preferred stock sold to investors in arm's length transactions and the rights, preferences, and privileges of our convertible preferred stock relative to those of our common stock;
- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering or a sale of our company, given prevailing market conditions;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and medical device industry sectors.

Our Board of Directors determined the fair value of our common stock by first determining the enterprise value of our business, and then allocating the value among the various classes of our equity securities to derive a per share value of our common stock. The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date.

In allocating enterprise value among the various classes of stock prior to July 2020, we utilized the Option Pricing Method (OPM) given our early stage of development and the absence of a near term liquidity event. Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the preferred and common stock are inferred by analyzing these options. From July 2020 onwards, we have utilized a hybrid OPM and the Probability Weighted Expected Return Method (PWERM). The PWERM is a scenario-based analysis that

estimates the value per share based on the probability-weighted present value of expected future investment returns, considering a number of discrete possible outcomes of the business, as well as the economic and control rights of each share class. Under this hybrid method, we considered expected initial public offering liquidity scenarios as well as other market-based non-initial public offering scenarios in the event a near-term initial public offering does not occur. Additionally, in determining the estimated fair value of our common stock, our Board of Directors also considered the fact that our stockholders could not previously freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity.

Following the completion of our IPO, our Board of Directors has determined the fair value of our common stock is based on our closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 1 to our condensed financial statements included in Part I of this Quarterly Report on Form 10-Q.

Implications of Being an Emerging Growth Company and Smaller Reporting Company

We are an "emerging growth company" within the meaning of the Jumpstart Our Business Startups Act ("JOBS Act"). As an emerging growth company, we may take advantage of certain exemptions from various public company reporting requirements, including the requirement that our internal control over financial reporting be audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), certain requirements related to the disclosure of executive compensation and in our periodic reports and proxy statements, the requirement that we hold a nonbinding advisory vote on executive compensation and any golden parachute payments. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult.

We will remain an emerging growth company until the earliest to occur of (i) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; (iii) the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; and (iv) until December 31, 2025 (the year ended December 31st following the fifth anniversary of our IPO).

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our common shares held by non-affiliates exceeds $250 million as of the end of that year's second fiscal quarter, or (ii) our annual revenues exceeded $100 million during such completed fiscal year and the market value of our common shares held by non-affiliates exceeds $700 million as of the end of that year's second fiscal quarter.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates.

Interest rate risk

We are exposed to market risk for changes in interest rates related primarily to our cash and cash equivalents, marketable securities and our indebtedness. We consider all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. We continually monitor our positions with, and the credit quality of, the financial institutions with which we invest. Periodically throughout the year, we have maintained balances in various operating accounts in excess of federally insured

limits. Included in cash and cash equivalents are money market funds recorded at $4.8 million at September 30, 2020 and December 31, 2019. As of September 30, 2020, a hypothetical 100 basis point increase in interest rates would not have a material impact on our investment portfolio, financial position or results of operations. This estimate is based on a sensitivity model that measures market value changes when changes in interest rates occur.

Our December 2019 Notes, August 2019 Notes and our long-term debt payable all accrue interest at fixed rates.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Management, with the participation and supervision of our Chief Executive Officer and our 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, as amended (the "Exchange Act") as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, 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 Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Disclosure Controls and Procedures

In designing and evaluating our disclosure controls and procedures and internal control over financial reporting, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures and internal control over financial reporting must reflect the fact that there are resource constraints and our management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. The design of any disclosure controls and procedures and internal control over financial reporting also are based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time we may become involved in legal proceedings or investigations which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition, or cash flows.

Item 1A. Risk Factors.

Risk Factors Summary

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the SEC before making investment decisions regarding our securities.

- We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we achieve profitability, we may not be able to sustain it.
- The commercial success of our current and future diagnostic tests and services depends upon attaining significant market acceptance among payers, providers, clinics, patients, and biopharmaceutical companies.
- We may encounter difficulties in managing our growth, which could disrupt our operations.
- If we fail to retain sales and marketing personnel and, as we grow, fail to increase our sales and marketing capabilities or develop broad awareness of our diagnostic tests in a cost-effective manner, we may not be able to generate revenue growth.
- If we cannot maintain our current relationships, or enter into new relationships, with biopharmaceutical companies, our revenue prospects could be reduced.
- Our commercial success and revenue growth are highly dependent on the demand for, and increased adoption of, our diagnostic tests, including our COVID-19 testing program, which are subject to a number of risks and uncertainty.
- We need to ensure strong product performance and reliability to maintain and grow our business.
- We depend upon third-party suppliers, including contract manufacturers and single source suppliers, making us vulnerable to supply problems and price fluctuations.
- Natural or man-made disasters, pandemics, outbreaks, or other similar events, including a sustained outbreak or second wave of the novel strain of coronavirus disease, COVID-19, could significantly disrupt our business, and negatively impact our business, financial condition and results of operations.
- Our industry is highly competitive and subject to rapid change, which could make our diagnostic tests and services obsolete. If we are unable to continue to innovate and expand and enhance our diagnostic tests and service offerings, we could lose customers or market share.
- Any failure to offer high-quality support for our diagnostic tests and services may adversely affect our relationships with providers and negatively impact our reputation among patients and providers, which may adversely affect our business, financial condition and results of operations.
- We may face additional costs, loss of revenue, significant liabilities, harm to our brand, decreased use of our, products or services and business disruption if there are disruptions in our information technology systems, including any security or data privacy breaches or other unauthorized or improper access.

Risk Factors

Investing in our securities involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, together with all of the other information included in this Quarterly Report on Form 10-Q, including our financial statements and related notes, before making an investment decision. The risks described below are not the only ones facing us. The occurrence of any of the following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition and results of operations. In such case, the trading price of our securities could decline, and you may lose all or part of your investment. This Quarterly Report on Form 10-Q also contains forward-looking statements and estimates that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks and uncertainties described below.

Risks Related to our Business and Industry

We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we achieve profitability, we may not be able to sustain it.

We have incurred losses since our inception, and expect to continue to incur losses for the foreseeable future. We have reported net losses of $26.8 million and $24.4 million for the nine months ended September 30, 2020 and 2019, respectively. As a result of these losses, as of September 30, 2020, we had $6.3 million in cash and cash equivalents, and an accumulated deficit of approximately $257.7 million. Based on our current planned operations, we expect our cash and cash equivalents, together with the proceeds from our initial public offering in October 2020, will enable us to fund our operating expenses for at least the next twelve months. We have based this estimate on assumptions that in the future may prove to be wrong, and we could use our capital resources sooner than we currently expect. We expect to continue to incur significant net losses for the foreseeable future.

Our sales and marketing, research and development, regulatory and other expenses continue to increase as we expand our marketing efforts for our diagnostic tests and services, expand existing relationships with our customers, obtain regulatory clearances or approvals for future enhancements to our existing diagnostic tests and services and conduct further clinical trials. In addition, our general and administrative expenses have increased due to the additional costs associated with scaling our business operations and testing capacity, particularly with respect to our COVID-19 diagnostic testing capacity, as well as being a public company, including due to legal, accounting, insurance, exchange listing and compliance, investor relations and other expenses. As a result, we expect to continue to incur operating losses and may never achieve profitability. We will need to generate significant additional revenue in order to achieve and sustain profitability. Even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material adverse effect on our business, financial condition and results of operations.

The commercial success of our current and future diagnostic tests and services and our revenue growth depends upon attaining significant market acceptance among payers, providers, clinics, patients, and biopharmaceutical companies.

Our commercial success depends, in part, on the acceptance of our diagnostic tests and services as being safe and relatively simple for medical personnel to learn and use, clinically flexible, operationally versatile and, with respect to providers and payers, cost effective. We cannot predict how quickly, if at all, payers, providers, clinics and patients will accept future diagnostic tests and services or, if accepted, how frequently they will be used. These constituents must believe that our diagnostic tests offer benefits over other available alternatives. The degree of market acceptance of our current and future diagnostic tests and services depends on a number of factors, including:

- whether there is adequate utilization of our tests by clinicians, biopharmaceutical companies and other target groups based on the potential and perceived advantages of our diagnostic tests over those of our competitors;
- the convenience and ease of use of our diagnostic tests relative to those currently on the market;
- the effectiveness of our sales and marketing efforts;
- our ability to provide incremental data that show the clinical benefits and cost effectiveness, and operational benefits, of our diagnostic tests;
- the coverage and reimbursement acceptance of our products and services;

- pricing pressure, including from group purchasing organizations ("GPOs"), seeking to obtain discounts on our diagnostic tests based on the collective bargaining power of the GPO members;
- negative publicity regarding our or our competitors' diagnostic tests resulting from defects or errors;
- the accuracy of our tests relative to those of our competitors;
- product labeling or product insert requirements by the FDA or other regulatory authorities; and
- limitations or warnings contained in the labeling cleared or approved by the FDA or other authorities.

Additionally, even if our diagnostic tests achieve widespread market acceptance, they may not maintain that market acceptance over time if competing diagnostic tests or technologies, which are more cost effective or are received more favorably, are introduced. Failure to achieve or maintain market acceptance and/or market share would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition and results of operations.

We expect increased revenues from our COVID-19 diagnostic and antibody testing program through the first quarter of 2021, and we expect that such revenue will comprise a significant portion of our revenue over the same period. However, there is no assurance that our COVID-19 diagnostic and antibody testing program will continue to be accepted by the market or that other diagnostic tests will become more accepted, produce quicker results or are more accurate. Further, the longevity and extent of the COVID-19 pandemic is uncertain. If the pandemic were to dissipate, whether due to a significant decrease in new infections, due to the availability and rapid distribution of vaccines, or otherwise, the need for a COVID-19 diagnostic test could decrease significantly and this could have an adverse effect on our results of operation and profitability.

We may encounter difficulties in managing our growth, which could disrupt our operations.

As of September 30, 2020, we had 186 employees. Over the next several years, we expect to increase significantly the number of our employees and the scope of our operations, particularly in the areas of sales, marketing and reimbursement, product development, regulatory affairs and other functional areas, including finance, accounting, quality and legal. Additionally, we expect to expand our testing capacity as we commercialize additional diagnostic tests. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational quality and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to manage the expansion of our operations or recruit and train additional qualified personnel in an effective manner. Any inability to manage growth could delay the execution of our business plans or disrupt our operations and have a material and adverse effect on our prospects.

Since our inception, we have experienced multiple cycles of growth and anticipate further growth in our business operations. This future growth could create strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service and sales organization management. We expect to continue to increase headcount and to hire more specialized personnel in the future as we grow our business. We will need to continue to hire, train and manage additional qualified scientists, laboratory personnel, client and account services personnel, and sales and marketing staff and improve and maintain our technology to properly manage our growth. If our new hires perform poorly, if we are unsuccessful in hiring, training, managing and integrating these new employees or if we are not successful in retaining our existing employees, our business may be harmed.

We may not be able to maintain the quality or expected turnaround times of our diagnostic tests and services, or satisfy customer demand as it grows. We may not be able to expand our COVID-19 testing capacity rapidly enough to meet the current and anticipated demand. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. The time and resources required to implement these new systems and procedures is uncertain, and failure to complete this in a timely and efficient manner could materially adversely affect our operations.

If we fail to retain sales and marketing personnel and, as we grow, fail to increase our sales and marketing capabilities or develop broad awareness of our diagnostic tests in a cost-effective manner, we may not be able to generate revenue growth.

We have limited experience marketing and selling our diagnostic tests. We currently rely on our direct sales force to sell our diagnostic tests in the United States, and any failure to maintain and grow our direct sales force will negatively affect our business, financial condition and results of operations. The members of our direct sales force are highly trained and possess substantial technical expertise, which we believe is critical in increasing adoption of our diagnostic tests. The members of our United States sales force are at-will employees. The loss of these personnel to competitors, or otherwise, will negatively affect our business, financial condition and results of operations. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical

expertise and qualifications, or if we are unable to successfully instill such technical expertise in replacement personnel, it may negatively affect our business, financial condition and results of operations.

In order to generate future growth, we plan to continue to expand and leverage our sales and marketing infrastructure. Identifying and recruiting qualified sales and marketing personnel and training them on how to promote our diagnostic tests, on applicable federal and state laws and regulations and on our internal policies and procedures requires significant time, expense and attention. It often takes several months or more before a sales representative is fully trained and productive. Our sales force may subject us to higher fixed costs than those of companies with competing techniques or diagnostic tests that utilize independent third parties, which could place us at a competitive disadvantage. It will negatively affect our business, financial condition and results of operations if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our diagnostic tests. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time, or timely reduce fixed costs, could negatively affect our business, financial condition and results of operations. Our ability to increase our customer base and achieve broader market acceptance of our diagnostic tests will depend to a significant extent on our ability to expand our marketing efforts. We plan to dedicate significant resources to our marketing programs. It will negatively affect our business, financial condition and results of operations if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our diagnostic tests in a cost-effective manner is critical to achieving broad acceptance of our diagnostic tests. Promotion activities may not generate patient or physician awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad use of our diagnostic tests, which in turn could have a material adverse effect on our business, financial condition and results of operations.

If we cannot maintain our current relationships, or enter into new relationships, with biopharmaceutical companies, our revenue prospects could be reduced.

We collaborate with biopharmaceutical companies to analyze patient samples for multiple applications primarily to support clinical trials, including patient identification, companion or complementary diagnostics and retrospective testing. In the nine months ended September 30, 2020 and 2019, revenue from our top biopharmaceutical customer accounted for 3.3% and 18.7% of our total revenue, respectively. The revenue attributable to our biopharmaceutical customers may also fluctuate in the future, which could have a material adverse effect on our financial condition and results of operations. In addition, the termination of these relationships could result in a temporary or permanent loss of revenue.

Our future success depends in part on our ability to maintain these relationships and to establish new relationships. Many factors have the potential to impact such collaborations, including the type of biomarker support required and our ability to deliver it and our biopharmaceutical customers' satisfaction with our tests or services and other factors that may be beyond our control. Furthermore, our biopharmaceutical customers may decide to decrease or discontinue their use of our tests due to changes in research and product development plans, failures in their clinical trials, financial constraints, or utilization of internal testing resources or tests performed by other parties, or other circumstances outside of our control. In addition to reducing our revenue, the loss of one or more of these relationships may reduce our exposure to research and clinical trials that facilitate the collection and incorporation of new information into our biobank and proprietary AI platform.

We engage in conversations with biopharmaceutical companies regarding potential commercial opportunities on an ongoing basis. There is no assurance that any of these conversations will result in a commercial agreement, or if an agreement is reached, that the resulting relationship will be successful or that clinical or research studies conducted as part of the engagement will produce successful outcomes. Speculation in the industry about our existing or potential relationships with biopharmaceutical companies can also be a catalyst for adverse speculation about us, our tests and our technology, which can adversely affect our reputation and our business.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual revenue and operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. Our quarterly and annual operating results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. These fluctuations may occur due to a variety of factors, including, but not limited to:

- the level of demand for our diagnostic tests, which may vary significantly;

- the timing and cost of manufacturing our diagnostic tests, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers and manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional tests and technologies;
- unanticipated pricing pressures;
- the rate at which we grow our sales force and the speed at which newly hired salespeople become effective, and the cost and level of investment therein;
- the degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future partners;
- coverage and reimbursement policies with respect to lung cancer treatment equipment, and potential future diagnostic tests that compete with our diagnostic tests;
- the timing and success or failure of clinical trials for our diagnostic tests or any enhancements to such tests we develop or competing diagnostic tests;
- positive or negative coverage, or public perception, of our diagnostic tests or those of our competitors or broader industry trends;
- the impact, if any, of the spread of COVID-19, and the resulting effects on the number of patients treated or the demand for our non-COVID-19 diagnostic tests;
- the timing and cost of, and level of investment in, research, development, licenses, regulatory approval, commercialization activities, acquisitions and other strategic transactions, or other significant events relating to our diagnostic tests, which may change from time to time;
- the timing and cost of obtaining regulatory approvals or clearances for planned or future improvements or enhancements to our diagnostic tests;
- changes in governmental regulations or in the status of regulatory approvals or applications;
- pricing, discounts and incentives for our diagnostic tests;
- future accounting pronouncements or changes in our accounting policies; and
- general market conditions.

In addition, we expect increased revenue from our COVID-19 diagnostic and antibody testing program through the first quarter of 2021, and we expect that such revenue will comprise a significant portion of our revenue over the same period. We can provide no assurances that the demand for our COVID-19 diagnostic and antibody testing program will be sustained, and even if it is, the period of time for which it would be sustained. As a result, the increase in revenue due to any increase in demand for our COVID-19 diagnostic and antibody testing program is not indicative of results expected for any future period.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual financial results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Further, our historical results are not necessarily indicative of results expected for any future period, and quarterly results are not necessarily indicative of the results to be expected for the full year or any other period, and accordingly should not be relied upon as indicative of future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any publicly stated guidance we may provide, and could in turn negatively impact our business, financial condition and results of operations.

We need to ensure strong product performance and reliability to maintain and grow our business.

We need to maintain and continuously improve the performance and reliability of our diagnostic tests, including our Biodesix WorkSafe testing program, the Nodify XL2 and Nodify CDT tests, and the GeneStrat and VeriStrat tests, to achieve our profitability objectives. Poor product performance and reliability could lead to customer dissatisfaction, adversely affect our reputation and revenues, and increase our service and distribution costs and working capital requirements. Our diagnostic tests may contain errors or defects, and while we have made efforts to test them extensively, we cannot assure that our current diagnostic tests, or those developed in the future, will not have performance problems. Performance issues with our diagnostic tests will increase our costs in the near-term and accordingly adversely affect our business, financial condition and results of operations.

We depend upon third-party suppliers, including contract manufacturers and single source suppliers, making us vulnerable to supply problems and price fluctuations.

We rely on third-party suppliers, including in some instances single source suppliers, to provide us with certain components of our diagnostic tests. The number of suppliers feeding into the production of our diagnostic tests is in excess of 65 worldwide. We consider a select few of these suppliers, located in the United States, Europe and China, as critical single source providers of components. Bio-Rad Laboratories, as described below, is the sole source supplier for our GeneStrat tests and COVID-19 diagnostic and antibody testing program. Oncimmune is also the sole source supplier for our Nodify CDT tests. While we have initiated the second source qualification process for the majority of these critical components, we may not be successful in securing second sourcing for all of them at all or on a timely basis.

In addition, we may purchase supplies through purchase orders and may not have long-term supply agreements with, or guaranteed commitments from, many of our suppliers, including single source suppliers. Additionally, at present, we rely on contract manufacturers for the production of supplies for our diagnostic test. Many of our suppliers and contract manufacturers are not obligated to perform services or supply diagnostic testing materials for any specific period, in any specific quantity or at any specific price, except as may be provided in a particular purchase order. We depend on our suppliers and contract manufacturers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements. These suppliers and contract manufacturers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand. These suppliers and contract manufacturers may cease producing the components we purchase from them or otherwise decide to cease doing business with us. Further, we maintain limited volumes of inventory from most of our suppliers and contract manufacturers. If we inaccurately forecast demand for finished goods, we may be unable to meet customer demand which could harm our competitive position and reputation. In addition, if we fail to effectively manage our relationships with our suppliers and contract manufacturers, we may be required to change suppliers or contract manufacturers. While we believe replacement suppliers exist for all materials, components and services necessary to manufacture our diagnostic tests, establishing additional or replacement suppliers for any of these materials, components or services, if required, could be time-consuming and expensive, may result in interruptions in our operations and product delivery, may affect the performance of our diagnostic tests or could require that we modify their processes. Even if we are able to find replacement suppliers, we will be required to verify that the new supplier maintains facilities, procedures and operations that comply with our quality expectations and applicable regulatory requirements. Any of these events could require that we obtain a new regulatory authority approval before we implement the change, which we may not obtain on a timely basis or at all.

If our third-party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of our diagnostic tests, the supply of our diagnostic tests to customers and the development of any future diagnostic tests will be delayed, limited or prevented, which could have material adverse effect on our business, financial condition and results of operations.

We entered into a nonexclusive license and supply agreement with Bio-Rad in August 2019. We rely on Bio-Rad to supply equipment and reagents used to perform ddPCR testing, a service offered by us under a variety of fee for service agreements and the core technology powering the GeneStrat test. Under the terms of this arrangement, we were granted non-exclusive rights to utilize the intellectual property, machinery, materials, reagents, supplies and know-how necessary for the performance of ddPCR in cancer detection testing for third parties in the United States. We agreed to purchase all of the necessary supplies and reagents for such testing exclusively from Bio-Rad. As further consideration for the non-exclusive license, we agreed to pay a royalty of two and one half percent (2.5%) on net service fees (such fees are defined in the Non-Exclusive License Agreement with Bio-Rad) collected from contracted third parties who receive ddPCR services from us. In addition, we have separately been granted permission by Bio-Rad to use the Bio-Rad SARS-CoV-2 ddPCR assay and Platelia SARS-CoV-2 Total Ab assay for commercial diagnostic services.

This relationship may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. We cannot be certain that, following the

realization of this relationship, we will achieve the revenue or specific net income that justifies our entry into it. Any termination of this relationship, or delays in entering into new strategic partnership agreements with Bio-Rad, could delay our sales and marketing efforts, which would harm our business prospects, financial condition and results of operations.

We may not be able to sufficiently reduce costs in the performance, manufacturing and production of our diagnostic tests to achieve sustainable gross margins.

We partner with contract manufacturers in the development and production of supplies for our diagnostic tests. While we are undertaking a number of initiatives designed to reduce the cost of performing our diagnostic tests, including reducing the costs of supplies, there is no guarantee that we will be able to achieve planned cost reductions from our various cost savings initiatives. There may also be unforeseen occurrences that increase our costs, such as increased prices of the components of our diagnostic tests, changes to labor costs or less favorable terms with third-party suppliers or contract manufacturing partners. If we are unable to reduce our costs, or if cost reductions are less significant or less timely than projected, we will not be able to achieve sustainable gross margins, which would adversely affect our ability to invest in and grow our business and adversely impact our business, financial condition and results of operations.

A pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide, including the outbreak of the novel strain of coronavirus disease, COVID-19, could adversely affect our business.

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide, our business may be adversely affected. COVID-19 has spread to most countries and throughout the United States. Numerous state and local jurisdictions have imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. In March 2020, the Governor of Colorado, where our headquarters are located, issued "stay at home" orders limiting non-essential activities, travel and business operations. Such orders or restrictions have resulted in reduced operations at our headquarters, work stoppages, slowdowns and delays, travel restrictions and cancellation of events. Other disruptions or potential disruptions include the inability of our suppliers to manufacture components and parts and to deliver these to us on a timely basis, or at all; disruptions in our production schedule and ability to assemble diagnostic tests; inventory shortages or obsolescence; delays in actions of regulatory bodies; diversion of or limitations on employee resources that would otherwise be focused on the operations of our business; delays in growing or reductions in our sales organization, including through delays in hiring, lay-offs, furloughs or other losses of sales representatives; business adjustments or disruptions of certain third parties, including suppliers, medical institutions and clinical investigators with whom we conduct business; and additional government requirements or other incremental mitigation efforts that may further impact our or our suppliers' capacity to manufacture our diagnostic tests.

The COVID-19 pandemic also has negatively affected, and we expect will continue to negatively affect, our non-COVID-19 testing-related revenue and our clinical studies. For example, cancer patients may have more limited access to hospitals, healthcare providers and medical resources as they take steps to control the spread of COVID-19. Our biopharmaceutical customers are facing challenges in recruiting patients and in conducting clinical trials to advance their pipelines, for which our tests could be utilized. As a result of the COVID-19 pandemic, beginning in the latter half of March 2020, we received fewer samples for non-COVID-19 testing on a daily average basis from our clinical and biopharmaceutical customers than before the outbreak of the COVID-19 pandemic. Further, our clinical studies, such as our ongoing INSIGHT study and our recently launched ALTITUDE study, as well as our arrangements with our biopharmaceutical customers, are expected to take longer to complete than what we expected before the outbreak of the COVID-19 pandemic.

The COVID-19 pandemic has also created an opportunity for our diagnostic tests and we have commercialized two diagnostic tests to test for the presence of COVID-19 and antibodies. We are expecting to increase our testing capacity for our COVID-19 diagnostic and antibody testing program in the near term to meet the rising demand for rapid and accurate testing. We expect that the revenue we generate from this expansion will comprise a significant portion of our revenue for the remainder of 2020 and the first quarter of 2021. However, there is no assurance that our COVID-19 diagnostic and antibody testing program will continue to be accepted by the market or that other diagnostic tests will become more accepted, produce quicker results or be accurate. Further, the longevity and extent of the COVID-19 pandemic is uncertain. If the pandemic were to dissipate, whether due to a significant decrease in new infections, due to the availability and rapid distribution of vaccines, or otherwise, the need for a COVID-19 diagnostic test could decrease significantly and this could have an adverse effect on our results of operations and profitability. As a result, the increase in revenue due to any increase in demand for these diagnostic tests may not be indicative of our future revenue.

The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity and spread of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. Furthermore there is no assurance that our diagnostic tests will continue to be effective against the virus in the future.

While the potential economic impact brought by, and the duration of, any pandemic, epidemic or outbreak of an infectious disease, including COVID-19, may be difficult to assess or predict, the widespread COVID-19 pandemic has resulted in, and may continue to result in, significant disruption of global financial markets and a reduction in our ability to access capital, which could adversely affect our liquidity. In addition, a recession or market correction resulting from the spread of an infectious disease, including COVID-19, could materially affect our business. Such economic recession could have a material adverse effect on our long-term business. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

Natural or man-made disasters and other similar events, including the COVID-19 pandemic, may significantly disrupt our business, and negatively impact our business, financial condition and results of operations.

A significant portion of our employee base, operating facilities and infrastructure are centralized in Boulder, Colorado and we operate a laboratory facility in De Soto, Kansas. Any of our facilities may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, wildfires, floods, nuclear disasters, riots, acts of terrorism or other criminal activities, infectious disease outbreaks or pandemic events, including the COVID-19 pandemic, power outages and other infrastructure failures, which may render it difficult or impossible for us to operate our business for some period of time. Our facilities would likely be costly to repair or replace, and any such efforts would likely require substantial time. Any disruptions in our operations could adversely affect our business, financial condition and results of operations and harm our reputation. Moreover, although we have disaster recovery plans, they may prove inadequate. We may not carry sufficient business insurance to compensate for losses that may occur. Any such losses or damages could have a material adverse effect on our business, financial condition and results of operations. In addition, the facilities of our suppliers and manufacturers may be harmed or rendered inoperable by such natural or man-made disasters, which may cause disruptions, difficulties or otherwise materially and adversely affect our business.

Any failure to offer high-quality support for our diagnostic tests and services may adversely affect our relationships with providers and negatively impact our reputation among patients and providers, which may adversely affect our business, financial condition and results of operations.

In implementing and using our diagnostic tests and services, providers depend on our support to resolve issues in a timely manner. We may be unable to respond quickly enough to accommodate short-term increases in demand for customer support. Increased customer demand for support could increase costs and adversely affect our business, financial condition and results of operations. Our sales are highly dependent on our reputation and on positive recommendations from our existing patients, care partners, providers and clinics. Any failure to maintain high-quality customer support, or a market perception that we do not maintain high-quality customer support, could adversely affect our reputation, our ability to sell our diagnostic tests and services, and in turn our business, financial condition and results of operations.

The sizes of the markets for our diagnostic tests and services and any future diagnostic tests and services may be smaller than we estimate and may decline.

Our estimates of the annual total addressable market for our diagnostic tests and services are based on a number of internal and third-party estimates and assumptions, including, without limitation, the assumed prices at which we can sell our diagnostic tests and services in the market. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors.

As a result, our estimates of the annual total addressable market for our diagnostic tests and services in different market segments may prove to be incorrect. If the actual number of patients who would benefit from our diagnostic tests, the price at which we can sell them or the annual total addressable market for them is smaller than we have estimated, it may impair our sales growth and negatively affect our business, financial condition and results of operations.

Our industry is subject to rapid change, which could make our solutions and the diagnostic tests we develop and services we offer, obsolete. If we are unable to continue to innovate and improve our diagnostic tests and services we offer, we could lose customers or market share.

Our industry is characterized by rapid changes, including technological and scientific breakthroughs, frequent new product introductions and enhancements and evolving industry standards, all of which could make our current diagnostic tests and others we are developing obsolete. Our future success will depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of scientific and technological advances. In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. There have also been advances in methods used to analyze very large amounts of molecular information. We must continuously enhance our

offerings and develop new and improved diagnostic tests to keep pace with evolving standards of care. If we do not leverage or scale our sample and data biobank to discover new diagnostic tests or applications or update our diagnostic tests to reflect new scientific knowledge, including about lung cancer biology, information about new cancer therapies or relevant clinical trials, our diagnostic tests could become obsolete and sales of our current diagnostic tests and any new tests we develop could decline or fail to grow as expected. This failure to make continuous improvements to our diagnostic tests to keep ahead of those of our competitors could result in the loss of customers or market share that would adversely affect our business, financial condition and results of operations.

We may face additional costs, loss of revenue, significant liabilities, harm to our brand, decreased use of our, products or services and business disruption if there are any security or data privacy breaches or other unauthorized or improper access.

In connection with various facets of our business, we collect and use a variety of personal data, such as names, mailing addresses, email addresses, mobile phone numbers, location information, prescription information and other medical information. Any failure to prevent or mitigate security breaches or improper access to, use, disclosure or other misappropriation of our data or consumers' personal data could result in significant liability under state (e.g., state breach notification and privacy laws such as the California Consumer Privacy Act ("CCPA")), federal (e.g., the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Health Information Technology for Economic and Clinical Health Act ("HITECH Act")) and international laws (e.g., the General Data Protection Regulation ("GDPR")). Such an incident may also cause a material loss of revenue from the potential adverse impact to our reputation and brand, affect our ability to retain or attract new users of our diagnostic tests and services and potentially disrupt our business.

Unauthorized disclosure of sensitive or confidential patient or employee data, including personally identifiable information, whether through a breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. To the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed. For example, the loss of or damage to clinical trial data, such as from completed or ongoing clinical trials, for any of our product candidates would likely result in delays in our marketing approval efforts and significantly increased costs in an effort to recover or reproduce the data.

As we become more dependent on information technologies to conduct our operations, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business. Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently and often are not recognized until launched against a target, we and our partners may be unable to anticipate these techniques or to implement adequate preventative measures. We have in the past experienced, and may in the future experience security incidents. While no security incidents in the past have had a material adverse effect on our business, financial condition and results of operations, we cannot predict the impact of any such future events. Further, we do not have any control over the operations of the facilities or technology of our cloud and service providers, including any third party vendors that collect, process and store personal data on our behalf. Our systems, servers and platforms and those of our service providers may be vulnerable to computer viruses or physical or electronic break-ins that our or their security measures may not detect. Individuals able to circumvent such security measures may misappropriate our confidential or proprietary information, disrupt our operations, damage our computers or otherwise impair our reputation and business. We may need to expend significant resources and make significant capital investments to protect against security breaches or to mitigate the impact of any such breaches. In addition, to the extent that our cloud and other service providers, experience security breaches that result in the unauthorized or improper use of confidential data, employee data or personal data, we may not be indemnified for any losses resulting from such breaches. There can be no assurance that we or our third party providers will be successful in preventing cyber-attacks or successfully mitigating their effects. If we are unable to prevent or mitigate the impact of such security breaches, our ability to attract and retain new customers, patients and other partners could be harmed as they may be reluctant to entrust their data to us, and we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business or other adverse consequences.

We have significant payer concentration, with a limited number of customers accounting for a substantial portion of our revenues.

For the nine months ended September 30, 2020, Medicare reimbursed to us 61% of our non-COVID-19 diagnostic test revenue and three healthcare providers accounted for 42% of our total diagnostic test revenue. There are risks whenever a large percentage of total revenues are concentrated with a limited number of payers and customers. It is not possible for us to predict the level of demand for our diagnostic tests and services that will be generated by any of these customers in the future. In addition, revenues from these larger customers may fluctuate from time to time based on these customers' business needs, the timing of which may be affected by

market conditions or other factors outside of our control. These payers and customers could also potentially pressure us to reduce the prices we charge for our diagnostic tests and services, which could have an adverse effect on our margins and financial position and could negatively affect our revenues and results of operations. If any of our largest payers terminates its relationship with us or our tests are no longer reimbursable by such payer, such termination could negatively affect our revenues and results of operations.

Our results of operations will be materially harmed if we are unable to accurately forecast customer demand for, and utilization of, our diagnostic tests and manage our inventory.

To ensure adequate inventory supply, we must forecast inventory needs and manufacture our diagnostic tests based on our estimates of future demand for our diagnostic tests. Our ability to accurately forecast demand for them could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our diagnostic tests or for those of our competitors, our failure to accurately forecast customer acceptance of new diagnostic tests, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate customer demand for our diagnostic tests, our supply chain, manufacturing partners and/or internal manufacturing team may not be able to deliver components and diagnostic tests to meet our requirements, and this could result in damage to our reputation, sales growth and customer relationships. In addition, if we experience a significant increase in demand, such as we are currently experiencing with respect to our COVID-19 diagnostic and antibody testing program, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, which will adversely affect our business, financial condition and results of operations.

If we experience significant disruptions in our information technology systems, our business may be adversely affected.

We depend on our information technology systems for the efficient functioning of our business, including the performance, distribution and maintenance of our diagnostic tests and services, as well as for accounting, data storage, compliance, purchasing and inventory management. We do not have redundant information technology in all aspects of our systems at this time. Our information technology systems may be subject to computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors, among other malfunctions. We could be subject to an unintentional event that involves a third party gaining unauthorized access to our systems, which could disrupt our operations, corrupt our data or result in release of our confidential information. Technological interruptions would disrupt our operations, including our ability to timely ship and track diagnostic test orders and results, project inventory requirements, manage our supply chain and otherwise adequately service our customers or disrupt our customers' ability to use our diagnostic tests. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our business, financial condition and results of operations.

Currently, we carry business interruption coverage to mitigate certain potential losses but this insurance is limited in amount, and we cannot be certain that such potential losses will not exceed our policy limits. The successful assertion of one or more large claims against us that exceed or are not covered by our insurance coverage or changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, financial condition and results of operations. We are increasingly dependent on complex information technology to manage our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a material adverse effect on our business, financial condition and results of operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our diagnostic tests and services. The expense and potential unavailability of insurance coverage for liabilities resulting from issues with our diagnostic tests and services could harm us and negatively impact sales.

We face an inherent risk of product liability as a result of the marketing and sale of our diagnostic tests and services. For example, we may be sued if our diagnostic tests or services cause or are perceived to cause injury or are found to be otherwise unsuitable during manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, medical personnel, care partners and patients collect samples for our diagnostic tests. If these medical personnel, care partners or patients are not properly trained, are negligent or use our diagnostic tests incorrectly, the

capabilities of such tests may be diminished or the patient may suffer critical injury. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and sub-assemblies for our diagnostic tests.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt the marketing and sale of our diagnostic tests and services. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our diagnostic tests and services;
- harm to our reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- adverse impact on the market price of our common stock; and
- exhaustion of any available insurance and our capital resources.

We believe we have adequate product liability insurance, but it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of our diagnostic tests and services. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry, significantly increase our expenses and reduce product sales.

We face competition from many sources, including larger companies, and we may be unable to compete successfully.

There are a number of lung cancer diagnostic solutions companies in the United States, Europe and Asia. Notable competitors in the United States include Veracyte, Inc., Guardant Health, Inc., and Foundation Medicine, Inc. These competitors all provide cancer-focused diagnostic tests to hospitals, researchers, clinicians, laboratories and other medical facilities. Many of these organizations are significantly larger with greater financial and personnel resources than us, and enjoy significantly greater market share and have greater resources than we do. As a consequence, they may be able to spend more on product development, marketing, sales and other product initiatives than we can. Some of our competitors have:

- substantially greater name recognition;
- broader, deeper or longer-term relations with healthcare professionals, customers and third-party payers;
- more established distribution networks;
- additional lines of diagnostic tests and the ability to offer rebates or bundle them to offer greater discounts or other incentives to gain a competitive advantage;

- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for diagnostic tests; and

- greater financial and human resources for product development, sales and marketing and patent litigation.

Our continued success depends on our ability to:

- further penetrate the lung disease diagnostic solutions market and increase utilization of our diagnostic tests;

- maintain and widen our technology lead over competitors by continuing to innovate and deliver new product enhancements on a continuous basis; and

- cost-effectively manufacture our diagnostic tests and their component parts as well as drive down the cost of service.

In addition, competitors with greater financial resources than ours could acquire other companies to gain enhanced name recognition and market share, as well as new technologies or diagnostic tests that could effectively compete with our existing diagnostic tests, which may cause our revenue to decline and would harm our business.

Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, development of our diagnostic tests. Because of the complex and technical nature of diagnostic testing and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize our diagnostic tests, which would have a material adverse effect on our business, financial condition and results of operations.

As we attain greater commercial success, our competitors are likely to develop diagnostic tests that offer features and functionality similar to our diagnostic tests that are currently on the market. Improvements in existing competitive diagnostic tests or the introduction of new competitive diagnostic tests may make it more difficult for us to compete for sales, particularly if those competitive diagnostic tests demonstrate better reliability, convenience or effectiveness or are offered at lower prices.

Performance issues, service interruptions or price increases by our shipping carriers and warehousing providers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.

Expedited, reliable shipping and delivery services and secure warehousing are essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our diagnostic tests to our customers and for tracking of these shipments, and from time to time require warehousing for our diagnostic tests, sample collection kits and supplies. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our diagnostic tests and increased cost and expense to our business. In addition, any significant increase in shipping or warehousing rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters, civil unrest and disturbances or other service interruptions affecting delivery or warehousing services we use would adversely affect our ability to process orders for our diagnostic tests on a timely basis.

We rely on commercial courier delivery services to transport samples to our laboratory facility in a timely and cost-efficient manner and if these delivery services are disrupted, our business will be harmed. Our business depends on our ability to quickly and reliably deliver test results to our customers. Blood samples are typically received within days from the United States and outside the United States for analysis at our Boulder, Colorado and De Soto, Kansas facilities. Disruptions in delivery service, whether due to labor disruptions, bad weather, natural disaster, civil unrest or disturbances, terrorist acts or threats or for other reasons 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.

Cost-containment efforts of our customers, purchasing groups and governmental purchasing organizations could have a material adverse effect on our sales and profitability.

In an effort to reduce costs, many hospitals in the United States have become members of GPOs and Integrated Delivery Networks (“IDNs”). GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors and then offer these negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down

pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain new, or maintain existing, contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our diagnostic tests, thereby reducing our revenue and margins.

While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to individual purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause by the GPO or IDN upon 60 to 90 days' notice. Accordingly, the members of such groups may choose to purchase alternative diagnostic tests due to the price or quality offered by other companies, which could result in a decline in our revenue.

Litigation and other legal proceedings may adversely affect our business.

From time to time we may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class action and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for our diagnostic tests and services, even if the regulatory or legal action is unfounded or not material to our operations.

We maintain product and professional liability insurance, but this insurance may not fully protect us from the financial impact of defending against product liability or professional liability 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.

General economic and financial market conditions may exacerbate our business risks.

Global macroeconomic conditions and the world's financial markets remain susceptible to significant stresses, resulting in reductions in available credit and government spending, economic downturn or stagnation, foreign currency fluctuations and volatility in the valuations of securities generally. As a result of uncertainties with respect to financial institutions and the global credit markets and other macroeconomic challenges currently or potentially affecting the economy of the United States and other parts of the world, customers and distributors may experience serious cash flow problems and other financial difficulties, decreasing demand for our products. Our customers and distributors may respond to such economic pressures by reducing or deferring their capital spending or reducing staff.

In addition, events in the United States or foreign markets, such as the United Kingdom's exit from the European Union, the worldwide effects from the spread of COVID-19 and political and social unrest in various countries around the world, can impact the global economy and capital markets. Additionally, if our customers and distributors are not successful in generating sufficient revenue or are precluded from securing financing, their businesses will suffer, which may materially and adversely affect our business, financial condition and results of operations.

We may not realize the benefits or costs of our Co-Development and Collaboration Agreement with AVEO.

In 2014, we entered into a Co-Development and Collaboration Agreement with AVEO whereby the two parties agreed to various terms and conditions necessary for the co-development of AVEO's compound ficlatuzumab (the "Collaboration Agreement").

We were granted a limited legal interest in ficlatuzumab and may not have the right to control the development and exploitation of ficlatuzumab. As consideration for the grant, we agreed to cover the first $15.0 million of ficlatuzumab's clinical development costs, with both parties then sharing all costs equally after the cap was reached.

In October of 2016, the Collaboration Agreement was amended to eliminate the requirement that we cover all of the initial costs. Under the amended terms, we agreed to allow AVEO to recapture its cost that it otherwise would not have been responsible for said recapture to occur out of any royalties or revenues eventually derived from the Collaboration Agreement. As part of the Collaboration Agreement, unless we or AVEO exercise our right to opt-out of co-development, we equally share in any income received from licensing rights to ficlatuzumab to any third parties. In September 2020, we exercised our opt-out right for the payment of half of the

development and regulatory costs for ficlatuzumab. This opt-out is effective as of December 2, 2020 with remaining obligations estimated to be $0.3 million. Following the effective date, we will be entitled to a 10% royalty of net sales of ficlatuzumab and 25% of license income generated from the licensing of ficlatuzumab. Ficlatuzumab is currently being evaluated in squamous cell carcinoma of the head and neck (SCCHN), metastatic pancreatic ductal cancer ("PDAC"), and acute myeloid leukemia ("AML").

Our relationship with AVEO may require us to incur non-recurring and other charges, increase our near and long-term expenditures, or disrupt our management and business. We cannot be certain that, following the realization of this relationship, we will achieve the revenue or specific net income that justifies our entry into it. Any termination of this relationship, or delays in entering into new strategic partnership agreements with AVEO, could delay our sales and marketing efforts, which would harm our business prospects, financial condition and results of operations.

We are exposed to significant future payments and other obligations associated with our acquisitions of Integrated Diagnostics and Oncimmune, U.S.A., and may not realize the advantages we expect from these acquisitions.

We purchased select assets and liabilities from Integrated Diagnostics, Inc. and IND Funding, LLC (collectively, the "Seller") which included the CLIA lab in Seattle, Washington, and all rights to the Nodify XL2 test and intellectual property rights related to that test. The purchase was made for total consideration of $27.6 million, consisting of $8.0 million (10,649,604 shares) of our Series G Preferred Stock and contingent consideration with an initial fair market value of $19.6 million. These shares of Series G Preferred Stock converted into 1,794,099 shares of our common stock upon the closing of our initial public offering.

The acquisition of Integrated Diagnostics included a contingent consideration arrangement that requires additional consideration to be paid by us to the Seller based on the milestone of the attainment of a three consecutive month gross margin target of $2 million within a seven-year period. The amount can be payable in stock or cash at our or the Seller's option. The total amount of undiscounted contingent consideration which we may be required to pay under the arrangement is $37.0 million. For the 6 months following the achievement of the milestone, the Seller has the option to require us to pay the contingent consideration in cash over 8 equal installments due each calendar quarter. If the Seller elects not to exercise this option, we have 12 months to either settle the contingent consideration in two equal quarterly cash installments or in 2,520,108 of common stock. As of September 30, 2020, we have not made any payments in connection with the contingent consideration.

In addition, on October 31, 2019 we completed an acquisition of United Kingdom-based Oncimmune's United States operations including its CLIA lab in De Soto Kansas and its incidental pulmonary nodule ("IPN") malignancy test, then marketed in the United States as the EarlyCDT®-Lung. We renamed the test and relaunched the test on February 28, 2020 as the Nodify CDT test and the De Soto, Kansas lab will be the sole United States provider of the Nodify CDT test.

As part of the acquisition, we and Oncimmune entered into several agreements to govern the relationship between the parties and to allow us to provide the Nodify CDT test. The overarching umbrella Purchase and Commercialization Agreement ("PCA") defines the general relationship between the parties. Included under the PCA was (a) an APA whereby we acquired all of the United States assets associated with the De Soto, Kansas clinical laboratory, as well as the trademarks and patent application associated with the test; (b) an intellectual property license granting us the rights necessary under Oncimmune's background intellectual property rights to perform the Nodify CDT test; (c) a supply agreement for supplying us with the necessary materials and reagents needed to run the Nodify CDT test; and (d) a development agreement where Oncimmune agrees to assist us in further developing the Nodify CDT test. We were also granted an option through December 31, 2020 to acquire the rights to expand the field of use of the Nodify CDT test to include lung cancer screening.

As consideration for the rights granted to us, we agreed to payments of $1.2 million and further agreed to an option fee for the screening option of $9.0 million due within 30 days of exercising the option. As of September 30, 2020, we have paid $1.2 million of the agreed upon payments. We also agreed to a revenue share payment of 8% of recognized revenue for non-screening tests up to an annual minimum volume and 5% thereafter, with an escalating minimum through the first four years of sales. Revenue share expenses of $0.2 million were incurred for the nine months ended September 30, 2020. In September 2020, we notified Oncimmune that we would not exercise this option for expansion of the field of use.

Our acquisitions may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. We cannot be certain that, following the realization of these acquisitions, we will achieve the revenue or specific net income that justifies our entry into them. This could delay our sales and marketing efforts, which would harm our business prospects, financial condition and results of operations.

We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.

We are highly dependent on our senior management and other key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales and marketing professionals, scientists, clinical specialists, and other highly skilled personnel and to integrate current and additional personnel in all departments. The loss of members of our senior management, sales and marketing professionals, scientists, clinical and regulatory specialists could result in delays in product development and harm our business. If we are not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition and results of operations.

Our research and development programs and laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the competition for qualified personnel among life science businesses, particularly near our headquarters in Boulder, Colorado and our laboratory facility in De Soto, Kansas. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. We may have difficulties locating, recruiting or retaining qualified sales people. Recruiting and retention difficulties can limit our ability to support our research and development and sales programs. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued and may continue to issue equity awards that vest over time. The value to employees of equity awards that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We also do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees.

Our corporate culture has contributed to our success, and if we cannot maintain this culture as we grow, we could lose the innovation, creativity and teamwork fostered by our culture and our business may be harmed.

We believe that our culture has been and will continue to be a critical contributor to our success. We expect to continue to hire aggressively as we expand, and we believe our corporate culture has been crucial in our success and our ability to attract highly skilled personnel. If we do not continue to develop our corporate culture or maintain and preserve our core values as we grow and evolve, we may be unable to foster the innovation, curiosity, creativity, focus on execution, teamwork and the facilitation of critical knowledge transfer and knowledge sharing we believe we need to support our growth. Our anticipated headcount growth and our transition from a private company to a public company may result in a change to our corporate culture, which could harm our business.

Our ability to utilize our net operating loss carryforwards and research and development credit may be limited.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code") a corporation that undergoes an ownership change, generally defined as a greater than 50% change by value in its equity ownership by certain shareholders over a three-year period, is subject to limitations on its ability to utilize its pre-change net operating losses ("NOLs") and its research and development credit carryforwards to offset future taxable income. The applicable rules generally operate by focusing on changes in ownership among stockholders considered by the rules as owning, directly or indirectly, 5% or more of the stock of a company, as well as changes in ownership arising from new issuances of stock by the company. We believe that our NOLs are currently not subject to limitation under these rules. However, if we undergo an ownership change in the future, our ability to utilize NOLs and research and development credit carryforwards could be limited by Sections 382 and 383 of the Code. Future changes in stock ownership may be beyond our control. In addition, our ability to deduct net interest expense may be limited if we have insufficient taxable income for the year during which the interest is incurred, and any carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOLs and other attributes. For these reasons, in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs, research and development credit carryforwards or disallowed interest expense carryovers, even if we attain profitability.

The terms of our secured credit agreement require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In February 2018, we entered into an agreement with Innovatus Life Sciences Lending Fund to refinance the 2018 Notes. The initial amount borrowed under the 2018 Notes was $23 million and the maturity date is February 2023. We are required to make quarterly interest payments that began in June 2018 and outstanding principal is due in 24 equal installments commencing in March 2021. The agreement has been amended multiple times to adjust terms to account for our acquisitions and growth. Further, we

granted the lender a security interest in all of our assets through a pledge and security agreement, patent security agreement and trademark security agreement, each between us and the lender.

The loan may be prepaid by us at any time, subject to a prepayment penalty of up to 3% of the principal amount, depending on the date of prepayment. Upon payment of the 2018 Notes at maturity or prepayment on any earlier date, unless waived, a 2% back-end facility fee will apply to the amounts paid or prepaid. The 2% fee is being recorded as additional interest expense over the term of the 2018 Notes.

The 2018 Notes contain customary affirmative and negative covenants for a loan, requires us to comply with a minimum daily liquidity covenant, and has a rolling monthly revenue requirement. Failure to comply with the covenants and loan requirements may result in early amortization of the loan in a 24- or 36-month payment schedule.

The 2018 Notes also contain certain covenants that prevent us from making acquisitions, incurring additional indebtedness, or making or terminating any agreement valued above a certain dollar threshold without the prior written consent of the lender. These covenants may restrict our ability to pursue new business opportunities and access additional capital.

In the event of a default, including, among other things, our failure to make any payment when due or our failure to comply with any covenant under the 2018 Notes, the lender could elect to declare all amounts outstanding to be immediately due and payable, and could proceed against the collateral granted to them to secure such indebtedness, including all of our intellectual property, which could have a material adverse effect on our business, financial condition, and results of operations.

We will need to raise additional capital to fund our existing operations, develop our platform, commercialize new diagnostic tests or expand our operations.

We will need to raise additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- increase our sales and marketing efforts to drive market adoption of and address competitive developments;
- fund development and marketing efforts of our diagnostic tests or any other future diagnostic tests;
- expand our technologies into other types of cancer management and lung disease detection diagnostic tests;
- acquire, license or invest in technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth;
- our rate of progress in establishing payer coverage and reimbursement arrangements with domestic and international commercial third-party payers and government payers;
- the cost of expanding our laboratory operations and offerings, including our sales and marketing efforts;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of and reimbursement for our diagnostic tests;
- our rate of progress in, and cost of research and development activities associated with, diagnostic tests in research and early development;
- the effect of competing technological and market developments;

- costs related to international expansion; and
- the potential cost of and delays in product development as a result of any regulatory oversight applicable to our diagnostic tests.

The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, our stockholders could experience dilution. Any preferred equity securities issued also could provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our platform technologies or diagnostic tests, pay a portion of our royalties, or grant licenses on terms that are not favorable to us.

We may acquire other businesses, which could require significant management attention, disrupt our business, dilute stockholder value and adversely affect our results of operations.

As part of our business strategy, we may in the future make additional acquisitions or investments in complementary companies, diagnostic tests or technologies that we believe fit within our business model and can address the needs of our customers and potential customers. In the future, we may not be able to acquire and integrate other companies, diagnostic tests or technologies in a successful manner. We may not be able to find suitable acquisition candidates, and we may not be able to complete such acquisitions on favorable terms, if at all. In addition, the pursuit of potential acquisitions may divert the attention of management and cause us to incur additional expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. If we do complete acquisitions, we may not ultimately strengthen our competitive position or achieve our goals, including increases in revenue, and any acquisitions we complete could be viewed negatively by our customers, investors and industry analysts.

Future acquisitions may reduce our cash available for operations and other uses and could result in amortization expense related to identifiable assets acquired. We may have to pay cash, incur debt or issue equity securities to pay for any such acquisition, each of which could adversely affect our financial condition or the value of our common stock. The sale or issuance of equity to finance any such acquisitions would result in dilution to our stockholders. The incurrence of indebtedness to finance any such acquisition would result in fixed obligations and could also include covenants or other restrictions that could impede our ability to manage our operations. In addition, our future results of operations may be adversely affected by the dilutive effect of an acquisition, performance earn-outs or contingent bonuses associated with an acquisition. Furthermore, acquisitions may require large, onetime charges and can result in increased debt or contingent liabilities, adverse tax consequences, additional stock-based compensation expenses and the recording and subsequent amortization of amounts related to certain purchased intangible assets, any of which items could negatively affect our future results of operations. We may also incur goodwill impairment charges in the future if we do not realize the expected value of any such acquisitions.

Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize, or such strategic alliance, joint venture or acquisition may be prohibited. For example, our 2018 Notes restrict our ability to pursue certain mergers, acquisitions, amalgamations or consolidations that we may believe to be in our best interest. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

Risks Related to our Governmental Regulation

The insurance coverage and reimbursement status of newly approved diagnostic tests, particularly in a new category of diagnostics and therapeutics, is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for current or future diagnostic tests could limit our ability, and that of our collaborators, to fully commercialize our diagnostic tests and decrease our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payers is essential for most patients to be able to afford the clinical diagnostic tests and cellular therapeutics that we and our collaborators currently or in the future plan to develop and sell. In addition, because our clinical diagnostics and diagnostic tests represent new approaches to the research, diagnosis, detection and treatment of diseases, we cannot accurately estimate how our diagnostic tests, and those jointly created with our collaborators, would be priced, whether reimbursement could be obtained or any potential revenue generated. Sales of our diagnostic tests will depend substantially, both domestically and internationally, on the extent to which the costs of our diagnostic tests are paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers. If reimbursement is not available, or is

available only to limited levels, we may not be able to successfully commercialize some of our diagnostic tests or services. Even if coverage is provided, the available reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment in any of our diagnostic tests or services. Changes in the reimbursement landscape may occur, which are outside of our control, and may impact the commercial viability of our diagnostic tests.

There is significant uncertainty related to the insurance coverage and reimbursement of newly launched, cleared, authorized or approved diagnostic tests. In the United States, many significant decisions about reimbursement for new diagnostics and medicines are typically made by the Centers for Medicare and Medicaid Services ("CMS"), an agency within the Department of Health and Human Services ("HHS"). CMS decides whether and to what extent a new diagnostic or medicine will be covered and reimbursed under Medicare, although it frequently delegates this authority to local Medicare Administrative Contractors ("MACs"). Private payers tend to follow Medicare to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel diagnostic tests such as ours. Additionally, reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement, or have been approved under restricted conditions, in certain European countries.

Outside the United States, the reimbursement process and timelines vary significantly. Certain countries, including a number of member states of the EU, set prices and make reimbursement decisions for diagnostics and pharmaceutical products, or medicinal products, as they are commonly referred to in the EU, with limited participation from the marketing authorization or Conformité Européenne ("CE") mark holders, or may take decisions that are unfavorable to the authorization or CE mark holder where they have participated in the process. We cannot be sure that such prices and reimbursement decisions will be acceptable to us or our collaborators. If the regulatory authorities in these foreign jurisdictions set prices or make reimbursement criteria that are not commercially attractive for us or our collaborators, our revenues and the potential profitability of our products in those countries would be negatively affected. An increasing number of countries are taking initiatives to attempt to control the healthcare budget by focusing cost-cutting efforts on medicinal products, and to a lesser extent, medical devices, provided under their state-run healthcare systems. These international price control efforts have impacted all regions of the world, but have been most prominent in the EU. Additionally, some countries require approval of the sale price of a product before it can be marketed or mandatory discounts or profit caps may be applied. Further, after the sale price is approved, it remains subject to review during the product lifecycle. In many countries, the pricing review period begins after marketing or product licensing approval is granted or the CE mark is obtained. As a result, we or our collaborators might obtain marketing approval for a product or service in a particular country, but then may experience delays in the reimbursement approval or be subject to price regulations that would delay the commercial launch of our product or service, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of that product or service in that particular country.

Moreover, increasing efforts by governmental and third-party payers, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for newly cleared, authorized or approved devices and medicines and, as a result, they may not cover or provide adequate payment for our clinical diagnostics to be sold by us or our collaborators. For example, in May 2018 the United States government released a "blueprint," or plan, to reduce the cost of drugs. This blueprint contains certain measures that HHS has been working to implement. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, which are, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect to experience pricing pressures on our clinical diagnostics sold by us and our collaborators due to the trend toward value-based pricing and coverage, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new diagnostic tests.

Measures to reduce healthcare costs may hurt our business.

The majority of our customers are healthcare providers who depend upon reimbursement by government and commercial insurance payers for lung cancer diagnostic solutions services. With a vast majority of United States patients with lung cancer covered by Medicare, the Medicare reimbursement rate is an important factor in a customer's decision to use our diagnostic tests and limits the prices we may charge for them. Commercial insurance payers may also exert downward pressure on payment rates for lung cancer treatment services. A reduction in reimbursement rates for lung cancer treatments may adversely affect our customers' businesses and cause them to enact cost reduction measures that may include reducing the scope of their programs, thereby potentially reducing demand for our diagnostic tests.

Healthcare reform measures could hinder or prevent the commercial success of our diagnostic tests.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that may harm our future revenues and profitability and the demand for our diagnostic tests. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our diagnostic tests. The effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our diagnostic tests. For example, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs.

There have been judicial challenges to certain aspects of the ACA, as well as efforts by the Trump administration and Congress to repeal, replace or alter the implementation of certain aspects of the ACA. For example, Congress eliminated the tax penalty, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance. The Further Consolidated Appropriations Act of 2020, Pub. L. No. 116-94, signed into law December 20, 2019, fully repealed the ACA's "Cadillac Tax" on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share (repeal effective in 2021), and the medical device excise tax on non-exempt medical devices. On December 14, 2018, a Texas District Court Judge invalidated the ACA in its entirety because he concluded that the individual mandate, which was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017 ("TCJA"), is unconstitutional and cannot be severed from the remainder of the ACA. The Fifth Circuit Court of Appeals affirmed the district court's ruling that the individual mandate was unconstitutional, but it remanded the case back to the district court for further analysis of whether the mandate could be severed from the ACA; that is, whether the entire ACA was therefore also invalid). The Supreme Court of the United States granted certiorari on March 2, 2020, heard oral arguments on November 10, 2020 and the case is expected to be decided by mid-2021. It is unclear how this decision, subsequent appeals, and other efforts to challenge, repeal, or replace, or alter the implementation of the ACA will affect our business, financial condition and results of operations.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to CMS payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken, with the exception of a temporary suspension of the 2% cut in Medicare payments from May 1, 2020 through December 31, 2020. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover Medicare overpayments to providers from three to five years.

The Trump administration and Congress may continue to pursue significant changes to the current healthcare laws. We face uncertainties that might result from modifications or repeal of any of the provisions of the ACA, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the medical device industry as a whole is currently unknown. Any changes to the ACA are likely to have an impact on our results of operations, and may negatively affect our business, financial condition and results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States on our business, financial condition and results of operations.

The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our diagnostic tests;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry. Future changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Future changes in healthcare policy could also decrease our revenue and impact sales of and reimbursement for our current and future diagnostic tests.

We must comply with anti-corruption, anti-bribery, anti-money laundering and similar laws.

We are subject to the Foreign Corrupt Practices Act of 1977 ("FCPA"), which generally prohibits companies in the United States from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business and requires companies to maintain accurate books and records and internal controls. We are also subject to requirements under the United States Treasury Department's Office of Foreign Assets Control, United States domestic bribery laws and other anti-corruption, anti-bribery and anti-money laundering laws. While we have policies and procedures in place designed to promote compliance with such laws, our employees or other agents may nonetheless engage in prohibited conduct under these laws for which we or our executives might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have an adverse effect on our business, financial condition and results of operations.

Furthermore, international customers may currently order our diagnostic tests, either directly from us or through a potential joint venture, and we are subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-United States government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Our reliance on independent distributors to sell our diagnostic tests internationally demands a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents and we could be held responsible for their actions. Other United States companies in the medical device and biopharmaceutical field have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including laws promulgated by OECD countries in which we operate, such as Israel. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees and could result in a material adverse effect on our business, prospects, financial condition and results of operations. We could also suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures.

We must comply with healthcare fraud and abuse laws.

Various federal and state laws, as well as the laws of foreign countries, prohibit payments to induce the referral, purchase, order or use of healthcare products or services and require medical device companies to limit prevent, and/or monitor, and report certain payments to third-party payers, health care professionals, and other individuals. These healthcare fraud and abuse anti-kickback, public reporting and aggregate spend laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with lung cancer treatment providers, hospitals, physicians or other potential purchasers or users, including patients, of medical devices and services. They also impose additional administrative and compliance burdens on us. In particular, these laws influence, among other things, how we structure our sales offerings, including discount practices, customer support, education and training programs and physician consulting and other service arrangements. These laws prohibit certain marketing initiatives that are commonplace in other industries. If we were to offer or pay inappropriate inducements for the purchase, order or use of our diagnostic tests or our services, or our arrangements are perceived as inappropriate inducements, we could be subject to claims under various healthcare fraud and abuse laws.

Restrictions under applicable United States federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute, a criminal law, prohibits, among other things, persons and entities from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, in cash or in kind, to induce or reward purchasing, leasing, ordering, or arranging for, referring, or recommending the purchase, lease, order of any good or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;

- the Eliminating Kickbacks in Recovery Act, which prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in return for the referral of a patient to, or in exchange for an individual using the services of certain entities, including laboratories, if the services are covered by a health care benefit program;

- the Beneficiary Inducement Statute, which prohibits any person, organization, or entity from giving anything of value to a federal health care program beneficiary that is likely to induce or influence the beneficiary's choice of provider, practitioner, or supplier for covered services;

- the federal civil False Claims Act, which may be enforced through civil whistleblower or *qui tam* actions and is often used to enforce the federal Anti-Kickback Statute and other healthcare laws and regulations, imposes civil penalties and potential exclusion from federal healthcare programs, against individuals or entities for, among other things, knowingly

presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or for making a false record or statement material to an obligation to pay the federal government or for knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government;

- federal criminal statutes created by HIPAA impose criminal liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private insurance plans, or, in any matter involving a healthcare benefit program, for knowingly and willfully making materially false, fictitious, or fraudulent statements in connection with the delivery of or payment for health care benefits; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers.

Other federal and state laws, as well as the laws of foreign countries, generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payments to government or commercial payers that are false or fraudulent, or for items or services that were not provided as claimed. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of product candidates and medical devices from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. Moreover, any investigation into our practices could cause adverse publicity and require a costly and time-consuming response. If any physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Manufacturers can also be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by providing inaccurate billing or coding information to customers, by providing improper financial inducements, or through certain other activities. We attempt to ensure that any billing and coding information we provide for our diagnostic tests emphasizes the need for physicians and other providers to make independent judgments, use accurate and appropriate billing and coding that complies with all applicable payer policies, and document the medical need for their patients as appropriate. Nevertheless, the government may not regard any billing errors that may be made by our customers as inadvertent and may examine our role in providing information to our customers, physicians and patients concerning the benefits and potential coverage of more frequent therapy.

FDA regulation of our industry generally or our tests specifically could be disruptive to our business.

Our operations are subject to extensive federal, state, local and foreign laws and regulations, including FDA laws and regulations, all of which are subject to change. These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. We believe that we are in material compliance with all statutory and regulatory requirements applicable to us, but there is a risk that one or more government agencies could take a contrary position, or that a private party could file suit under the qui tam provisions of the federal False Claims Act or a similar state law. Such occurrences, regardless of their outcome, could damage our reputation and adversely affect important business relationships with third parties, including managed care organizations, and other private third-party payers.

The FDA has recently increased its attention to marketing of pharmacogenetic tests. For example, in late 2018, the FDA issued a safety communication regarding genetic laboratory tests with claims to predict a patient's response to specific medications that have not been reviewed by the FDA and may not be supported by clinical evidence. Among other tests, the FDA notice cited genetic tests that claim results can be used to help physicians identify which antidepressant medication would have increased effectiveness or side effects compared to other antidepressant medications. As explained by the FDA in its update to this safety communication, the FDA sent notices to several firms marketing such pharmacogenetic tests where the FDA believes the relationship between genetic variations and the medication's effects has not been established, including a warning letter sent to a laboratory, in part, for failing to obtain premarket review of its test. HHS recently issued an announcement stating that the FDA cannot require premarket review of any LDT without engaging in formal notice-and-comment rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances.

The HHS announcement was made on the Department's website and we can provide no assurances that the HHS statement will not be rescinded or revised or that it would preclude the FDA from renewing its attention on diagnostic tests, including those that we

provide. If this were to happen, it may impact our marketing practices relating to the relevant tests, which in turn may have an adverse impact on our business, financial condition and results of operations.

The SARS-CoV-2 tests we perform are currently the subject of EUAs, which permit the use of unapproved medical products or unapproved uses of medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives, as provided under section 564 for the Federal Food, Drug, and Cosmetic Act ("FDCA"). EUAs are temporary authorizations that are revoked at the end of the public health emergency, when there is an adequate, approved, or available alternative, or when there are performance or safety concerns. These EUAs also set out conditions for laboratories who are authorized to perform the particular test. The HHS statement mentioned above did not affect EUAs for COVID-19 laboratory-developed tests that were already in effect at the time the statement was released. The HHS statement did not affect EUAs issued for commercially-developed COVID-19 IVD tests, which apply to test developers and authorized laboratories.

The EUA for Bio-Rad's SARS-CoV-2 Droplet Digital PCR test provides several conditions for authorized laboratories, including that the test result reports will include Fact Sheets that are authorized as part of the EUA, deviations from the authorized procedures, including specimen types, are not permitted, notification of public health authorities of intent to run the test prior to initiating testing, collection and reporting of performance data to the FDA, including false positives, false negatives, and significant deviations from the established performance characteristics, and appropriate training and protective equipment for laboratory staff. This EUA also states that authorized laboratories must maintain records associated with the EUA and be made available to the FDA for inspection upon request. Printed materials, advertising, and promotion related to use of the test must be consistent with the authorized labeling and Fact Sheets, as well as other terms set forth in the EUA and any applicable requirements under the FDCA and its implementing regulations, and conspicuously bear the following statements:

- This test has not been FDA cleared or approved;
- This test has been authorized by the FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Other statements that appear in advertising and promotional materials must not represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

The EUA for Bio-Rad's serological test for the antibodies associated with SARS-CoV-2, also sets out several conditions for authorized laboratories that mirror the conditions for the PCR test described above, except that the printed materials, advertising, and promotion of the test must conspicuously bear the following statements:

- This test has not been FDA cleared or approved;
- This test has been authorized by the FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of total antibodies, including IgM/IgG/IgA, against SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Failure to comply with federal, state and foreign laboratory licensing requirements and the applicable requirements of the FDA or any other regulatory authority, could cause us to lose the ability to perform our tests, experience disruptions to our business, or become subject to administrative or judicial sanctions.

The diagnostic testing industry is subject to extensive laws and regulations, many of which have not been interpreted by the courts, including the application of the FDA's EUA authority. As noted above, the EUAs for the COVID-19 tests that are part of our Biodesix WorkSafe testing program set out certain conditions for authorized laboratories using the tests, which have not received

premarket clearance, approval, or a de novo from the FDA. If we fail to meet these conditions, the FDA may take enforcement action, such as issuing a warning letter, seeking an injunction, seizure, fines, or criminal penalties. Pursuant to the August 19, 2020 statement by HHS, the FDA cannot require any LDT to undergo premarket approval until it has engaged in notice-and-comment rulemaking. Laboratory tests that have already received an EUA to detect the COVID-19 virus were "unaffected" by the announcement. Tests without FDA clearance, approval, or authorization would not be considered covered countermeasures under the Public Readiness and Emergency Preparedness Act ("PREP Act"). The HHS statement also did not affect EUAs issued for commercially-developed COVID-19 IVD tests, which apply to test developers and authorized laboratories.

We are also subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA requires virtually all laboratories to be certified by the federal government and mandates compliance with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure that testing services are accurate, reliable and timely. CLIA certification is also a prerequisite to be eligible to bill state and federal health care programs, as well as many private third-party payers, for laboratory testing services. As a condition of CLIA certification, each of our laboratories is subject to survey and inspection every other year, in addition to being subject to additional random inspections. The biennial survey is conducted by CMS, a CMS agent (typically a state agency), or, if the laboratory holds a CLIA certificate of accreditation, a CMS-approved accreditation organization. Sanctions for failure to comply with CLIA requirements, including proficiency testing violations, may include suspension, revocation, or limitation of a laboratory's CLIA certificate, which is necessary to conduct our business, as well as the imposition of significant fines or criminal penalties.

Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state or foreign license, or accreditation, could have a material adverse effect on our business. If the CLIA certificate of any one of our laboratories is revoked, CMS could seek revocation of the CLIA certificates of our other laboratories based on their common ownership or operation, even though they are separately certified.

In addition, we are subject to state laws and regulations governing laboratory licensure. Some states have enacted state licensure laws that are more stringent than CLIA. Although we have obtained licenses from states where we believe we are required to be licensed, we may become aware of other states that require out-of-state laboratories to obtain licensure in order to accept specimens from the state, and it is possible that other states currently have such requirements or will have such requirements in the future.

We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations that may limit our ability to make our tests available outside of the United States. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming and subject us to significant and unanticipated delays. Changes in state or foreign licensure laws that affect our ability to offer and provide diagnostic services across state or foreign country lines could materially and adversely affect our business. In addition, state and foreign requirements for laboratory certification may be costly or difficult to meet and could affect our ability to receive specimens from certain states or foreign countries.

Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including suspension, limitation or revocation of our CLIA certificate and/or state licenses, imposition of a directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions and revocation of the laboratory's approval to receive Medicare and Medicaid payment for its services, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure or our failure to renew our CLIA certificate, a state or foreign license or accreditation, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

Our Boulder, Colorado and De Soto, Kansas laboratories are College of American Pathologists ("CAP")-accredited (Boulder) or COLA (De Soto) clinical laboratories regulated by CMS pursuant to CLIA. We also have a current CLIA certificate for each facility. To maintain these certificates, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our laboratory from time to time. Furthermore, our diagnostic tests are categorized as Laboratory Developed Tests ("LDTs") and are not currently subject to FDA regulation, although certain components provided by third parties and used to create and/or administer the test may be. LDTs are a subset of in vitro diagnostics ("IVDs") that are intended for clinical use and developed, validated, and offered within a single laboratory for use only in that laboratory. The FDA's authority to regulate LDTs has been frequently contested, and HHS recently issued a public statement purporting to rescind the FDA's policies regarding the premarket review of LDTs. According to the HHS statement, the FDA will not require premarket review of LDTs unless it engages in notice-and-comment rulemaking. There is no guarantee, however, that the HHS statement will not be revised or rescinded, that legislation reforming the federal government's regulation of LDTs will not be passed, or that LDTs will otherwise continue to be able to operate

without first receiving FDA premarket review. Failure to adhere to any new FDA regulation would result in fines, product suspensions, warning letters, recalls, injunctions and other civil and criminal penalties.

Changes in the way that the FDA regulates tests performed by laboratories like ours could result in delay or additional expense in offering our tests and tests that we may develop in the future.

Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA publicly announced its intention to regulate certain LDTs and issued two draft guidance documents that set forth a proposed phased-in risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. However, these guidance documents were withdrawn at the end of the Obama administration and replaced by an informal discussion paper reflecting some of the feedback that the FDA had received on LDT regulation. The FDA acknowledged that the discussion paper in January 2017 does not represent the formal position of the FDA and is not enforceable. Nevertheless, the FDA wanted to share its synthesis of the feedback that it had received in the hope that it might advance public discussion on future LDT oversight. HHS has since issued a statement purporting to rescind FDA's policies regarding the premarket review of LDTs, stating that FDA must engage in notice and comment rulemaking (as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances) prior to requiring premarket review of LDTs. HHS issued this statement on its website and it may be subject to change. Also, it is possible that Congress will pass legislation to reform the federal government's regulation of LDTs or that FDA will engage in notice-and-comment rulemaking to require premarket review of LDTs, which could result in delay or additional expense in offering our tests and tests that we may develop in the future.

Our current line of diagnostic tests are covered under CLIA and CMS, although our COVID testing program and select partnerships we may enter may cause us to be subject to additional FDA requirements.

The laws and regulations governing the marketing of diagnostic products are evolving, extremely complex and in many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Pursuant to its authority under the FDCA, the FDA has jurisdiction over medical devices, including in vitro diagnostics and, therefore, potentially our clinical laboratory tests.

Pursuant to the FDCA and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. Although the FDA has asserted that it has authority to regulate the development and use of LDTs, such as our and many other laboratories' tests, as medical devices, it has generally exercised enforcement discretion and is not otherwise regulating most tests developed and performed within a single high complexity CLIA-certified laboratory. On August 19, 2020, HHS issued a statement purporting to rescind the FDA's policies regarding the premarket review of LDTs, absent notice-and-comment rulemaking. the FDA's policies to date have been articulated through guidance documents, compliance manuals, website statements, and other informal issuances. The FDA could, at any time, engage in notice-and-comment rulemaking, or Congress could take action to amend the law to change the current regulatory framework for in vitro diagnostics and LDTs. Further, the HHS statement was issued on its website and may be subject to change, particularly given the reasoning that additional flexibility is needed due to the COVID-19 pandemic.

We believe that our tests, as utilized in our clinical laboratory, are and would be considered LDTs and that as a result, the FDA does not require that we obtain regulatory clearances or approvals for our LDTs or their components pursuant to the FDA's current policies and guidance. Although we believe that our tests and test components are either exempt from FDA medical device regulations or are subject to an enforcement discretion policy, it is possible that the FDA would not agree with our determinations or that the FDA will change its regulations and policies such that our products become regulated as medical devices.

In contrast with our LDTs, the FDA has regulatory jurisdiction over the two FDA EUA-authorized COVID-19 tests that were developed by Bio-Rad, which we offer as part of our Biodesix WorkSafe testing programs.

Our operations, therefore, are or may become subject to extensive regulation by the FDA in the United States. Government regulations specific to medical devices are wide ranging and govern, among other things:

- test design, development, manufacture, and release;
- laboratory and clinical testing, labeling, packaging, storage and distribution;

- product safety and efficacy;
- premarketing clearance or approval;
- service operations;
- record keeping;
- product marketing, promotion and advertising, sales and distribution;
- post-marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals;
- post-market approval studies; and
- product import and export.

The FDA classifies medical devices into one of three classes on the basis of the intended use of the device, the risk associated with the use of the device for that indication, as determined by the FDA, and on the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices, which have the lowest level of risk associated with them, are subject to general controls. Class II devices are subject to general controls and special controls, including performance standards. Class III devices, which have the highest level of risk associated with them, are subject to general controls and premarket approval.

Before a new medical device or service, or a new intended use for an existing product or service, can be marketed in the United States, a company must first submit and receive either 510(k) clearance, de-novo authorization, or premarket approval ("PMA") from the FDA, unless an exemption applies. Most Class I devices and some Class II devices are exempt from these requirements. 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 (preamendments device), a device that was originally on the United States 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, 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 FDA also allows the submission of a direct de-novo petition. This procedure allows a manufacturer whose novel device is automatically 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. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012 ("FDASIA"), a medical device could only be eligible for de novo classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the de novo classification pathway by permitting manufacturers to request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination.

The 510(k), de-novo or PMA process can be expensive, lengthy and unpredictable. The FDA can delay, limit, or deny clearance or approval of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that the diagnostic tests are safe or effective for their proposed intended uses;
- the disagreement of the FDA with the design or implementation of our clinical trials or the interpretation of data from clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;

- the data from our clinical trials may be insufficient to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by any such agency, which may include any of the following sanctions:

- adverse publicity, warning letters, untitled letters, it has come to our attention letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our diagnostic tests;
- operating restrictions, partial suspension or total shutdown of production;
- denial of our requests for regulatory clearance or premarket approval of new diagnostic tests or services, new intended uses or modifications to existing diagnostic tests or services;
- withdrawal of regulatory clearance or premarket approvals that have already been granted; or
- criminal prosecution.

As discussed above, we believe that our current line of diagnostic tests and their components are LDTs, subject to state licensing requirements and federal regulation by CMS under CLIA, although our COVID testing program and select partnerships we may enter may cause us to be subject to additional FDA regulations discussed above.

While we believe that we are currently in material compliance with applicable laws and regulations, it is possible that the FDA, or other regulatory agencies, would not agree with our determinations. If our products became become subject to 510(k) or other similar FDA regulations, we would need to comply with the applicable regulations or face significant civil and criminal penalties. In addition, IVDs and CDx tests are widely considered to be Class III devices, and it is possible that in the future, we may develop tests that fall into this category. CDx tests in particular may require further administrative procedures in the PMA process. Exposure to these additional regulatory requirements would also affect our business, financial condition and results of operations.

Our future success depends on our ability to develop, receive regulatory clearance or approval for, and introduce new diagnostic tests or enhancements to existing diagnostic tests that will be accepted by the market in a timely manner. There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future diagnostic tests and failure to obtain necessary clearances or approvals for our future diagnostic tests would adversely affect our ability to grow our business.

It is important to our business that we build a pipeline of diagnostic test offerings that address limitations of current lung disease diagnostic tests. As such, our success will depend in part on our ability to develop and introduce new diagnostic tests. However, we may not be able to successfully develop and obtain regulatory clearance or approval for enhancements to our existing diagnostic tests, or new diagnostic tests for any number of reasons, including due to the cost associated with certain regulatory approval requirements, or these diagnostic tests may not be accepted by physicians or users.

The success of any new diagnostic test or enhancement to an existing diagnostic test will depend on a number of factors, including our ability to, among others:

- identify and anticipate physician and patient needs properly;
- develop and introduce new diagnostic tests or enhancements to our existing diagnostic tests in a timely manner;
- avoid infringing upon, misappropriating or violating the intellectual property rights of third parties;
- demonstrate, if required, the safety and efficacy of new diagnostic tests with data from clinical studies;

- obtain the necessary regulatory clearances or approvals for new diagnostic tests or enhancements to existing diagnostic tests;
- comply fully with FDA and foreign regulations on marketing of new diagnostic tests or modified diagnostic tests; and
- provide adequate training to potential users of our diagnostic tests.

If we do not develop new diagnostic tests or enhancements to our existing diagnostic tests in time to meet market demand or if there is insufficient demand for these diagnostic tests or enhancements, or if our competitors introduce new diagnostic tests with functionalities that are superior to ours, our results of operations will suffer.

Some of our future diagnostic tests may require FDA clearance of a 510(k) submission. Other diagnostic tests may require the approval of a PMA. In addition some of our future diagnostic tests may require clinical trials to support regulatory approval and we may not successfully complete these clinical trials. The FDA may not approve or clear these diagnostic tests for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or premarket approval of new diagnostic tests. Failure to receive clearance or approval for our new diagnostic tests would have an adverse effect on our ability to expand our business.

Modifications to our marketed tests may require new 510(k) clearances or PMA approvals, or may require us to cease marketing or recall the modified tests until clearances or approvals are obtained.

Modifications to our diagnostic tests may require new regulatory approvals or clearances, including 510(k) clearances or premarket approvals, or require us to recall or cease marketing the modified systems until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our diagnostic tests in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our diagnostic tests as modified, which could require us to redesign our diagnostic tests and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or efficacy, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a premarket approval application. Where we determine that modifications to our diagnostic tests require a new 510(k) clearance or premarket approval application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. Obtaining clearances and approvals can be a time consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced diagnostic tests in a timely manner, which in turn would harm our future growth.

If we or our suppliers fail to comply with ongoing FDA or other domestic and foreign regulatory authority requirements, or if we experience unanticipated problems with our diagnostic tests, they could be subject to restrictions or withdrawal from the market.

Any medical device that we manufacture, including those for which we obtain regulatory clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such diagnostic test, will be subject to continued regulatory review, oversight, and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers may be required to comply with FDA's Quality System Regulations (QSR codified at 21 C.F.R. § 820) for medical devices and International Standards Organization ("ISO") regulations for the manufacture of our diagnostic tests and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any diagnostic test for which we obtain clearance or approval. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, one or more of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;

- customer notifications for repair, replacement, or refunds;
- recall, detention or seizure of our diagnostic tests;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval of new diagnostic tests or modified versions of current diagnostic tests;
- operating restrictions;
- withdrawing 510(k) clearances on PMA approvals that have already been granted;
- refusal to grant export approval for our diagnostic tests; and
- criminal prosecution.

If any of these actions were to occur it would harm our reputation and cause our diagnostic test sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our diagnostic tests on a timely basis and in the required quantities, if at all.

In addition, we are required to conduct surveillance to monitor the safety or effectiveness of our diagnostic tests, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our diagnostic tests. Later discovery of previously unknown problems with our diagnostic tests, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such diagnostic tests or manufacturing processes, withdrawal of the diagnostic tests from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

Our diagnostic tests and services may in the future be subject to product recalls that could harm our reputation, business and financial results.

Medical devices can experience performance problems in the field that require review and possible corrective action. The occurrence of component failures, manufacturing errors, software errors, design defects or labeling inadequacies affecting a medical device could lead to a government-mandated or voluntary recall by the device manufacturer, in particular when such deficiencies may endanger health. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our diagnostic tests and services in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. Product recalls may divert management attention and financial resources, expose us to product liability or other claims, harm our reputation with customers and adversely impact our business, financial condition and results of operations.

Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of any future diagnostic tests and to manufacture, market and distribute our diagnostic tests after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. For example, the Verifying Accurate, Leading-edge IVCT Development (“VALID”) Act recently introduced in Congress would codify into law the term “in vitro clinical test” in order to create a new medical product category separate from medical devices that would include products currently regulated as in vitro diagnostics as well as LDTs.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our diagnostic tests. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of planned or future diagnostic tests. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Any change in the laws or regulations that govern the clearance and approval processes relating to our current, planned and future diagnostic tests could make it more difficult and costly to obtain clearance or approval for new diagnostic tests or to produce, market and distribute existing diagnostic tests. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for any new diagnostic tests would have an adverse effect on our ability to expand our business.

Clinical trials may be necessary to support future product submissions to FDA. These clinical trials are expensive and will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new diagnostic tests and will adversely affect our business, operating results and prospects.

Initiating and completing clinical trials necessary to support any future PMA applications, and additional safety and efficacy data beyond that typically required for a 510(k) clearance, for our possible future product candidates, will be time consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials.

Conducting successful clinical studies will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. 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 effectiveness of our diagnostic tests or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our diagnostic tests or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, the FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval for or commercialize our diagnostic tests and services.

We may not have the ability to independently conduct our pre-clinical and clinical trials for our future diagnostic tests and services and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our diagnostic tests and services on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

Our use, disclosure, and other processing of personally identifiable information, including health information, is subject to HIPAA and other federal, state, and foreign privacy and security regulations, and our failure to comply with those regulations or to adequately secure the information we hold could result in significant liability or reputational harm and, in turn, a material adverse effect on our business, operating results and prospects.

We maintain and process, and our third-party vendors, collaborators, contractors and consultants maintain and process on our behalf, a large quantity of sensitive information, including confidential business, personal and patient health information in connection with our clinical studies and our employees, and are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. Failure by us or our third-party vendors, collaborators, contractors and consultants to comply with any of these laws and regulations could result in notification obligations or

enforcement actions against us, which could result in fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects. These laws, rules and regulations evolve frequently and their scope may continually change, through new legislation, amendments to existing legislation and changes in enforcement, and may be inconsistent from one jurisdiction to another. The interpretation and application of consumer, health-related and data protection laws, especially with respect to genetic samples and data, in the United States, the European Union ("EU") and elsewhere, are often uncertain, contradictory and in flux. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future.

In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators.

Domestic laws in this area are complex and developing rapidly. Many state legislatures have adopted legislation relating to privacy, data security and data breaches. Laws in all 50 states require businesses to provide notice to customers whose personally identifiable information has been disclosed as a result of a data breach. The laws are not consistent, and compliance in the event of a widespread data breach is costly. States are also frequently amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California recently enacted the CCPA, which became effective on January 1, 2020. The CCPA, among other things, requires new disclosures to California consumers and affords such consumers new abilities to access and delete their personal information, opt-out of certain sales of personal information and receive detailed information about how their personal information is used. The CCPA provides for fines of up to $7,500 per violation, as well as a private right of action for data breaches that is expected to increase the frequency of data breach litigation. While the CCPA has already been amended multiple times, it is unclear how this legislation will be further modified or how it will be interpreted. Interpretations of the CCPA may continue to evolve with regulatory guidance. Additionally, a new California ballot initiative, the California Privacy Rights Act, has qualified to be included on the November 2020 ballot, and if voted into law by California voters, would impose additional data protection obligations on companies doing business in California, including additional consumer rights, including regarding certain uses of sensitive data. It would also create a new California data protection agency specifically tasked to enforce the law, which would likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. The effects of this legislation potentially are far-reaching, however, and may require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses. The CCPA and other changes in laws or regulations relating to privacy, data protection and information security, particularly any new or modified laws or regulations that require enhanced protection of certain types of data or new obligations with regard to data retention, transfer or disclosure, could increase the cost of providing our offerings, require significant changes to our operations or even prevent us from providing certain offerings in jurisdictions in which we currently operate and in which we may operate in the future.

Because of the breadth of these data protection laws and the narrowness of their exceptions and safe harbors, it is possible that our business or data protection policies could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of heightened regulatory focus on data privacy and security issues. Although we endeavor to comply with our published policies and documentation and ensure their compliance with current laws, rules and regulations, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policy and other documentation that provide promises and assurances about privacy and security can subject us to potential state and federal action in the United States if they are found to be deceptive, unfair, or misrepresentative of our actual practices. Any failure by us or other parties with whom we do business to comply with this documentation or with federal, state, local or international regulations could result in proceedings against us by governmental entities, private parties or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising.

If our operations are found to be in violation of any of the data protection laws described above or any other laws that apply to us, we may be subject to penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in government healthcare programs, injunctions, private qui tam actions brought by individual whistleblowers in the name of the government, class action litigation and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corrective action plan or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our results of operations.

In addition, numerous state and federal laws and regulations govern the collection, dissemination, use, privacy, confidentiality, security, availability, integrity, and other processing of PHI and PII. These laws and regulations include HIPAA. HIPAA establishes a set of national privacy and security standards for the protection of protected health information (as defined in HIPAA, 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. We are a covered entity under HIPAA when we are conducting our clinical trials. We are a covered entity with regard to our observational studies and clinical trials, and also a business associate under HIPAA for certain other business activities, and we execute business associate agreements with our clients.

HIPAA requires covered entities and business associates, such as us, to develop and maintain policies with respect to the protection of, use and disclosure of electronic PHI, including the adoption of administrative, physical and technical safeguards to protect such information, and certain notification requirements in the event of a data breach.

HIPAA imposes mandatory penalties for certain violations. Penalties for violations of HIPAA and its implementing regulations start at $119 per violation and are subject to a cap of $1,785,651 for violations of the same standard in a single calendar year. However, a single breach incident can result in violations of multiple standards. HIPAA also authorizes state attorneys general to file suit on behalf of their residents. Courts may 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 violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA covered entities and business associates. With regard to business associates, those audits assess the business associate's compliance with the HIPAA Privacy and Security Standards. Such audits are conducted randomly and after an entity experiences a breach affecting more than 500 individuals' data. Undergoing an audit can be costly, can result in fines or onerous obligations, and can damage a business associate's reputation.

In addition to HIPAA, numerous other federal, state, and foreign laws and regulations protect the confidentiality, privacy, availability, integrity and security of PHI and other types of PII. Some of these laws and regulations may be preempted by HIPAA with respect to PHI, or may exclude PHI from their scope but impose obligations with regard to PII that is not PHI, and in some cases, can impose additional obligations with regard to PHI. These laws and regulations are often uncertain, contradictory, and subject to changing or differing interpretations, and we expect new laws, rules and regulations regarding privacy, data protection, and information security to be proposed and enacted in the future. This complex, dynamic legal landscape regarding privacy, data protection, and information security creates significant compliance issues for us and our clients and potentially exposes us to additional expense, adverse publicity and liability. While we have implemented data privacy and security measures in an effort to comply with applicable laws and regulations relating to privacy and data protection, some PHI and other PII or confidential information is transmitted to us by third parties, who may not implement adequate security and privacy measures, but it is possible that laws, rules and regulations relating to privacy, data protection, or information security may be interpreted and applied in a manner that is inconsistent with our practices or those of third parties who transmit PHI and other PII or confidential information to us. If we or these third parties are found to have violated such laws, rules or regulations, it could result in government-imposed fines, orders requiring that we or these third parties change our or their practices, or criminal charges, which could adversely affect our business. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business.

We may eventually operate in a number of countries outside of the United States whose laws may in some cases be more stringent than the requirements in the United States. For example, the EU has specific requirements relating to cross-border transfers of personal data to certain jurisdictions, including to the United States. In addition, some countries have stricter consumer notice or consent requirements relating to personal data collection, use or sharing, have more stringent requirements relating to organizations' privacy programs and provide stronger individual rights. Moreover, international privacy and data security regulations may become more complex and result in greater penalties. For instance, since May 25, 2018, the GDPR regulates the collection and use of personal data of data subjects in the EU and the European Economic Area ("EEA"). The GDPR applies extra-territorially under certain circumstances and imposes stringent requirements on controllers and processors of personal data, including, for example, requirements to obtain consent or other legal bases from individuals to process their personal data, provide robust disclosures to individuals, accommodate a set of individual data rights, provide data security breach notifications within 72 hours after discovering the breach, limit retention of personal information and apply enhanced protections to health data and other special categories of personal data. The GDPR also applies to pseudonymized data, which is defined as "the processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information," and imposes additional obligations when we contract with third-party processors in connection with the processing of any personal data. The GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share personal data, could cause our costs to increase and could harm our financial condition. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20 million or up to 4% of the total worldwide annual turnover of our preceding fiscal year, whichever is higher, and other administrative penalties. Further, as the GDPR has only recently become enforceable, enforcement priorities and official interpretations of certain provisions are still unclear. To comply with the new data protection rules imposed by

the GDPR, we may be required to put in place additional mechanisms ensuring compliance, which may result in other substantial expenditures. This may be onerous and adversely affect our business, financial condition, results of operations and the profitability of our platform of diagnostic tests. Failure to comply with the GDPR and other countries' privacy or data security-related laws, rules or regulations could result in material penalties imposed by regulators, affect our compliance with contracts entered into with our collaborators and other third-party payers, and have an adverse effect on our business and financial condition. Currently, the GDPR is only applicable to us as a processor, but as we continue to expand into the European market, the GDPR will have direct applicability to us as a controller.

The GDPR also imposes strict rules on the transfer of personal data out of the EU to the United States. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. In addition, these rules are consistently under scrutiny. For example, following a decision of the Court of Justice of the EU (the "ECJ") in October 2015, the transfer of personal data to United States companies that had certified as members of the United States Safe Harbor Scheme ("Safe Harbor Scheme") was declared invalid. In July 2016, the European Commission adopted the EU-United States Privacy Shield Framework ("Privacy Shield Framework) which replaced the Safe Harbor Scheme. The Privacy Shield Framework is reviewed by European authorities annually, and the ECJ recently ruled that the Privacy Shield Framework is no longer a lawful mechanism for EU-United States data transfers under the GDPR. There is currently litigation challenging other EU mechanisms for adequate data transfers. It is uncertain whether and for how long national regulators will permit companies that have relied on the Privacy Shield Framework to come into compliance with the recent ruling and whether alternative methods for EU-United States data transfers or the standard contractual clauses might similarly be invalidated by European courts. The ECJ's ruling may lead to increased transaction, compliance, and technological costs to support international data transfers.

Organizations operating in Canada and covered by the Personal Information Protection and Electronic Documents Act ("PIPEDA"), or equivalent Canadian provincial laws, must obtain an individual's consent when they collect, use or disclose that individual's personal information. Individuals have the right to access and challenge the accuracy of their personal information held by an organization, and personal information may only be used for the purposes for which it was collected. If an organization intends to use personal information for another purpose, it must again obtain that individual's consent.

We regularly monitor, defend against and respond to attacks to our networks and other information security incidents. Despite our information security efforts, our facilities, systems, and data, as well as those of our third-party service providers, may be vulnerable to privacy and information security incidents such as data breaches, viruses or other malicious code, coordinated attacks, data loss, phishing attacks, ransomware, denial of service attacks, or other security or IT incidents caused by threat actors, technological vulnerabilities or human error. If we, or any of our vendors that support our IT or have access to our data, including any third party vendors that collect, process and store personal data on our behalf, fail to comply with laws requiring the protection of personal information, or fail to safeguard and defend personal information or other critical data assets or IT systems, we may be subject to regulatory enforcement and fines as well as private civil actions. We may be required to expend significant resources in the response, containment, mitigation of cybersecurity incidents as well as in defense against claims that our information security was unreasonable or otherwise violated applicable laws or contractual obligations.

Our employees, collaborators, independent contractors and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, collaborators, independent contractors and consultants may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates:

- FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA authorities;
- federal and state healthcare fraud and abuse laws and regulations; or
- laws that require the true, complete and accurate reporting of financial information or data.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee, contractor, or other agent, or our company, receiving an

FDA debarment or exclusion by the HHS Office of Inspector General ("OIG") could result in penalties, a loss of business from third parties, and severe reputational harm.

We have adopted a Code of Business Conduct and Ethics and compliance policies to govern and deter such behaviors, but it is not always possible to identify and deter misconduct by our employees and other agents, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, treble damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Our ongoing research and development and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. We are currently conducting pre-and post-market clinical studies of some of our tests. In the future we may conduct clinical trials to support approval of new diagnostic tests and services. Clinical studies may need to be conducted in compliance with FDA regulations or the FDA may take enforcement action. The data collected from these clinical studies may ultimately be used to support marketing authorization for these diagnostic tests and services. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities and Notified Bodies will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our tests are safe and effective for the proposed indicated uses, which could cause us to abandon development of our tests and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, may impact our ability to commercialize our tests and generate revenues.

Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial.

We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the trials, and would control only certain aspects of their activities. Nevertheless, we would be responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties would not relieve us of our regulatory responsibilities. We and our third-party contractors are required to comply with good clinical practices ("GCPs") which are regulations and guidelines enforced by the FDA, and comparable regulations enforced by foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any third-party contractor fails to comply with applicable GCPs, the clinical data generated in clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before clearing or approving our marketing applications. A failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory clearance or approval process. In addition, if these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated.

Many of these factors could be beyond our control. We may not be able to undertake additional trials, repeat trials or enter into new arrangements with third parties without undue delays or considerable expenditures. If there are delays in testing or clearances or approvals as a result of the failure to perform by third parties, our research and development costs would increase and we may not be able to obtain regulatory clearance or approval for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests, or to achieve sustained profitability.

The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.

We cannot be certain that the results of our future clinical trials will support our future product claims or that the FDA will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the future product's profile.

Our billing, collections and claims processing activities are complex and time-consuming, and any delay in transmitting and collecting claims or failure to comply with applicable billing requirements, could have an adverse effect on our future revenue.

Billing for our tests is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill various payers, such as government payers, insurance companies and patients, all of which may have different billing requirements. We may face increased risk in our collection efforts, including long collection cycles and the risk that we may never collect at all, either of which could adversely affect our business, financial condition and results of operations. Several factors make the billing process complex, including:

- differences between the list price for our tests and the reimbursement rates of payers;
- compliance with complex federal and state regulations related to billing government healthcare programs, including Medicare and Medicaid, to the extent our tests are covered by such programs;
- differences in coverage among payers and the effect of patient co-payments or co-insurance;
- differences in information and billing requirements among payers;
- changes to codes and coding instructions governing our tests;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

These billing complexities and the related uncertainty in obtaining payment for our tests could negatively affect our revenue and cash flow, our ability to achieve profitability and the consistency and comparability of our results of operations. In addition, if claims for our tests are not submitted to payers on a timely basis, or if we fail to comply with applicable billing requirements, it could have an adverse effect on our revenue and our business.

Third-party payers require us to identify the test for which we are seeking reimbursement using a Current Procedural Terminology ("CPT") code. The CPT code set is maintained by the American Medical Association ("AMA"). In cases where there is not a specific CPT code to describe a test, such as with Nodify CDT and GeneStrat, the test may be billed under an unlisted molecular pathology procedure code or through the use of a combination of single gene CPT codes, depending on the payer. The PAMA authorized the adoption of new, temporary billing codes and unique test identifiers for FDA-cleared or approved tests as well as advanced diagnostic laboratory tests. The AMA has created a new section of CPT codes, Proprietary Laboratory Analyses codes to facilitate implementation of this section of PAMA. In addition, CMS may assign unique level II Healthcare Common Procedure Coding System codes to tests that are not already described by a unique CPT code. VeriStrat and Nodify XL2 both have test specific CPT codes, but GeneStrat and Nodify CDT do not at this time.

In the instance where a code used does not describe a specific test, the insurance claim must be examined to determine what test was provided, whether the test was appropriate and medically necessary, and whether payment should be rendered, which may require a letter of medical necessity from the ordering physician. This process can result in a delay in processing the claim, a lower reimbursement amount or denial of the claim. As a result, obtaining approvals from third-party payers to cover our tests and establishing adequate reimbursement levels is an unpredictable, challenging, time-consuming and costly process and we may never be successful.

We and our third-party manufacturers and suppliers must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do, or interrupt our, business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the generation, use, storage and disposal of hazardous materials. We work with materials, including chemicals, biological agents and compounds and samples that could be hazardous to human health and safety or the environment. Our operations also produce hazardous and biological waste products. Accordingly, we and our third-party manufacturers and suppliers are subject to federal, state, local and foreign environmental, health and safety laws and regulations, and permitting and licensing requirements, including those governing the generation, use, manufacture, storage, handling, transportation, release and disposal of, and exposure to, these materials, and worker health and safety.

We cannot eliminate the risk of contamination or injury resulting from such hazardous materials. We also cannot guarantee that the procedures utilized by our third-party manufacturers for handling and disposing of hazardous materials and wastes comply with all applicable environmental, health and safety laws and regulations. As a result, we may be held liable for any resulting damages, costs or liabilities, including cleanup costs and liabilities, which could be significant, or our commercialization, research and development efforts and business operations may be restricted or interrupted.

Environmental, health and safety laws and regulations are complex, change frequently and have tended to become more stringent. Compliance with such laws and regulations is expensive, and current or future environmental, health and safety laws and regulations may restrict our operations. If we do not comply with applicable environmental health and safety laws and regulations, and permitting and licensing requirements, we may be subject to fines, penalties, a suspension of our business or other sanctions.

Risks Related to our Intellectual Property

Our success may be impaired if we are unable to obtain, maintain and protect our intellectual property rights.

Our commercial success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our diagnostic tests, products and services and technology. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, to protect our proprietary technology and prevent others from duplicating our suite of diagnostic tests and products. However, these means may afford only limited protection and may not:

- prevent our competitors from duplicating our diagnostic tests and products, including our COVID-19 testing program and Nodify XL2, Nodify CDT, GeneStrat and VeriStrat tests;
- prevent our competitors from gaining access to our proprietary information and technology, including the Diagnostic Cortex platform, tech platforms such as the DeepMALDI analysis and intellectual property covering technologies that allow us to develop "test algorithms"; or
- allow us to gain or maintain a competitive advantage.

Any of our patents, including those we may license, may be challenged, invalidated, rendered unenforceable or circumvented. Consequently, we do not know whether any of our diagnostic tests, products and services will be protectable or remain protected by valid and enforceable patents. We may not prevail if our patents are challenged by competitors or other third parties. The United States federal courts or equivalent national courts or patent offices elsewhere may invalidate our patents, find them unenforceable, or narrow their scope. Furthermore, competitors may be able to design around our patents by developing similar or alternative technologies or products in a non-infringing manner, or obtain patent protection for more effective technologies, designs or methods, including for treating lung cancer. If these developments were to occur, our diagnostic tests and products may become less competitive and sales may decline.

We have filed numerous patent applications seeking protection of diagnostic tests and other inventions originating from our research and development. Our patent applications may not result in issued patents, and any patents that are issued may not provide meaningful protection against competitors or competitive technologies. Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The scope of a patent may also be reinterpreted and significantly reduced after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with the protection or competitive advantages we are seeking.

Moreover, some of our owned and in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain or maintain an exclusive license to any such third party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. Various courts, including the United States Supreme Court have rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to biotechnology. These decisions state, among other things, that a patent claim that recites an abstract idea, natural phenomenon or law of nature (for example, the relationship between particular genetic variants and cancer) are not themselves patentable. Precisely what constitutes a law of nature or abstract idea is uncertain, and it is possible that certain aspects of our technology could be considered unpatentable under applicable law. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Depending on decisions by the United States Congress, the federal courts and the United States Patent and Trademark Office ("USPTO"), the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' ability to obtain new patents or to enforce our existing owned or in-licensed patents and patents that we might obtain or in-license in the future. Additionally, our pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. The scope of patent protection outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property rights or narrow the scope of our owned and licensed patents.

If we are unable to obtain and maintain patent protection for our technology, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize diagnostic tests, products and services similar or superior to ours, and our competitive position may be adversely affected. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. In addition, the patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Additionally, while software and other of our proprietary works may be protected under copyright law, we have chosen not to register any copyrights in these works, and instead, primarily rely on protecting our software as a trade secret. In order to bring a copyright infringement lawsuit in the United States, the copyright must be registered. Accordingly, the remedies and damages available to us for unauthorized use of our copyrights may be limited.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to seeking patent protection for the patents underlying our diagnostic tests, products and services, we also rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain a competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect such proprietary information, in part, through confidentiality agreements with our employees, collaborators, contractors, advisors, consultants and other third parties and invention assignment agreements with our employees. We also have agreements with some of our consultants that require them to assign to us any inventions created as a result of their working with us. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses containing invention assignment, to grant us ownership of technologies that are developed through a relationship with employees or third parties.

We cannot guarantee that we have entered into such agreements with each party that has or may have had access to our trade secrets or proprietary information. Additionally, despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any

of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor or other third party, our competitive position would be materially and adversely harmed. Furthermore, we expect these trade secrets, know-how and proprietary information to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel from academic to industry scientific positions. Consequently, we may be unable to prevent our proprietary technology from being exploited in the United States and abroad, which could affect our ability to expand in domestic and international markets or require costly efforts to protect our technology.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known, or be independently discovered by, competitors. To the extent that our employees, consultants, contractors or collaborators use intellectual property rights owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions, which could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to claims that we or our employees have misappropriated the intellectual property rights of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors, and third parties may claim an ownership interest in intellectual property we regard as our own.

Many of our employees and consultants were previously employed at or engaged by universities or other medical device, diagnostic, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and independent contractors do not use the intellectual property rights, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, used, infringed, misappropriated or otherwise violated the intellectual property rights or disclosed the alleged trade secrets or other proprietary information, of these former employers, competitors or other third parties, or to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Any litigation or the threat of litigation may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize potential diagnostic tests, products and services, which could harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees.

Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property rights we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any other claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our diagnostic tests or products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers.

An inability to incorporate technologies or features that are important or essential to our diagnostic tests or products could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling our rights to our COVID-19 testing program, either of the Nodify XL2 and Nodify CDT tests, or the VeriStrat and GeneStrat tests.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property rights to execute agreements assigning such intellectual property rights to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property rights that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property rights. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future diagnostic tests, products and services.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy-Smith America Invents Act ("Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a first-to-invent system to a first-inventor-to-file system, allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. Under a first-inventor-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor was the first to invent the claimed invention. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the United States Supreme Court and the United States Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Recent United States Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

If our trademarks and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be violating or infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these trademarks or trade names, which we need to build name recognition among potential partners and customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement or dilution claims brought by owners of other trademarks. 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 have not yet registered certain of our trademarks in all of our potential markets, although we have registered several connected to our diagnostic tests, products and services in the United States. If we apply to register these and trademarks in the United States and other countries, our applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

Our efforts to enforce or protect our rights related to trademarks, trade secrets, domain names or other intellectual property rights may be ineffective, could result in substantial costs and diversion of resources and could adversely affect our business, financial condition and results of operations.

We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors or other third parties may infringe, misappropriate or otherwise violate our patents, the patents of our licensors or other intellectual property rights, or we may be required to defend against claims of infringement, misappropriation or other violations. In addition, our patents also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke those parties to assert counterclaims against us alleging that we infringe their patents or other intellectual property. In any such proceeding, a court or other administrative body may decide that a patent or other intellectual property right owned by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover such technology. Grounds for a validity challenge could include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include reexamination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions, including opposition proceedings. Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our diagnostic tests, products and services or prevent third parties from competing with our diagnostic tests, products and services. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which the patent examiner and we or our licensing partners were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on our diagnostic tests, products and services. An adverse result in any litigation or other proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation.

Moreover, some of our owned and in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing diagnostic tests, products, services or technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

Even if resolved in our favor, litigation or other proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our management and other personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

The intellectual property landscape in the field of precision oncology is in flux, and it may remain uncertain for the coming years. There may be significant intellectual property related litigation and proceedings relating to our owned and in-licensed, and other third party, intellectual property and proprietary rights in the future. As we move into new markets and applications for our diagnostic tests, products or services, incumbent participants in such markets may assert their patents and other intellectual property rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. Our competitors and others may now and, in the future, have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product or service revenue and against whom our own patents may provide little or no deterrence or protection. Therefore, our commercial success depends in part on our non-infringement of the patents or other intellectual property rights of third parties.

However, we may in the future be subject to claims that we, or other parties we have agreed to indemnify, infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Because patent applications are published sometime after filing, and because applications can take several years to issue, there may be additional currently pending third-party patent applications that are unknown to us, which may later result in issued patents. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We may not have sufficient resources to bring these actions to a successful conclusion.

There is a substantial amount of litigation and other patent challenges, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology industry, including patent infringement lawsuits, interferences, oppositions and *inter partes* review proceedings before the USPTO, and corresponding foreign patent offices. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, including our competitors, exist in the fields in which we are developing diagnostic tests and in which we may develop future diagnostic tests, products and services. As the precision oncology industry expands and more patents are issued, the risk increases that our diagnostic tests may be subject to claims of infringement of the patent rights of third parties. Numerous significant intellectual property issues have been litigated, are being litigated and will likely continue to be litigated, between existing and new participants in our existing and targeted markets, and competitors have and may assert that our diagnostic tests or services infringe their intellectual property rights as part of a business strategy to impede our successful entry into or growth in those markets.

We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources.

Because of the inevitable uncertainty in intellectual property litigation, we could lose a patent infringement or other action asserted against us regardless of our perception of the merits of the case. There is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that these third party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third party patents. In order to successfully challenge the validity of any such United States patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such United States patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such United States patent.

Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell diagnostic tests, products or services, and could result in the award of substantial damages against us, including treble damages, attorney's fees, costs, and expenses if we are found to have willfully infringed. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties, which could be significant, and obtain one or more licenses from third parties, or be prohibited from selling certain diagnostic tests, products or services. We may not be able to obtain these licenses on acceptable or commercially reasonable terms, if at all, or these licenses may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we could encounter delays in diagnostic test introductions while we attempt to develop alternative diagnostic tests, products or services to avoid infringing third-party patents or intellectual property rights. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing diagnostic tests, products or services, and the prohibition of sale of any of our diagnostic tests, products or services could materially affect our business and our ability to gain market acceptance for our diagnostic tests, products and services.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition, our agreements with some of our customers, suppliers or 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 in instances where we are not obligated to do so if we determine it would be important to 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 or financial condition.

We may be subject to claims challenging the priority or inventorship of our patents and other intellectual property rights.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property rights as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property rights. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property rights that are important to our product candidates.

If we or our licensors are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of our diagnostic tests, products or services. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations, or prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent protection depends on compliance with various required procedures, document submissions, fee payments and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States at several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-United States patent agencies. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property rights. The USPTO and various non-US governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors may be able to enter the market without infringing our patents and this circumstance would have a material adverse effect on our business.

Issued patents covering our diagnostic tests and any other or future diagnostic tests, products or services could be found invalid or unenforceable if challenged.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and some of our patents or patent applications, including licensed patents, may be challenged, in courts or patent offices in the United States and abroad, in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference. Additionally, if we and our licensing partners initiate or become involved in legal proceedings against a third party to enforce a patent covering one of our diagnostic tests, products, services or technologies, the defendant could counterclaim that the patent covering our diagnostic tests, products or services is invalid or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including patent eligible subject matter, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement during prosecution. In addition, the United States now awards patent priority to the first party to file a patent application, and others may submit patent claims covering our inventions prior to us. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our diagnostic tests or any diagnostic tests, products and services that we may develop.

A successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights, which could have a material adverse impact on

our business. Furthermore, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future diagnostic tests, products or services.

We may not be aware of all third-party intellectual property rights potentially relating to our current or future diagnostic tests, products or services. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until approximately 18 months after filing or, in some cases, not until such patent applications issue as patents. We, or our current or future license partners or collaborators, might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings or other post-grant proceedings declared by the USPTO. The outcome of such proceedings is uncertain, and other patent applications may have priority over our patent applications. Such proceedings could also result in substantial costs to us and divert our management's attention and resources.

We rely on licenses from third parties in relation to certain diagnostic tests, products and services and if we lose these licenses then we may be subjected to future litigation.

We are a party to license agreements that grant us rights to use certain intellectual property rights, including patents and patent applications, typically in certain specified fields of use, in connection with our diagnostic tests, products and services. Some of those licensed rights could provide us with freedom to operate for aspects of our diagnostic tests, products and services. We may need to obtain additional licenses from others to advance our research, development and commercialization activities.

The in-licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire the third-party intellectual property rights for product candidates on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to suitable product candidates, our business, financial condition, results of operations and prospects for growth could suffer.

Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, royalty payment, milestone payment, insurance and other obligations on us. If we fail to comply with these obligations or other obligations in our license agreements, our licensors may have the right to terminate these agreements, in which event we may not be able to develop and market any product or use any technology that is covered by these agreements. If our license agreements terminate, or we experience a reduction or elimination of licensed rights under these agreements, we may have to negotiate new or reinstated licenses with less favorable terms or we may not have sufficient intellectual property rights to operate our business. The occurrence of such events could materially harm our business.

Our success may depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for our licensed intellectual property rights. Our licensors may not successfully prosecute the patent applications we license. Even if patents issue in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents or may pursue such litigation less aggressively than we would. Without protection for the intellectual property rights we license, other companies might be able to offer substantially identical diagnostic tests for sale, which could adversely affect our competitive business position and harm our business prospects.

Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Moreover, disputes may also arise between us and our current or future licensors regarding intellectual property rights subject to a license agreement, including those relating to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether, and the extent to which, our diagnostic tests, products, services, technology and processes infringe on intellectual property rights of the licensor that is not subject to the licensing agreement;

- whether our licensor or its licensor had the right to grant the license agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property rights without their authorization;
- our involvement in the prosecution of licensed patents and our licensors' overall patent enforcement strategy;
- the amounts of royalties, milestones or other payments due under the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property rights by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If we do not prevail in such disputes, we may lose any or all of our rights under such license agreements.

In addition, the agreements under which we currently license intellectual property rights or technology from third parties are complex and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property rights or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, or are insufficient to provide us the necessary rights to use the intellectual property rights, we may be unable to successfully develop and commercialize any affected diagnostic tests, products or services, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Absent the license agreements, we may infringe patents subject to those agreements, and if the license agreements are terminated, we may be subject to litigation by the licensor. Litigation could result in substantial costs to us and distract our management. If we do not prevail, we may be required to pay damages, including treble damages, attorneys' fees, costs and expenses and royalties or be enjoined from selling our diagnostic tests, products or services, which could adversely affect our ability to offer diagnostic tests, products or services, our ability to continue operations and our financial condition.

Some intellectual property that we in-license may have been developed through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for companies based in the United States. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with manufacturers that are not based in the United States.

Certain of the intellectual property that we license may have been developed through the use of United States government funding and therefore may be subject to certain federal regulations. As a result, the United States government may have certain rights to intellectual property embodied in our diagnostic tests, products and services pursuant to the Bayh-Dole Act of 1980 ("Bayh-Dole Act"). These United States government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the United States government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). To date, none of our commercialized products are subject to march-in rights. The United States government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the United States government requires that any products of the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for United States manufacturers may limit our ability to contract with product manufacturers outside of the United

States for products covered by such intellectual property. To the extent any of our current or future owned or licensed intellectual property is generated through the use of United States government funding, the provisions of the Bayh-Dole Act may similarly apply. Any failure by us to comply with federal regulations regarding intellectual property rights that were developed through the use of United States government funding could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Patent terms may be inadequate to protect our competitive position on our diagnostic tests, products and services for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited.

Even if patents covering our diagnostic tests, products and services are obtained, once the patent life has expired, we may be open to competition from competitive diagnostic tests, products and services. Given the amount of time required for the development, testing and regulatory review of potential new diagnostic tests, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing diagnostic tests, products or services similar or identical to ours.

We may not be able to protect our intellectual property rights throughout the world.

Third parties may attempt to commercialize competitive diagnostic tests, products or services in foreign countries where we do not have any patents or patent applications and/or where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting and defending patents on our diagnostic tests, products and services in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing diagnostic tests or products made using our inventions in and into the United States or other jurisdictions. Competitors may use our diagnostic tests, products, services and technologies in jurisdictions where we have not obtained patent protection to develop their own diagnostic tests and, further, may export otherwise infringing diagnostic tests or products to territories where we have patent protection but enforcement is not as strong as that in the United States. These diagnostic tests and products may compete with our diagnostic tests, products or services and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing diagnostic tests, products and services in violation of our intellectual property rights generally. Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries, including India, China, and certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our current or future licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition and results of operations may be adversely affected.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make diagnostic tests or products that are similar to our Nodify XL2, Nodify CDT, GeneStrat or VeriStrat tests or the COVID-19 tests that we use in our COVID-19 testing program or utilize similar technology that is not covered by the claims of our patents or that incorporates certain technology in our Nodify XL2, Nodify CDT, GeneStrat or VeriStrat tests or such COVID-19 tests that is in the public domain;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the applicable issued patent or pending patent application that we own or license now or may own or license in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future pending patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive diagnostic tests, products and services for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property rights.

Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to our Common Stock

We expect that the price of our common stock will fluctuate substantially.

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

- volume and customer mix for our COVID-19, Nodify XL2, Nodify CDT, GeneStrat and VeriStrat testing;
- the introduction of new diagnostic tests or enhancements to such tests by us or others in our industry;
- disputes or other developments with respect to our or others' intellectual property rights;
- our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced diagnostic tests on a timely basis;
- product liability claims or other litigation;
- quarterly variations in our results of operations or those of others in our industry;
- media exposure of our diagnostic tests or of those of others in our industry;
- changes in governmental regulations or in the status of our regulatory approvals or applications;

- changes in earnings estimates or recommendations by securities analysts; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance.

In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management's attention and resources from our business.

Securities analysts may not publish favorable research or reports about our business or may publish no information at all, which could cause our stock price or trading volume to decline.

The trading market for our common stock is influenced to some extent by the research and reports that industry or financial analysts publish about us and our business. We do not control these analysts. If one or more of these analysts cease coverage of us or fail to publish reports covering us regularly, we could lose visibility in the market, which in turn could cause our stock price or trading volume to decline.

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

We are an "emerging growth company," as defined in the JOBS Act. We may take advantage of certain exemptions and relief from various public reporting requirements, including the requirement that our internal control over financial reporting be audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act. While we are an "emerging growth company," we are exempt from any rules that could be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor's report on financial statements; we are subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and we are not required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved.

Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we are not subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult. Additionally, because we have taken advantage of certain reduced reporting requirements, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

We will remain an "emerging growth company" until the earliest to occur of (i) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; (iii) the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; and (iv) the last day of the fiscal year ending after the fifth anniversary of the completion of our initial public offering.

We are also a *"*smaller reporting company*"* as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our common shares held by non-affiliates exceeds $250 million as of the end of that year's second fiscal quarter, or (2) our annual revenues exceeded $100 million during such completed fiscal year and the market value of our common shares held by nonaffiliates exceeds $700 million as of the end of that year's second fiscal quarter. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

Investors may find our common stock less attractive to the extent we rely on the exemptions and relief granted by the JOBS Act. 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 decline or become more volatile.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. It is possible that interpretation, industry practice and guidance may evolve over time. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell their shares, could result in a decrease in the market price of our common stock. As of the effective date of our IPO, we have 26,254,072 outstanding shares of common stock. Of the shares, 22,254,072 shares are currently restricted as a result of securities laws or 180-day lock-up agreements from our initial public offering. Holders of an aggregate of 20,090,745 shares of our common stock issuable upon the conversion of the shares of our convertible preferred stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered all shares of common stock that we may issue under our equity compensation plans, which can be freely sold in the public market, subject to volume limitations applicable to affiliates and the lock-up agreements.

Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

On the effective date of our IPO, our officers, directors and principal stockholders each holding more than 5% of our common stock collectively control approximately 60.7% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to control the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change of control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders.

We incur significant additional costs as a result of being a public company, which may adversely affect our business, financial condition and results of operations.

We incur costs associated with corporate governance requirements, including rules and regulations of the SEC, under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and the Exchange Act, as well as the rules of Nasdaq. These rules and regulations significantly increase our accounting, legal and financial compliance costs and make some activities more time-consuming. These rules and regulations make it more expensive for us to maintain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our Board of Directors or as executive officers. Accordingly, increases in costs incurred as a result of becoming a publicly traded company may adversely affect our business, financial condition and results of operations.

If we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

As a result of becoming a public company, we are required, under Section 404 of the Sarbanes-Oxley Act to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with our Annual Report on Form 10-K for the year ended December 31, 2021. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. 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 a company's annual and interim financial statements will not be detected or prevented on a timely basis.

We are further enhancing internal controls, processes and related documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. The effectiveness of our controls and procedures may be limited by a variety of factors, including:

- faulty human judgment and simple errors, omissions or mistakes;
- fraudulent action of an individual or collusion of two or more people;
- inappropriate management override of procedures; and
- the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial control.

When we cease to be an "emerging growth company" under the federal securities laws, our auditors will be required to express an opinion on the effectiveness of our internal controls. If we are unable to confirm that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which could cause the price of our common stock to decline.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our 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 amended and restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions

involving actions brought against us by stockholders. Notwithstanding the foregoing, the exclusive forum provision will not apply to any claim to enforce any liability or duty created by the Exchange Act or the Securities Act and for which the federal courts have exclusive jurisdiction. We believe this exclusive forum provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in such action.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated articles of incorporation provide that we will indemnify our directors and officers to the fullest extent permitted by Section 145 of the Delaware General Corporate Law.

In addition, as permitted by the Delaware General Corporate Law, our amended and restated articles of incorporation and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by applicable law. Such law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- the rights conferred in our amended and restated articles of incorporation are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated articles of incorporation provisions to reduce our indemnification obligations to directors, officers, employees and agents.

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

(a) Sales of Unregistered Securities.

None.

(b) Use of Proceeds from Public Offering of Common Stock.

We filed our Registration Statement on Form S-1 (File No. 333-249260) with the SEC on October 29, 2020. We sold 4,000,000 shares of common stock at a price to the public of $18.00 per share. The Company received aggregate net proceeds of $63.0 million after deducting offering costs, underwriting discounts and commissions. The underwriters of the offering were Morgan Stanley & Co. LLC, William Blair & Company, L.L.C., Canaccord Genuity LLC and BTIG, LLC. Following the sale of the shares in connection with the closing of the IPO, the offering terminated. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

There has been no material change in the expected use of the net proceeds from our IPO, as described in our final prospectus filed with the SEC on October 29, 2020 pursuant to Rule 424(b) under the Securities Act.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
3.1*	Amended and Restated Certificate of Incorporation of Biodesix, Inc., dated October 30, 2020.
3.2*	Amended and Restated Bylaws of Biodesix, Inc.
4.1†	Specimen stock certificate evidencing shares of Common Stock (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 21, 2020).
10.1†+	Biodesix, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 26, 2020).
10.2†+	Biodesix, Inc. 2020 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 26, 2020).
10.3†+	Form of Indemnification Agreement, by and between Biodesix, Inc. and each of its directors and executive officers (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 14, 2020).
10.4†+	Consulting Agreement, by and between David Brunel and Biodesix, Inc., dated September 19, 2020 (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).
10.5†	Third Amendment to COVID-19 Testing Laboratory Services Agreement by and between Biodesix, Inc. and Centura Health Corporation, dated August 7, 2020 (incorporated by reference to Exhibit 10.28 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).
10.6†	Contract Agreement between Biodesix, Inc. and the Colorado Department of Public Health and Environment, dated September 11, 2020 (incorporated by reference to Exhibit 10.29 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).
10.7†	Letter from Bio-Rad Laboratories, Inc. dated August 7, 2020 (incorporated by reference to Exhibit 10.33 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 21, 2020).
10.8†	Letter from Bio-Rad Laboratories, Inc. dated August 14, 2020 (incorporated by reference to Exhibit 10.34 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 21, 2020).
31.1*	Certification of Principal Executive Officer 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.
31.2*	Certification of Principal Financial Officer 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.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL 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.
† Previously filed.
+ Management contract or compensatory plan.

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.

Biodesix, Inc.

Date: December 10, 2020 By: /s/ Scott Hutton

Scott Hutton
Chief Executive Officer

Date: December 10, 2020 By: /s/ Robin Harper Cowie

Robin Harper Cowie
Chief Financial Officer

Exhibit 3.1

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

OF

BIODESIX, INC.,

a Delaware corporation

Biodesix, Inc., a corporation organized and existing under the laws of the State of Delaware (the "***Corporation***"), hereby certifies as follows:

A. The name of the Corporation is Biodesix, Inc. The Corporation was originally incorporated under the name Elston Technologies, Inc. The Corporation's original certificate of incorporation was filed with the office of the Secretary of State of the State of Delaware on December 23, 2005.

B. This amended and restated certificate of incorporation was duly adopted in accordance with Sections 242 and 245 of the General Corporation Law of the State of Delaware, as amended (the "***DGCL***"), restates and amends the provisions of the Corporation's certificate of incorporation and has been duly approved by the written consent of the stockholders of the Corporation in accordance with Section 228 of the DGCL.

C. The text of the certificate of incorporation of this Corporation is hereby amended and restated to read in its entirety as follows:

ARTICLE I
NAME

The name of the Corporation is Biodesix, Inc.

ARTICLE II
REGISTERED OFFICE

The address of the Corporation's registered office in the State of Delaware is 1209 Orange Street, City of Wilmington, County of New Castle, 19801. The name of its registered agent at such address is The Corporation Trust Company.

ARTICLE III
PURPOSE

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the DGCL.

ARTICLE IV
CAPITAL STOCK

4.1 Authorized Capital Stock. The total number of shares of all classes of capital stock that the Corporation is authorized to issue is 205,000,000 shares, consisting of 200,000,000 shares of common stock, par value $0.001 per share ("***Common Stock***"), and 5,000,000 shares of preferred stock, par value $0.001 per share ("***Preferred Stock***").

4.2 Increase or Decrease in Authorized Capital Stock. The number of authorized shares of Common Stock or Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority in voting power of the stock of the Corporation entitled to vote generally in the election of directors, irrespective of the provisions of Section 242(b)(2) of the DGCL (or any successor provision thereto), voting together as a single class, without a separate vote of the holders of the class or classes the number of authorized shares of which are being increased or decreased, unless a vote by any holders of one or more series of Preferred Stock is required by the express terms of any series of Preferred Stock as provided for or fixed pursuant to the provisions of Section 4.4 of this amended and restated certificate of incorporation of the Corporation (as further amended from time to time in accordance with the provisions hereof and including, without limitation, the terms of any certificate of designation with respect to any series of Preferred Stock, this "***Certificate of Incorporation***").

4.3 Common Stock.

(a) The holders of shares of Common Stock shall be entitled to one vote for each such share on each matter properly submitted to the stockholders of the Corporation on which the holders of shares of Common Stock are entitled to vote. The holders of shares of Common Stock shall not have cumulative voting rights. Except as otherwise required by law or this Certificate of Incorporation, and subject to the rights of the holders of shares of Preferred Stock, if any, at any annual or special meeting of the stockholders of the Corporation, the holders of shares of Common Stock shall have the right to vote for the election of directors of the Corporation and on all other matters properly submitted to a vote of the stockholders of the Corporation; provided, however, that, except as otherwise required by law, holders of shares of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation that relates solely to the terms, number of shares, powers, designations, preferences or relative, participating, optional or other special rights (including, without limitation, voting rights), or to qualifications, limitations or restrictions thereof, of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation or pursuant to the DGCL.

(b) Subject to the rights of the holders of shares of Preferred Stock, the holders of shares of Common Stock shall be entitled to receive such dividends and other distributions (payable in cash, property or capital stock of the Corporation) when, as and if declared thereon by the board of directors of the Corporation (the "***Board***") from time to time out of any assets or funds of the Corporation legally available therefor and shall share equally on a per share basis in such dividends and distributions.

(c) In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Corporation, after payment or provision for payment of the debts and other liabilities of the Corporation, and subject to the rights of the holders of shares of Preferred Stock in respect thereof, the holders of shares of Common Stock shall be entitled to receive all of the remaining assets of the Corporation available for distribution to its stockholders, ratably in proportion to the number of shares of Common Stock held by them.

4.4 Preferred Stock.

(a) The Board is expressly authorized to issue from time to time shares of Preferred Stock in one or more series pursuant to a resolution or resolutions providing for such issue duly adopted by the Board. The Board is further authorized, subject to limitations prescribed by law, to fix by resolution or resolutions and to set forth in a certification of designation filed pursuant to the DGCL the powers, designations, preferences and relative, participating, optional or other special rights, if any, and the qualifications, limitations or restrictions thereof, if any, of any wholly unissued series of Preferred Stock, including, without limitation, dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including, without limitation, sinking fund provisions), redemption price or prices and liquidation preferences of any such series, and the number of shares constituting any such series and the designation thereof, or any of the foregoing.

(b) The Board is further authorized to increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares of any such series then outstanding) the number of shares of any series of Preferred Stock, the number of which was fixed by it, subsequent to the issuance of shares of such series then outstanding, subject to the powers, preferences and rights, and the qualifications, limitations and restrictions thereof, stated in this Certificate of Incorporation or the resolution of the Board originally fixing the number of shares of such series. If the number of shares of any series of Preferred Stock is so decreased, then the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series.

ARTICLE V
BOARD OF DIRECTORS

5.1 General Powers. The business and affairs of the Corporation shall be managed by or under the direction of the Board.

5.2 Number of Directors; Election; Term.

(a) The number of directors that shall be fixed, from time to time, exclusively by the Board in accordance with the bylaws of the Corporation (as amended from time to time in accordance with the provisions hereof and thereof, the "***Bylaws***"), subject to the rights of holders of any series of Preferred Stock with respect to the election of directors, if any.

(b) Subject to the rights of holders of any series of Preferred Stock with respect to the election of directors, the directors of the Corporation shall be divided into three classes as nearly equal in number as is practicable, hereby designated Class I, Class II and Class III. The Board is authorized to assign members of the Board already in office to such classes. The term of office of the initial Class I directors shall expire upon the election of directors at the first annual meeting of stockholders following the effectiveness of this Article V; the term of office of the initial Class II directors shall expire upon the election of directors at the second annual meeting of stockholders following the effectiveness of this Article V; and the term of office of the initial Class III directors shall expire upon the election of directors at the third annual meeting of stockholders following the effectiveness of this Article V. At each annual meeting of stockholders, commencing with the first annual meeting of stockholders following the effectiveness of this Article V, each of the successors elected to replace the directors of a class whose term shall have expired at such annual meeting shall be elected to hold office until the third annual meeting next succeeding his or her election and until his or her respective successor shall have been duly elected and qualified. Subject to the rights of holders of any series of Preferred Stock with respect to the election of directors, if the number of directors that constitutes the Board is changed, any newly created directorships or decrease in directorships shall be so apportioned by the Board among the classes as to make all classes as nearly equal in number as is practicable, provided that no decrease in the number of directors constituting the Board shall shorten the term of any incumbent director.

(c) Notwithstanding the foregoing provisions of this Section 5.2, and subject to the rights of holders of any series of Preferred Stock with respect to the election of directors, each director shall serve until such director's successor is duly elected and qualified or until such director's earlier death, resignation or removal.

(d) Elections of directors need not be by written ballot unless the Bylaws shall so provide.

(e) Notwithstanding any of the other provisions of this Article V, whenever the holders of any one or more series of Preferred Stock issued by the Corporation shall have the right, voting separately by series, to elect directors at an annual or special meeting of stockholders, the election, term of office, filling of vacancies and other features of such directorships shall be governed by the terms of the certificate of designation for such series of Preferred Stock, and such directors so elected shall not be divided into classes pursuant to this Article V unless expressly provided by such terms. During any period when the holders of any series of Preferred Stock have the right to elect additional directors as provided for or fixed pursuant to the provisions of this Article V, then upon commencement and for the duration of the period during which such right continues; (i) the then otherwise total authorized number of directors of the Corporation shall automatically be increased by such specified number of directors, and the holders of such Preferred Stock shall be entitled to elect the additional directors so provided for or fixed pursuant to such provisions, and (ii) each such additional director shall serve until such director's successor shall have been duly elected and qualified, or until such director's right to hold such office terminates pursuant to such provisions, whichever occurs earlier, subject to such director's earlier death, resignation or removal. Except as otherwise provided by the Board in the resolution or resolutions establishing such series, whenever the holders of any series of Preferred Stock having such right to elect additional directors are divested of such right pursuant to the provisions of such series of stock, the terms of office of all such additional directors elected by the holders of such stock, or elected to fill any vacancies resulting from the death, resignation or removal of such additional directors, shall forthwith terminate, and the total authorized number of directors of the Corporation shall be reduced accordingly.

5.3 Removal. Subject to the rights of holders of any series of Preferred Stock with respect to the election of directors, a director may be removed from office by the stockholders of the Corporation only for cause and only by the affirmative vote of the holders of at least a majority of the voting power of all then outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class.

5.4 Vacancies and Newly Created Directorships. Subject to the rights of holders of any series of Preferred Stock with respect to the election of directors, vacancies occurring on the Board for any reason and newly created directorships resulting from an increase in the number of directors shall be filled only by vote of a majority of the remaining members of the Board, although less than a quorum, or by a sole remaining director, and not by the stockholders. A person so elected by the Board to fill a vacancy or newly created directorship shall hold office until the next election of the class for which such person shall have been assigned by the Board and until such person's successor shall be duly elected and qualified or until such director's earlier death, resignation or removal.

ARTICLE VI
AMENDMENT OF BYLAWS

In furtherance and not in limitation of the powers conferred by statute, the Board is expressly authorized to adopt, amend, alter or repeal the Bylaws. The Bylaws may also be adopted, amended, altered or repealed by the stockholders of the Corporation by the affirmative vote of the holders of at least a majority of the voting power of all then outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class; provided, however, that, in the case of any adoption, amendment, alteration or repeal of the Bylaws by the stockholders of the Corporation, notwithstanding any other provision of the Bylaws, and in addition to any other vote that may be required by law or the terms of any series of Preferred Stock, the affirmative vote of the holders of at least sixty six and two-thirds percent (66 2/3%) of the voting power of all of the then outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to amend, alter, repeal or adopt any provision inconsistent with Section 1.7(b), 1.16, 1.17, or 2.14 or Article VI of the Bylaws.

ARTICLE VII
STOCKHOLDERS

7.1 No Action by Written Consent of Stockholders. Except as otherwise expressly provided by the terms of any series of Preferred Stock permitting the holders of such series of Preferred Stock to act by written consent, any action required or permitted to be taken by the stockholders of the Corporation must be effected at a duly called annual or special meeting of the stockholders of the Corporation and may not be effected by written consent in lieu of a meeting.

7.2 Special Meetings. Except as otherwise expressly provided by the terms of any series of Preferred Stock permitting the holders of such series of Preferred Stock to call a special meeting of the holders of such series, special meetings of the stockholders of the Corporation may be called only by the chairperson of the Board, the chief executive officer of the Corporation or the Board, and the ability of the stockholders to call a special meeting of the stockholders is hereby specifically denied.

7.3 Advance Notice. Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the Corporation shall be given in the manner provided in the Bylaws.

ARTICLE VIII
LIMITATION OF LIABILITY AND INDEMNIFICATION

8.1 Limitation of Personal Liability. No director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except to the extent such exemption from liability or limitation thereof is not permitted under the DGCL, as it presently exists or may hereafter be amended from time to time. If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

8.2 Indemnification and Advancement of Expenses. The Corporation shall indemnify its directors and officers to the fullest extent authorized or permitted by the DGCL, as now or hereafter in effect, and such right to indemnification shall continue as to a person who has ceased to be a director or officer of the Corporation and shall inure to the benefit of such person's heirs, executors and personal and legal representatives. A director's or officer's right to indemnification conferred by this Section 8.2 shall include the right to be paid by the Corporation the expenses incurred in defending or otherwise participating in any proceeding in advance of its final disposition, provided that such director or officer presents to the Corporation a written undertaking to repay such amount if it shall ultimately be determined that such director or officer is not entitled to be indemnified by the Corporation under this Article VIII or otherwise. Notwithstanding the foregoing, except for proceedings to enforce any director's or officer's rights to indemnification or rights to advancement of expenses, the Corporation shall not be obligated to indemnify any director or officer, or advance expenses of any director or officer, (or such director's or officer's heirs, executors or personal or legal representatives) in connection with any proceeding (or part thereof) initiated by such person unless such proceeding (or part thereof) was authorized by the Board.

8.3 Non-Exclusivity of Rights. The rights to indemnification and advancement of expenses conferred in Section 8.2 of this Certificate of Incorporation shall neither be exclusive of, nor be deemed in limitation of, any rights to which any person may otherwise be or become entitled or permitted under this Certificate of Incorporation, the Bylaws, any statute, agreement, vote of stockholders or disinterested directors or otherwise.

8.4 Insurance. To the fullest extent authorized or permitted by the DGCL, the Corporation may purchase and maintain insurance on behalf of any current or former director or officer of the Corporation against any liability asserted against such person, whether or not the Corporation would have the power to indemnify such person against such liability under the provisions of this Article VIII or otherwise.

8.5 Persons Other Than Directors and Officers. This Article VIII shall not limit the right of the Corporation, to the extent and in the manner permitted by law, to indemnify and to advance expenses to, or to purchase and maintain insurance on behalf of, persons other than those persons described in the first sentence of Section 8.2 of this Certificate of Incorporation or to advance expenses to persons other than directors or officers of the Corporation.

8.6 Effect of Modifications. Any amendment, repeal or modification of any provision contained in this Article VIII shall, unless otherwise required by law, be prospective only (except to the extent such amendment or change in law permits the Corporation to further limit or eliminate the liability of directors or officers) and shall not adversely affect any right or protection of any current or former director or officer of the Corporation existing at the time of such amendment, repeal or modification with respect to any acts or omissions occurring prior to such amendment, repeal or modification.

ARTICLE IX
MISCELLANEOUS

9.1 Corporate Opportunities.

(a) For purposes of this Section 9.1, the following terms shall have the following meanings:

(i) "***Affiliate***" has the meaning given to such term in Rule 12b-2 under the Securities Exchange Act of 1934, as amended.

(ii) "***Covered Person***" means (A) any director of the Corporation who is also an officer, director, employee or managing director of any IPO Investor and (B) any IPO Investor.

(iii) "***IPO Investor***" means (A) any stockholder of the Corporation that, together with its Affiliates, held at least one percent (1%) of the Corporation's common stock outstanding as of immediately prior to the closing of the Corporation's initial public offering, and (B) any Affiliate of the foregoing (in each case, other than the Corporation and its subsidiaries).

(v) "***Specified Corporate Opportunity***" means any business opportunity, potential transaction, interest or other matter that is offered or presented to any Covered Person other than any business opportunity, potential transaction, interest or other matter that is offered or presented to such Covered Person solely in such Covered Person's capacity as an officer, director or stockholder of the Corporation.

(b) To the fullest extent permitted by applicable law (including, without limitation, Section 122(17) of the DGCL), the Corporation, on behalf of itself and its subsidiaries, hereby renounces any interest or expectancy of the Corporation or any of its subsidiaries in, or being offered any opportunity to participate in, any Specified Corporate Opportunity, even if such Specified Corporate Opportunity is one that the Corporation or any of its subsidiaries might reasonably be deemed to have pursued or had the ability or desire to pursue if offered or presented the opportunity to do so. No Covered Person shall have any duty to offer or communicate information regarding any Specified Corporate Opportunity to the Corporation or any of its subsidiaries and, to the fullest extent permitted by applicable law, shall not be liable to the Corporation or any of its subsidiaries for breach of any fiduciary duty, as a director, officer, controlling stockholder or otherwise, solely by reason of the fact that such Covered Person (i) pursues or acquires such Specified Corporate Opportunity for its own account or the account of any of the IPO Investors, (ii) directs such Specified Corporate Opportunity to another person or entity or (iii) fails to present such Specified Corporate Opportunity, or information regarding such Specified Corporate Opportunity, to the Corporation or any of its subsidiaries. For the avoidance of doubt, the foregoing provisions of this Section 9.1(b) shall not apply to any business opportunity, potential transaction, interest or other matter that is offered or presented to any Covered Person solely in such Covered Person's capacity as an officer, director or stockholder of the Corporation.

(c) Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the Corporation shall be deemed to have notice of and to have consented to the provisions of this Section 9.1.

(d) The provisions of this Section 9.1 shall have no further force or effect at such time as no IPO Investor continues to beneficially own, in the aggregate, at least one percent (1%) of the Corporation's then outstanding common stock; provided, however, that such termination shall not terminate the effect of the foregoing provisions of this Section 9.1 with respect to any Specified Corporate Opportunity that first arose prior to such termination.

9.2 Forum for Certain Actions.

(a) Forum. Unless a majority of the Board, acting on behalf of the Corporation, consents in writing to the selection of an alternative forum (which consent may be given at any time, including during the pendency of litigation), the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court located within the State of Delaware or, if no court located within the State of Delaware has jurisdiction, the federal district court for the District of Delaware), to the fullest extent permitted by law, shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim against the Corporation or any of its directors, officers or other employees arising pursuant to any provision of the DGCL, this Certificate of Incorporation or the Bylaws (in each case, as may be amended from time to time), (iv) any action asserting a claim against the Corporation or any of its directors, officers or other employees governed by the internal affairs doctrine of the State of Delaware or (v) any other action asserting an "internal corporate claim," as defined in Section

115 of the DGCL, in all cases subject to the court's having personal jurisdiction over all indispensable parties named as defendants; provided that the foregoing provision will not apply to any claim to enforce any liability or duty created by the Securities Act of 1933, as amended or the Securities Exchange Act of 1934, as amended and for which the federal courts have exclusive jurisdiction. Unless a majority of the Board, acting on behalf of the Corporation, consents in writing to the selection of an alternative forum (which consent may be given at any time, including during the pendency of litigation), the federal district courts of the United States of America, to the fullest extent permitted by law, shall be the sole and exclusive forum for any action asserting a cause of action arising under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

(b) Personal Jurisdiction. If any action the subject matter of which is within the scope of subparagraph (a) of this Section 9.2 is filed in a court other than a court located within the State of Delaware (a "***Foreign Action***") in the name of any stockholder, such stockholder shall be deemed to have consented to (i) the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce subparagraph (a) of this Section 9.2 (an "***Enforcement Action***") and (ii) having service of process made upon such stockholder in any such Enforcement Action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder.

(c) Enforceability. If any provision of this Section 9.2 shall be held to be invalid, illegal or unenforceable as applied to any person, entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law, the validity, legality and enforceability of such provision in any other circumstance and of the remaining provisions of this Section 9.2, and the application of such provision to other persons or entities and circumstances shall not in any way be affected or impaired thereby.

(d) Notice and Consent. To the fullest extent permitted by law, any person or entity purchasing or otherwise acquiring or holding any interest in any security of the Corporation shall be deemed to have notice of and consented to the provisions of this Section 9.2.

9.3 Amendment. The Corporation reserves the right to amend, alter or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by this Certificate of Incorporation and the DGCL, and all rights, preferences and privileges herein conferred upon stockholders of the Corporation by and pursuant to this Certificate of Incorporation in its present form or as hereafter amended are granted subject to the right reserved in this Section 9.3. In addition to any other vote that may be required by law, applicable stock exchange rule or the terms of any series of Preferred Stock, the affirmative vote of the holders of at least a majority of the voting power of all then outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to amend, alter, repeal or adopt any provision of this Certificate of Incorporation. Notwithstanding any other provision of this Certificate of Incorporation, and in addition to any other vote that may be required by law, applicable stock exchange rule or the terms of any series of Preferred Stock, the affirmative vote of the holders of at least sixty six and two-thirds percent (66 2/3%) of the voting power of all then outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to amend, alter, repeal or adopt any provision of this Certificate of Incorporation inconsistent with the purpose and intent of Article V, Article VI, Article VII, Article VIII or this Article IX (including, without limitation, any such Article as renumbered as a result of any amendment, alternation, repeal or adoption of any other Article).

9.4 Severability. If any provision or provisions of this Certificate of Incorporation shall be held to be invalid, illegal or unenforceable as applied to any circumstance for any reason whatsoever, the validity, legality and enforceability of such provision in any other circumstance and of the remaining provisions of this Certificate of Incorporation (including, without limitation, each portion of any paragraph of this Certificate of Incorporation containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby.

IN WITNESS WHEREOF, the Corporation has caused this Amended and Restated Certificate of Incorporation to be signed by a duly authorized officer of the Corporation on this 30th day of October, 2020.

/s/ Robin Harper Cowie

By: Robin Harper Cowie

Its: Chief Financial Officer

AMENDED AND RESTATED BYLAWS
OF
BIODESIX, INC.

(hereinafter called the "***Corporation***")

ARTICLE I
MEETINGS OF STOCKHOLDERS

Section 1.1. Place of Meetings. Meetings of the stockholders of the Corporation for the election of directors or for any other purpose shall be held at such time and place, if any, either within or without the State of Delaware, as shall be designated from time to time by the board of directors of the Corporation (the "***Board***"). The Board may, in its sole discretion, determine that a meeting shall not be held at any place, but may instead be held solely by means of remote communication in accordance with Section 211(a) of the General Corporation Law of the State of Delaware, as amended (the "***DGCL***").

Section 1.2. Annual Meetings. The annual meeting of stockholders of the Corporation for the election of directors and for the transaction of such other business as may properly be brought before the meeting in accordance with these amended and restated bylaws of the Corporation (as amended from time to time in accordance with the provisions hereof, these "***Bylaws***") shall be held on such date and at such time as may be designated from time to time by the Board. The Board may postpone, reschedule or cancel any annual meeting of stockholders previously scheduled by the Board.

Section 1.3. Special Meetings. Unless otherwise required by law or by the certificate of incorporation of the Corporation (including, without limitation, the terms of any certificate of designation with respect to any series of preferred stock), as amended and restated from time to time (the "***Certificate of Incorporation***"), special meetings of the stockholders of the Corporation, for any purpose or purposes, may be called only by the Chairperson of the Board, the Chief Executive Officer or the Board. The ability of the stockholders of the Corporation to call a special meeting of stockholders is hereby specifically denied. At a special meeting of stockholders, only such business shall be conducted as shall be specified in the notice of meeting. The Chairperson of the Board, the Chief Executive Officer or the Board may postpone, reschedule or cancel any special meeting of stockholders previously called by any of them.

Section 1.4. Notice. Whenever stockholders of the Corporation are required or permitted to take any action at a meeting, a written notice of the meeting shall be given which shall state the place, if any, date and time of the meeting, the record date for determining the stockholders entitled to vote at the meeting, if such date is different from the record date for determining stockholders entitled to notice of meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called and the means of remote communications, if any, by which stockholders and proxy holders may be deemed present in person and vote at such meeting. Unless otherwise required by law or the Certificate of Incorporation, written notice of any meeting shall be given either personally, by mail or by electronic transmission (as defined below) (if permitted under the circumstances by the DGCL) not less than ten (10) nor more than sixty (60) days before the date of the meeting, by or at the direction of the Chairperson of the

Board, the Chief Executive Officer or the Board, to each stockholder entitled to vote at such meeting as of the record date for determining stockholders entitled to notice of the meeting. If mailed, such notice shall be deemed to be given when deposited in the United States mail with postage thereon prepaid, addressed to the stockholder at the stockholder's address as it appears on the stock transfer books of the Corporation. If notice is given by means of electronic transmission, such notice shall be deemed to be given at the times provided in the DGCL. Any stockholder may waive notice of any meeting before or after the meeting. The attendance of a stockholder at any meeting shall constitute a waiver of notice at such meeting, except where the stockholder attends the meeting for the express purpose of objecting, and does so object, at the beginning of the meeting to the transaction of any business because the meeting is not lawfully called or convened. For the purposes of these Bylaws, "***electronic transmission***" means any form of communication, not directly involving the physical transmission of paper, that creates a record that may be retained, retrieved and reviewed by a recipient thereof and that may be directly reproduced in paper form by such a recipient through an automated process.

Section 1.5. Adjournments. Any meeting of stockholders of the Corporation may be adjourned or recessed from time to time to reconvene at the same or some other place, if any, by holders of a majority of the voting power of the Corporation's capital stock issued and outstanding and entitled to vote thereat, present in person or represented by proxy, though less than a quorum, or by any officer entitled to preside at or to act as secretary of such meeting, and notice need not be given of any such adjourned or recessed meeting if the time and place, if any, thereof, and the means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned or recessed meeting, are announced at the meeting at which the adjournment or recess is taken. At the adjourned or recessed meeting, the Corporation may transact any business that might have been transacted at the original meeting. If the adjournment is for more than thirty (30) days, notice of the adjourned meeting in accordance with the requirements of Section 1.4 of these Bylaws shall be given to each stockholder of record entitled to vote at the meeting. If, after the adjournment, a new record date for determination of stockholders entitled to vote is fixed for the adjourned meeting, the Board shall fix as the record date for determining stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote at the adjourned meeting and shall give notice of the adjourned meeting to each stockholder of record as of the record date so fixed for notice of such adjourned meeting.

Section 1.6. Quorum. Unless otherwise required by applicable law or the Certificate of Incorporation, the holders of a majority of the voting power of the Corporation's capital stock issued and outstanding and entitled to vote thereat, present in person, present by means of remote communication, if any, or represented by proxy, shall constitute a quorum at a meeting of stockholders. Where a separate vote by a class or classes or series is required, a majority of the voting power of the shares of such class or classes or series present in person, present by means of remote communication, if any, or represented by proxy shall constitute a quorum entitled to take action with respect to such vote. If a quorum shall not be present or represented at any meeting of stockholders, either the chairperson of the meeting or the stockholders entitled to vote thereat, present in person or represented by proxy, shall have power to adjourn the meeting from time to time, in the manner provided in Section 1.5 of these Bylaws, until a quorum shall be present or represented. A quorum, once established, shall not be broken by the withdrawal of enough votes to leave less than a quorum.

Section 1.7. Voting.

(a) Matters Other Than Election of Directors. Any matter brought before any meeting of stockholders of the Corporation, other than the election of directors, shall be decided by the affirmative vote of the holders of a majority of the voting power of the Corporation's capital stock present in person or represented by proxy at the meeting and entitled to vote on such matter, voting as a single class, unless the matter is one upon which, by express provision of law, the Certificate of Incorporation or these Bylaws, a different vote is required, in which case such express provision shall govern and control the decision of such matter. Except as provided in the Certificate of Incorporation, every stockholder having the right to vote shall have one vote for each share of stock having voting power registered in such stockholder's name on the books of the Corporation. Such votes may be cast in person or by proxy as provided in Section 1.10 of these Bylaws. The Board, in its discretion, or the officer of the Corporation presiding at a meeting of stockholders, in such officer's discretion, may require that any votes cast at such meeting shall be cast by written ballot.

(b) Election of Directors. Subject to the rights of the holders of any series of preferred stock to elect directors under specified circumstances, election of directors at all meetings of the stockholders at which directors are to be elected shall be by a plurality of the votes cast at any meeting for the election of directors at which a quorum is present.

Section 1.8. Voting of Stock of Certain Holders. Shares of stock of the Corporation standing in the name of another corporation or entity, domestic or foreign, and entitled to vote may be voted by such officer, agent or proxy as the bylaws or other internal regulations of such corporation or entity may prescribe or, in the absence of such provision, as the board of directors or comparable body of such corporation or entity may determine. Shares of stock of the Corporation standing in the name of a deceased person, a minor, an incompetent or a debtor in a case under Title 11, United States Code, and entitled to vote may be voted by an administrator, executor, guardian, conservator, debtor-in-possession or trustee, as the case may be, either in person or by proxy, without transfer of such shares into the name of the official or other person so voting. A stockholder whose shares of stock of the Corporation are pledged shall be entitled to vote such shares, unless on the transfer records of the Corporation such stockholder has expressly empowered the pledgee to vote such shares, in which case only the pledgee, or the pledgee's proxy, may vote such shares.

Section 1.9. Treasury Stock. Shares of stock of the Corporation belonging to the Corporation, or to another corporation a majority of the shares entitled to vote in the election of directors of which are held by the Corporation, shall not be voted at any meeting of stockholders of the Corporation and shall not be counted in the total number of outstanding shares for the purpose of determining whether a quorum is present. Nothing in this Section 1.9 shall limit the right of the Corporation to vote shares of stock of the Corporation held by it in a fiduciary capacity.

Section 1.10. Proxies. Each stockholder entitled to vote at a meeting of stockholders of the Corporation may authorize another person or persons to act for such stockholder by proxy filed with the secretary of the Corporation (the "***Secretary***") before or at the time of the meeting. No such proxy shall be voted or acted upon after three (3) years from its date, unless the proxy provides for a longer period. A duly executed proxy shall be irrevocable if it states that it is

irrevocable and if, and only as long as, it is coupled with an interest sufficient in law to support an irrevocable power. A stockholder may revoke any proxy which is not irrevocable by attending the meeting and voting in person or by filing with the Secretary an instrument in writing revoking the proxy or another duly executed proxy bearing a later date.

Section 1.11. No Consent of Stockholders in Lieu of Meeting. Except as otherwise expressly provided by the terms of any series of preferred stock permitting the holders of such series of preferred stock to act by written consent, any action required or permitted to be taken by the stockholders of the Corporation must be effected at a duly called annual or special meeting of stockholders of the Corporation, and, as specified by the Certificate of Incorporation, the ability of the stockholders to consent in writing to the taking of any action is specifically denied.

Section 1.12. List of Stockholders Entitled to Vote. The officer of the Corporation who has charge of the stock ledger of the Corporation shall prepare and make or have prepared and made, at least ten (10) days before every meeting of stockholders of the Corporation, a complete list of the stockholders entitled to vote at the meeting (provided, however, that if the record date for determining the stockholders entitled to vote is less than ten (10) days before the meeting date, the list shall reflect the stockholders entitled to vote as of the tenth (10th) day before the meeting date), arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Nothing in this Section 1.12 shall require the Corporation to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder for any purpose germane to the meeting for a period of at least ten (10) days prior to the meeting: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the principal place of business of the Corporation. If the meeting is to be held at a place, then the list shall be produced and kept at the time and place of the meeting during the whole time thereof and may be examined by any stockholder who is present. In the event that the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting.

Section 1.13. Record Date. In order that the Corporation may determine the stockholders entitled to notice of any meeting of stockholders of the Corporation or any adjournment thereof, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board, and which record date shall not be more than sixty (60) nor less than ten (10) days before the date of such meeting. If the Board so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of

stockholders shall apply to any adjournment of the meeting, but the Board may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance with the foregoing provisions of this Section 1.13 at the adjourned meeting.

Section 1.14. Organization and Conduct of Meetings. The Chairperson of the Board shall act as chairperson of meetings of stockholders of the Corporation. The Board may designate any other director or officer of the Corporation to act as chairperson of any meeting in the absence of the Chairperson of the Board, and the Board may further provide for determining who shall act as chairperson of any meeting of stockholders in the absence of the Chairperson of the Board and such designee. The Board may adopt by resolution such rules and regulations for the conduct of any meeting of stockholders as it shall deem appropriate. Except to the extent inconsistent with such rules and regulations as adopted by the Board, the chairperson of any meeting of stockholders shall have the right and authority to convene and (for any or no reason) to recess or adjourn the meeting to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such chairperson, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board or prescribed by the chairperson of the meeting, may include, without limitation, the following: (a) the establishment of an agenda or order of business for the meeting; (b) the determination of when the polls shall open and close for any given matter to be voted on at the meeting; (c) rules and procedures for maintaining order at the meeting and the safety of those present; (d) limitations on attendance at or participation in the meeting to stockholders of record of the Corporation, their duly authorized proxies or such other persons as the chairperson of the meeting shall determine; (e) restrictions on entry to the meeting after the time fixed for the commencement of the meeting; (f) limitations on the time allotted to questions or comments by participants; (g) removal of any stockholder or any other individual who refuses to comply with meeting procedures, rules or guidelines; (h) conclusion, recess or adjournment of the meeting, regardless of whether a quorum is present, to a later date and time and at a place, if any, announced at the meeting; (i) restrictions on the use of audio and video recording devices, cell phones and other electronic devices; (j) rules, regulations or procedures for compliance with any state and local laws and regulations concerning safety, health and security; (k) procedures (if any) requiring attendees to provide the Corporation advance notice of their intent to attend the meeting and (l) any guidelines and procedures as the chairperson may deem appropriate regarding the participation by means of remote communication of stockholders and proxyholders not physically present at a meeting, whether such meeting is to be held at a designated place or solely by means of remote communication. The chairperson of a stockholder meeting, in addition to making any other determinations that may be appropriate to the conduct of the meeting, shall determine and declare to the meeting that a matter or business was not properly brought before the meeting, and, if the chairperson should so determine, the chairperson shall so declare to the meeting and any such matter of business not properly brought before the meeting shall not be transacted or considered. Except to the extent determined by the Board or the person presiding over the meeting, meetings of stockholders shall not be required to be held in accordance with the rules of parliamentary procedure.

Section 1.15. Inspectors of Election. In advance of any meeting of stockholders of the Corporation, the Chairperson of the Board, the Chief Executive Officer or the Board, by

resolution, shall appoint one or more inspectors to act at the meeting and make a written report thereof. One or more other persons may be designated as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is able to act at a meeting of stockholders, the chairperson of the meeting shall appoint one or more inspectors to act at the meeting. Unless otherwise required by applicable law, inspectors may be officers, employees or agents of the Corporation. Each inspector, before entering upon the discharge of the duties of inspector, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of such inspector's ability. The inspector shall have the duties prescribed by law and shall take charge of the polls and, when the vote is completed, shall make a certificate of the result of the vote taken and of such other facts as may be required by applicable law.

Section 1.16. Notice of Stockholder Proposals and Director Nominations.

(a) Annual Meetings of Stockholders. Nominations of persons for election to the Board and the proposal of business other than nominations to be considered by the stockholders may be made at an annual meeting of stockholders only: (i) pursuant to the Corporation's notice of meeting (or any supplement thereto) with respect to such annual meeting given by or at the direction of the Board (or any duly authorized committee thereof), (ii) otherwise properly brought before such annual meeting by or at the direction of the Board (or any duly authorized committee thereof) or (iii) by any stockholder of the Corporation who (A) is a stockholder of record on the date of the giving of the notice provided for in this Section 1.16 through the date of such annual meeting, (B) is entitled to vote at such annual meeting and (C) complies with the notice procedures set forth in this Section 1.16. For the avoidance of doubt, compliance with the foregoing clause (iii) shall be the exclusive means for a stockholder to make nominations, or to propose any other business (other than a proposal included in the Corporation's proxy materials pursuant to and in compliance with Rule 14a-8 under the Securities Exchange Act of 1934, as amended (such act, and the rules and regulations promulgated thereunder, the "***Exchange Act***")), at an annual meeting of stockholders.

(b) Timing of Notice for Annual Meetings. In addition to any other applicable requirements, for nominations or other business to be properly brought before an annual meeting by a stockholder pursuant to Section 1.16(a)(iii) above, the stockholder must have given timely notice thereof in proper written form to the Secretary, and, in the case of business other than nominations, such business must be a proper matter for stockholder action. To be timely, such notice must be received by the Secretary at the principal executive offices of the Corporation not later than the Close of Business on the ninetieth (90th) day, or earlier than the Close of Business on the one hundred twentieth (120th) day, prior to the first anniversary of the date of the preceding year's annual meeting of stockholders; provided, however, that in the case of the first annual meeting after October 14, 2020, if the date of the annual meeting of stockholders is more than thirty (30) days prior to, or more than sixty (60) days after, the first anniversary of the date of the preceding year's annual meeting or if no annual meeting was held in the preceding year, to be timely, a stockholder's notice must be so received not later than the Close of Business on the later of (i) the ninetieth (90th) day prior to such annual meeting and (ii) the tenth (10th) day following the day on which public disclosure (as defined below) of the date of the meeting is first made by the Corporation. In no event shall the adjournment, recess, postponement or rescheduling of an annual meeting (or the public disclosure thereof) commence a new time period (or extend any time period) for the giving of notice as described above.

(c) Form of Notice. To be in proper written form, the notice of any stockholder giving notice under this Section 1.16 (each, a "***Noticing Party***") must set forth:

(i) as to each person whom such Noticing Stockholder proposes to nominate for election or reelection as a director (each, a "***Proposed Nominee***"), if any:

(A) the name, age, business address and residence address of such Proposed Nominee;

(B) the principal occupation and employment of such Proposed Nominee;

(B) a written questionnaire with respect to the background and qualification of such Proposed Nominee, completed by such Proposed Nominee in the form required by the Corporation (which form such Noticing Stockholder shall request in writing from the Secretary prior to submitting notice and which the Secretary shall provide to such Noticing Stockholder within ten (10) days after receiving such request);

(C) a written representation and agreement completed by such Proposed Nominee in the form required by the Corporation (which form such Noticing Stockholder shall request in writing from the Secretary prior to submitting notice and which the Secretary shall provide to such Noticing Stockholder within ten (10) days after receiving such request) providing that such Proposed Nominee: (I) is not and will not become a party to any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity as to how such Proposed Nominee, if elected as a director of the Corporation, will act or vote on any issue or question (a "***Voting Commitment***") that has not been disclosed to the Corporation or any Voting Commitment that could limit or interfere with such Proposed Nominee's ability to comply, if elected as a director of the Corporation, with such Proposed Nominee's fiduciary duties under applicable law; (II) is not and will not become a party to any agreement, arrangement or understanding with any person or entity other than the Corporation with respect to any direct or indirect compensation, reimbursement or indemnification in connection with service or action as a director or nominee that has not been disclosed to the Corporation; (III) will, if elected as a director of the Corporation, comply with all applicable rules of any securities exchanges upon which the Corporation's securities are listed, the Certificate of Incorporation, these Bylaws and all applicable publicly disclosed corporate governance, ethics, conflict of interest, confidentiality and stock ownership and trading policies and other guidelines and policies of the Corporation generally applicable to directors (which will be provided to such Proposed Nominee within five (5) business days after the Secretary receives any written request therefor from such Proposed Nominee), and all applicable fiduciary duties under state law; (IV) consents to being named as a nominee in the Corporation's proxy statement and form of proxy for the meeting and to serving a full term as a director of the Corporation, if elected; and (V) will provide facts, statements and other information in all communications with the Corporation and its stockholders that are or will be true and correct in all material respects and that do not and will not omit to state a

material fact necessary in order to make the statements made, in light of the circumstances under which they are made, not misleading;

(D) a description of all direct and indirect compensation and other material monetary agreements, arrangements and understandings, written or oral, during the past three (3) years, and any other material relationships, between or among such Proposed Nominee, on the one hand, and such Noticing Stockholder or any Stockholder Associated Person (as defined below), on the other hand, including, without limitation, all information that would be required to be disclosed pursuant to Item 404 promulgated under Regulation S-K as if such Noticing Stockholder and any Stockholder Associated Person were the "registrant" for purposes of such rule and the Proposed Nominee were a director or executive officer of such registrant; and

(E) all other information relating to such Proposed Nominee or such Proposed Nominee's associates that would be required to be disclosed in a proxy statement or other filing required to be made by such Noticing Party or any Stockholder Associated Person in connection with the solicitation of proxies for the election of directors in a contested election or otherwise required pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder (collectively, the "***Proxy Rules***");

(ii) as to any other business that such Noticing Stockholder proposes to bring before the meeting:

(A) a reasonably brief description of the business desired to be brought before the meeting and the reasons for conducting such business at the meeting;

(B) the text of the proposal or business (including the complete text of any resolutions proposed for consideration and, in the event that such business includes a proposal to amend the Certificate of Incorporation or these Bylaws, the language of the proposed amendment); and

(C) all other information relating to such business that would be required to be disclosed in a proxy statement or other filing required to be made by such Noticing Stockholder or any Stockholder Associated Person in connection with the solicitation of proxies in support of such proposed business by such Noticing Party or any Stockholder Associated Person pursuant to the Proxy Rules; and

(iii) as to such Noticing Party, each Proposed Nominee and each Stockholder Associated Person:

(A) the name and address of such Noticing Party, each Proposed Nominee and each Stockholder Associated Person (including, as applicable, as they appear on the Corporation's books and records);

(B) the class, series and number of shares of each class or series of capital stock (if any) of the Corporation that are, directly or indirectly, owned beneficially and/or of record by such Noticing Party, any Proposed Nominee or

any Stockholder Associated Person and the date or dates such shares were acquired and the investment intent of such acquisition;

(C) the name of each nominee holder for, and number of, any securities of the Corporation owned beneficially but not of record by such Noticing Party, any Proposed Nominee or any Stockholder Associated Person and any pledge by such Noticing Party, any Proposed Nominee or any Stockholder Associated Person with respect to any of such securities;

(D) any Short Interest (as defined below) held by or involving such Noticing Party, any Proposed Nominee or any Stockholder Associated Person;

(E) a complete and accurate description of all agreements, arrangements or understandings, written or oral, (including any derivative or short positions, profit interests, hedging transactions, options, warrants, convertible securities, stock appreciation or similar rights and borrowed or loaned shares) that have been entered into by, or on behalf of, such Noticing Party, any Proposed Nominee or any Stockholder Associated Person, the effect or intent of which is to mitigate loss, manage risk or benefit from changes in the price of any securities of the Corporation, or maintain, increase or decrease the voting power of such Noticing Party, any Proposed Nominee or any Stockholder Associated Person with respect to securities of the Corporation, whether or not such instrument or right shall be subject to settlement in underlying shares of capital stock of the Corporation (any of the foregoing, a "***Derivative Instrument***");

(F) any substantial interest, direct or indirect (including any existing or prospective commercial, business or contractual relationship with the Corporation), by security holdings or otherwise, of such Noticing Party, any Proposed Nominee or any Stockholder Associated Person in the Corporation or any affiliate thereof, other than an interest arising from the ownership of Corporation securities where such Noticing Party, such Proposed Nominee or such Stockholder Associated Person receives no extra or special benefit not shared on a *pro rata* basis by all other holders of the same class or series;

(G) a complete and accurate description of all agreements, arrangements or understandings, written or oral, (I) between or among such Noticing Party and any of the Stockholder Associated Persons or (II) between or among such Noticing Party or any Stockholder Associated Person and any other person or entity (naming each such person or entity) or any Proposed Nominee, including, without limitation, (x) any proxy, contract, arrangement, understanding or relationship pursuant to which such Noticing Party or any Stockholder Associated Person has a right to vote any security of the Corporation, (y) any understanding, written or oral, that such Noticing Party or any Stockholder Associated Person may have reached with any stockholder of the Corporation (including the name of such stockholder) with respect to how such stockholder will vote such stockholder's shares in the Corporation at any meeting of the Corporation's stockholders or take other action in support of any Proposed Nominee or other business, or other action to be taken, by such Noticing Party or any Stockholder

Associated Person and (z) any other agreements that would be required to be disclosed by such Noticing Party, any Proposed Nominee, any Stockholder Associated Person or any other person or entity pursuant to Item 5 or Item 6 of a Schedule 13D pursuant to Section 13 of the Exchange Act and the rules and regulations promulgated thereunder (regardless of whether the requirement to file a Schedule 13D is applicable to such Noticing Party, any Proposed Nominee, any Stockholder Associated Person or any other person or entity);

(H) any rights to dividends on the shares of the Corporation owned beneficially by such Noticing Party, any Proposed Nominee or any Stockholder Associated Person that are separated or separable from the underlying shares of the Corporation;

(I) any proportionate interest in shares of the Corporation or Derivative Instruments held, directly or indirectly, by a general or limited partnership, limited liability company or similar entity in which such Noticing Party, any Proposed Nominee or any Stockholder Associated Person is (I) a general partner or, directly or indirectly, beneficially owns an interest in a general partner of such general or limited partnership or (II) the manager, managing member or, directly or indirectly, beneficially owns an interest in the manager or managing member of such limited liability company or similar entity;

(J) any significant equity interests or any Derivative Instruments or Short Interests in any principal competitor of the Corporation held by such Noticing Party, any Proposed Nominee or any Stockholder Associated Person;

(K) any direct or indirect interest of such Noticing Party, any Proposed Nominee or any Stockholder Associated Person in any contract with the Corporation, any affiliate of the Corporation or any principal competitor of the Corporation (including, without limitation, any employment agreement, collective bargaining agreement or consulting agreement);

(L) a description of any material interest of such Noticing Party, any Proposed Nominee or any Stockholder Associated Person in the business proposed by such Noticing Party, if any, or the election of any Proposed Nominee;

(M) a complete an accurate description of any performance-related fees (other than an asset-based fee) to which such Noticing Party, any Proposed Nominee or any Stockholder Associated Person may be entitled as a result of any increase or decrease in the value of the Corporation's securities or any Derivative Instruments, including, without limitation, any such interests held by members of any Proposed Nominee's or Stockholder Associated Person's immediate family sharing the same household;

(N) the investment strategy or objective, if any, of such Noticing Party, any Proposed Nominee or any Stockholder Associated Person who is not an individual and a copy of the prospectus, offering memorandum or similar

document, if any, provided to investors or potential investors in the Noticing Party or any Stockholder Associated Person; and

(O) all other information relating to such Noticing Party or any Stockholder Associated Person, or such Noticing Party's or any Stockholder Associated Person's associates, that would be required to be disclosed in a proxy statement or other filing in connection with the solicitation of proxies in support of the business proposed by such Noticing Party, if any, or for the election of any Proposed Nominee in a contested election or otherwise pursuant to the Proxy Rules.

(iv) a representation that such Noticing Party intends to appear in person or by proxy at the meeting to bring such business before the meeting or nominate any Proposed Nominees, as applicable, and an acknowledgment that, if such Noticing Party (or a Qualified Representative (as defined below) of such Noticing Party) does not appear to present such business or Proposed Nominees, as applicable, at such meeting, the Corporation need not present such business or Proposed Nominees for a vote at such meeting, notwithstanding that proxies in respect of such vote may have been received by the Corporation;

(v) a complete and accurate description of any pending or, to such Noticing Party's knowledge, threatened legal proceeding in which such Noticing Party, any Proposed Nominee or any Stockholder Associated Person is a party or participant involving the Corporation or, to such Noticing Party's knowledge, any officer, affiliate or associate of the Corporation;

(vi) a representation from such Noticing Party as to whether such Noticing Party or any Stockholder Associated Person intends or is part of a group that intends (I) to deliver a proxy statement and/or form of proxy to a number of holders of the Corporation's voting shares reasonably believed by such Noticing Party to be sufficient to approve or adopt the business to be proposed or elect the Proposed Nominees, as applicable, or (II) engage in a solicitation (within the meaning of Exchange Act Rule 14a-1(l) with respect to the nomination or other business, as applicable, and if so, the name of each participant (as defined in Item 4 of Schedule 14A under the Exchange Act) in such solicitation; and

(vii) a description of any agreement, arrangement or understanding, written or oral, the effect or intent of which is to increase or decrease the voting power of such Noticing Party or any Stockholder Associated Person with respect to any shares of the capital stock of the Corporation, without regard to whether such agreement, arrangement or understanding is required to be reported on a Schedule 13D in accordance with the Exchange Act.

(d) Additional Information. In addition to the information required above, the Corporation may require any Noticing Party to furnish such other information as the Corporation may reasonably require to determine the eligibility or suitability of a Proposed Nominee to serve as a director of the Corporation or that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such Proposed Nominee, under the listing standards of each securities exchange upon which the Corporation's securities are listed, any

applicable rules of the Securities and Exchange Commission, any publicly disclosed standards used by the Board in selecting nominees for election as a director and for determining and disclosing the independence of the Corporation's directors, including those applicable to a director's service on any of the committees of the Board, or the requirements of any other laws or regulations applicable to the Corporation. If requested by the Corporation, any supplemental information required under this paragraph shall be provided by a Noticing Party within ten (10) days after it has been requested by the Corporation.

(e) Special Meetings of Stockholders. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting pursuant to the Corporation's notice of meeting (or any supplement thereto). Nominations of persons for election to the Board may be made at a special meeting of stockholders at which directors are to be elected pursuant to the Corporation's notice of meeting (or any supplement thereto) (i) by or at the direction of the Board (or any duly authorized committee thereof) or (ii) provided that one or more directors are to be elected at such meeting pursuant to the Corporation's notice of meeting, by any stockholder of the Corporation who (A) is a stockholder of record on the date of the giving of the notice provided for in this Section 1.16(e) through the date of such special meeting, (B) is entitled to vote at such special meeting and upon such election and (C) complies with the notice procedures set forth in this Section 1.16(e). In addition to any other applicable requirements, for director nominations to be properly brought before a special meeting by a stockholder pursuant to the foregoing clause (ii), such stockholder must have given timely notice thereof in proper written form to the Secretary. To be timely, such notice must be received by the Secretary at the principal executive offices of the Corporation not earlier than the Close of Business on the one hundred twentieth (120th) day prior to such special meeting and not later than the Close of Business on the later of (x) the ninetieth (90th) day prior to such special meeting and (y) the tenth (10th) day following the day on which public disclosure of the date of the meeting is first made by the Corporation. In no event shall an adjournment, recess, postponement or rescheduling of a special meeting (or the public disclosure thereof) commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above. To be in proper written form, such notice shall include all information required pursuant to Section 1.16(c) and Section 1.16(d) above.

(e) General.

(i) No person shall be eligible for election as a director of the Corporation unless the person is nominated by a stockholder in accordance with the procedures set forth in this Section 1.16 or the person is nominated by the Board, and no business shall be conducted at a meeting of stockholders of the Corporation except business brought by a stockholder in accordance with the procedures set forth in this Section 1.16 or by the Board. Except as otherwise provided by law, the chairperson of a meeting shall have the power and the duty to determine whether a nomination or any business proposed to be brought before the meeting has been made in accordance with the procedures set forth in these Bylaws, and, if the chairperson of the meeting determines that any proposed nomination or business was not properly brought before the meeting, the chairperson shall declare to the meeting that such nomination shall be disregarded or such business shall not be transacted, and no vote shall be taken with respect to such nomination or proposed business, in each case, notwithstanding that proxies with respect to such vote may have been received by the Corporation. Notwithstanding the foregoing provisions of

this Section 1.16, unless otherwise required by law, if the Noticing Party (or a Qualified Representative of the Noticing Party) proposing a nominee for director or business to be conducted at a meeting does not appear at the meeting of stockholders of the Corporation to present such nomination or propose such business, such proposed nomination shall be disregarded or such proposed business shall not be transacted, as applicable, and no vote shall be taken with respect to such nomination or proposed business, notwithstanding that proxies with respect to such vote may have been received by the Corporation.

(ii) A Noticing Party shall update such notice, if necessary, such that the information provided or required to be provided in such notice shall be true and correct (A) as of the record date for determining the stockholders entitled to receive notice of the meeting and (B) as of the date that is ten (10) business days prior to the meeting (or any postponement, rescheduling or adjournment thereof), and such update shall be received by the Secretary at the principal executive offices of the Corporation (x) not later than the Close of Business five (5) business days after the record date for determining the stockholders entitled to receive notice of such meeting (in the case of an update required to be made under clause (A)) and (y) not later than the Close of Business seven (7) business days prior to the date for the meeting or, if practicable, any postponement, rescheduling or adjournment thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been postponed, rescheduled or adjourned) (in the case of an update required to be made pursuant to clause (B)). For the avoidance of doubt, any information provided pursuant to this Section 1.16(e)(ii) shall not be deemed to cure any deficiencies in a notice previously delivered pursuant to this Section 1.16 and shall not extend the time period for the delivery of notice pursuant to this Section 1.16. If a Noticing Party fails to provide such written update within such period, the information as to which written update relates may be deemed to not have been provided in accordance with this Section 1.16.

(iii) If any information submitted pursuant to this Section 1.16 by any Noticing Party proposing individuals to nominate for election or reelection as a director or business for consideration at a stockholder meeting shall be inaccurate in any respect, such information shall be deemed not to have been provided in accordance with this Section 1.16. Any such Noticing Party shall notify the Secretary in writing at the principal executive offices of the Corporation of any inaccuracy or change in any information submitted pursuant to this Section 1.16 within two (2) business days after becoming aware of such inaccuracy or change. Upon written request of the Secretary on behalf of the Board (or a duly authorized committee thereof), any such Noticing Party shall provide, within seven (7) business days after delivery of such request (or such other period as may be specified in such request), (A) written verification, reasonably satisfactory to the Board, any committee thereof or any authorized officer of the Corporation, to demonstrate the accuracy of any information submitted by such Noticing Party pursuant to this Section 1.16 and (B) a written affirmation of any information submitted by such Noticing Party pursuant to this Section 1.16 as of an earlier date. If a Noticing Party fails to provide such written verification or affirmation within such period, the information as to which written verification or affirmation was requested may be deemed not to have been provided in accordance with this Section 1.16.

(iv) Notwithstanding the foregoing provisions of this Section 1.16, a stockholder shall also comply with all applicable requirements of state law and the Exchange Act with respect to the matters set forth in this Section 1.16. Nothing in this Section 1.16 shall be deemed to affect any rights of (A) stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act, (B) stockholders to request inclusion of nominees in the Corporation's proxy statement pursuant to the Proxy Rules or (C) the holders of any series of preferred stock to elect directors pursuant to any applicable provisions of the Certificate of Incorporation.

(v) For purposes of these Bylaws, (A) "***affiliate***" and "***associate***" each shall have the respective meanings set forth in Rule 12b-2 under the Exchange Act; (B) "***beneficial owner***" or "***beneficially owned***" shall have the meaning set forth for such terms in Section 13(d) of the Exchange Act; (C) "***Close of Business***" shall mean 5:00 p.m. Eastern Time on any calendar day, whether or not the day is a business day; (D) "***public disclosure***" shall mean disclosure in a press release reported by a national news service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Exchange Act; (E) a "***Qualified Representative***" of a Noticing Party means (I) a duly authorized officer, manager or partner of such Noticing Party or (II) a person authorized by a writing executed by such Noticing Party (or a reliable reproduction or electronic transmission of the writing) delivered by such Noticing Party to the Corporation prior to the making of any nomination or proposal at a stockholder meeting stating that such person is authorized to act for such Noticing Party as proxy at the meeting of stockholders, which writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, must be produced at the meeting of stockholders; (F) "***Short Interest***" shall mean any agreement, arrangement, understanding, relationship or otherwise, including, without limitation, any repurchase or similar so-called "stock borrowing" agreement or arrangement, involving any Noticing Party or any Stockholder Associated Person of any Noticing Party directly or indirectly, the purpose or effect of which is to mitigate loss to, reduce the economic risk (of ownership or otherwise) of any class or series of shares of the Corporation by, manage the risk of share price changes for, or increase or decrease the voting power of, such Noticing Party or any Stockholder Associated Person of any Noticing Party with respect to any class or series of shares of the Corporation, or which provides, directly or indirectly, the opportunity to profit or share in any profit derived from any decrease in the price or value of any class or series of shares of the Corporation; and (G) "***Stockholder Associated Person***" shall mean, with respect to any Noticing Party, (I) any person directly or indirectly controlling, controlled by, under common control with such Noticing Party, (II) any member of the immediate family of such Noticing Party sharing the same household, (III) any person who is a member of a "group" (as such term is used in Rule 13d-5 under the Exchange Act (or any successor provision at law)) with or otherwise acting in concert with such Noticing Party or Stockholder Associated Person with respect to the stock of the Corporation, (IV) any beneficial owner of shares of stock of the Corporation owned of record by such Noticing Party or Stockholder Associated Person (other than a stockholder that is a depositary), (V) any affiliate or associate of such Noticing Party or any Stockholder Associated Person, (VI) any participant (as defined in paragraphs (a)(ii)-(vi) of Instruction 3 to Item 4 of

Schedule 14A) with such Noticing Party or Stockholder Associated Person with respect to any proposed business or nominations, as applicable, and (VII) any Proposed Nominee.

ARTICLE II
DIRECTORS

Section 2.1. Number. Within the limit set forth in the Certificate of Incorporation, the number of directors that shall constitute the entire Board shall be fixed, from time to time, exclusively by the Board, subject to the rights of the holders of any series of preferred stock with respect to the election of directors, if any.

Section 2.2. Duties and Powers. The business and affairs of the Corporation shall be managed by or under the direction of the Board, which may exercise all such powers of the Corporation and do all such lawful acts and things as are not by law or by the Certificate of Incorporation required to be exercised or done by the stockholders.

Section 2.3. Meetings. The Board may hold meetings, both regular and special, either within or without the State of Delaware. Regular meetings of the Board may be held at such time and at such place as may from time to time be determined by the Board. Special meetings of the Board may be called by the Chairperson of the Board (if there be one), the Chief Executive Officer or the Board and shall be held at such place, on such date and at such time as he, she or it shall specify.

Section 2.4. Notice. Notice of any meeting of the Board stating the place, date and time of the meeting shall be given to each director by mail posted not less than five (5) days before the date of the meeting, by nationally recognized overnight courier deposited not less than two (2) days before the date of the meeting or by email, facsimile or other means of electronic transmission delivered or sent not less than twenty-four (24) hours before the date and time of the meeting, or on such shorter notice as the person or persons calling such meeting may deem necessary or appropriate in the circumstances. If mailed or sent by overnight courier, such notice shall be deemed to be given at the time when it is deposited in the United States mail with first class postage prepaid or deposited with the overnight courier. Notice by facsimile or other electronic transmission shall be deemed given when the notice is transmitted. Any director may waive notice of any meeting before or after the meeting. The attendance of a director at any meeting shall constitute a waiver of notice of such meeting, except where the director attends the meeting for the express purpose of objecting, and does so object, at the beginning of the meeting to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the Board need be specified in any notice of such meeting unless so required by law. A meeting may be held at any time without notice if all of the directors are present or if those not present waive notice of the meeting in accordance with Section 5.6 of these Bylaws.

Section 2.5. Chairperson of the Board. The Chairperson of the Board shall be chosen from among the directors and may be the Chief Executive Officer. Except as otherwise provided by law, the Certificate of Incorporation or Section 2.6 or Section 2.7 of these Bylaws, the Chairperson of the Board shall preside at all meetings of stockholders and of the Board. The

Chairperson of the Board shall have such other powers and duties as may from time to time be assigned by the Board.

Section 2.6. Lead Director. The Board may include a Lead Director. The Lead Director shall be one of the directors who has been determined by the Board to be an "independent director" (any such director, an "***Independent Director***"). The Lead Director shall preside at all meetings of the Board at which the Chairperson of the Board is not present, preside over the executive sessions of the Independent Directors, serve as a liaison between the Chairperson of the Board and the Board and have such other responsibilities, and perform such duties, as may from time to time be assigned to him or her by the Board. The Lead Director shall be elected by a majority of the Independent Directors.

Section 2.7. Organization. At each meeting of the Board, the Chairperson of the Board, or, in the Chairperson's absence, the Lead Director, or, in the Lead Director's absence, a director chosen by a majority of the directors present, shall act as chairperson. The Secretary shall act as secretary at each meeting of the Board. In case the Secretary shall be absent from any meeting of the Board, an assistant secretary shall perform the duties of secretary at such meeting, and in the absence from any such meeting of the Secretary and all assistant secretaries, the chairperson of the meeting may appoint any person to act as secretary of the meeting.

Section 2.8. Resignations and Removals of Directors. Any director of the Corporation may resign at any time, by giving notice in writing or by electronic transmission to the Chairperson of the Board, the Chief Executive Officer or the Secretary. Such resignation shall be effective upon receipt unless it is specified to be effective at some other time or upon the occurrence of some other event, and, unless otherwise specified in such notice, the acceptance of such resignation shall not be necessary to make it effective. Subject to the rights of holders of any series of preferred stock with respect to the election of directors, a director may be removed from office by the stockholders of the Corporation only for cause and only by the affirmative vote of the holders of at least a majority of the voting power of all then outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class.

Section 2.9. Quorum. At all meetings of the Board, a majority of directors constituting the Board shall constitute a quorum for the transaction of business, and the act of a majority of the directors present at any meeting at which there is a quorum shall be the act of the Board. If a quorum shall not be present at any meeting of the Board, the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting of the time and place of the adjourned meeting, until a quorum shall be present.

Section 2.10. Actions of the Board by Written Consent. Any action required or permitted to be taken at any meeting of the Board or of any committee thereof may be taken without a meeting, if all the members of the Board or committee, as the case may be, consent thereto in writing or by electronic transmission, and the writing or writings or electronic transmission are filed with the minutes of proceedings of the Board or committee.

Section 2.11. Telephonic Meetings. Members of the Board, or any committee thereof, may participate in a meeting of the Board or such committee by means of a conference telephone or other communications equipment by means of which all persons participating in the meeting

can hear and speak with each other, and participation in a meeting pursuant to this Section 2.11 shall constitute presence in person at such meeting.

Section 2.12. Committees. The Board may designate one or more committees, each committee to consist of one or more of the directors of the Corporation and, to the extent permitted by law, to have and exercise such authority as may be provided for in the resolutions creating such committee, as such resolutions may be amended from time to time. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of any such committee. In the absence or disqualification of a member of a committee, and in the absence of a designation by the Board of an alternate member to replace the absent or disqualified member, the member or members thereof present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in the place of any absent or disqualified member. Each committee shall keep regular minutes and report to the Board when required. A majority of any committee may determine its action and fix the time and place of its meetings, unless the Board shall otherwise provide. The Board shall have the power at any time to fill vacancies in, to change the membership of or to dissolve any such committee.

Section 2.13. Compensation. The Board shall have the authority to fix the compensation of directors. The directors shall be paid their reasonable expenses, if any, of attendance at each meeting of the Board or any committee thereof and may be paid a fixed sum for attendance at each such meeting and an annual retainer or salary for service as director or committee member, payable in cash or securities. No such payment shall preclude any director from serving the Corporation in any other capacity and receiving compensation therefor. Directors who are full-time employees of the Corporation shall not receive any compensation for their service as director.

Section 2.14. Interested Directors. No contract or transaction between the Corporation and one or more of its directors or officers, or between the Corporation and any other corporation, partnership, association or other organization in which one or more of the Corporation's directors or officers are directors or officers or have a financial interest, shall be void or voidable solely for this reason, or solely because the director or officer is present at or participates in the meeting of the Board or committee thereof that authorizes the contract or transaction, or solely because any such director's or officer's vote is counted for such purpose if: (a) the material facts as to the director's or officer's relationship or interest and as to the contract or transaction are disclosed or are known to the Board or the committee and the Board or committee in good faith authorizes the contract or transaction by the affirmative vote of a majority of the disinterested directors, even though the disinterested directors be less than a quorum; (b) the material facts as to the director's or officer's relationship or interest and as to the contract or transaction are disclosed or are known to the stockholders entitled to vote thereon and the contract or transaction is specifically approved in good faith by vote of the stockholders; or (c) the contract or transaction is fair as to the Corporation as of the time it is authorized, approved or ratified by the Board, a committee thereof or the stockholders. Interested directors may be counted in determining the presence of a quorum at a meeting of the Board or of a committee that authorizes the contract or transaction.

ARTICLE III

OFFICERS

Section 3.1. General. The officers of the Corporation shall be chosen by the Board (or, in the case of any officer other than the Chief Executive Officer, by either the Board or the Chief Executive Officer) and shall be a Chief Executive Officer, a Chief Financial Officer, a President, a Secretary and a Treasurer. The Board or the Chief Executive Officer, in their discretion, may also choose one or more Executive Vice Presidents, Senior Vice Presidents, Vice Presidents, Assistant Secretaries, Assistant Treasurers and such other officers as either the Board or the Chief Executive Officer, as applicable, from time to time may deem appropriate. Any two or more offices may be held by the same person. The officers of the Corporation need not be stockholders of the Corporation.

Section 3.2. Election; Term. The Board (or, in the case of any officer other than the Chief Executive Officer, either the Board or the Chief Executive Officer) shall elect the officers of the Corporation who shall hold their offices for such terms and shall exercise such powers and perform such duties as shall be determined from time to time by the Board or the Chief Executive Officer, as applicable, and each officer of the Corporation shall hold office until such officer's successor is elected and qualified, or until such officer's earlier death, resignation or removal. Any officer may be removed at any time by the Board or the Chief Executive Officer. Any officer may resign upon notice given in writing or electronic transmission to the Chief Executive Officer or the Secretary. Such resignation shall be effective upon receipt unless it is specified to be effective at some other time or upon the occurrence of some other event. Any vacancy occurring in any office of the Corporation shall be filled in the manner prescribed in this Article III for the regular election to such office.

Section 3.3. Voting Securities Owned by the Corporation. Powers of attorney, proxies, waivers of notice of meeting, consents and other instruments relating to securities owned by the Corporation may be executed in the name of and on behalf of the Corporation by the Chief Executive Officer, the Secretary or any other officer authorized to do so by the Board, and any such officer may, in the name of and on behalf of the Corporation, take all such action as any such officer may deem advisable to vote in person or by proxy at any meeting of security holders of any corporation in which the Corporation may own securities and at any such meeting shall possess and may exercise any and all rights and power incident to the ownership of such securities and which, as the owner thereof, the Corporation might have exercised and possessed if present. The Board may, by resolution, from time to time confer like powers upon any other person or persons.

Section 3.4. Chief Executive Officer. The Chief Executive Officer shall, subject to the control of the Board, have general supervision over the business of the Corporation and shall direct the affairs and policies of the Corporation. The Chief Executive Officer may also serve as Chairperson of the Board and may also serve as President, if so elected by the Board. The Chief Executive Officer shall also perform such other duties and may exercise such other powers as may from time to time be assigned to such officer by these Bylaws or by the Board.

Section 3.5. President. The President shall act in a general executive capacity and shall assist the Chief Executive Officer in the administration and operation of the Corporation's business and general supervision of its policies and affairs. The President shall, in the absence of

or because of the inability to act of the Chief Executive Officer, perform all duties of the Chief Executive Officer. The President shall also perform such other duties and may exercise such other powers as may from time to time be assigned to such officer by these Bylaws, the Board or the Chief Executive Officer.

Section 3.6. Chief Financial Officer. The Chief Financial Officer shall be the principal financial officer of the Corporation. The Chief Financial Officer shall also perform such other duties and may exercise such other powers as may from time to time be assigned to such officer by these Bylaws, the Board or the Chief Executive Officer.

Section 3.7. Executive Vice Presidents, Senior Vice Presidents and Vice Presidents. The Executive Vice Presidents (if any), Senior Vice Presidents (if any) and such other Vice Presidents as shall have been chosen by the Board shall have such powers and shall perform such duties as shall be assigned to them by the Board or the Chief Executive Officer.

Section 3.8. Secretary. The Secretary shall give the requisite notice of meetings of stockholders and directors and shall record the proceedings of such meetings, shall have custody of the seal of the Corporation and shall affix it or cause it to be affixed to such instruments as require the seal and attest it and, besides the Secretary's powers and duties prescribed by law, shall have such other powers and perform such other duties as shall at any time be assigned to such officer by the Board or the Chief Executive Officer.

Section 3.9. Treasurer. The Treasurer shall exercise general supervision over the receipt, custody and disbursement of corporate funds. The Treasurer shall cause the funds of the Corporation to be deposited in such banks as may be authorized by the Board or in such banks as may be designated as depositaries in the manner provided by resolution of the Board. The Treasurer shall have such other powers and perform such other duties as shall at any time be assigned to such officer by the Board or the Chief Executive Officer.

Section 3.10. Assistant Secretaries. Assistant Secretaries, if there be any, shall assist the Secretary in the discharge of the Secretary's duties, shall have such powers and perform such other duties as shall at any time be assigned to them by the Board and, in the absence or disability of the Secretary, shall perform the duties of the Secretary's office, subject to the control of the Board or the Chief Executive Officer.

Section 3.11. Assistant Treasurers. Assistant Treasurers, if there be any, shall assist the Treasurer in the discharge of the Treasurer's duties, shall have such powers and perform such other duties as shall at any time be assigned to them by the Board and, in the absence or disability of the Treasurer, shall perform the duties of the Treasurer's office, subject to the control of the Board or the Chief Executive Officer.

Section 3.12. Other Officers. Such other officers as the Board or the Chief Executive Officer may choose shall perform such duties and have such powers as from time to time may be assigned to them by the Board or the Chief Executive Officer. The Board may delegate to any other officer of the Corporation the power to choose such other officers and to prescribe their respective duties and powers.

ARTICLE IV

STOCK

Section 4.1. Uncertificated Shares. Unless otherwise provided by resolution of the Board, each class or series of shares of the Corporation's capital stock shall be issued in uncertificated form pursuant to the customary arrangements for issuing shares in such form. Shares shall be transferable only on the books of the Corporation by the holder thereof in person or by attorney upon presentment of proper evidence of succession, assignation or authority to transfer in accordance with the customary procedures for transferring shares in uncertificated form.

Section 4.2. Record Date. In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted and which record date shall be not more than sixty (60) days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be the close of business on the day on which the Board adopts the resolution relating thereto.

Section 4.3. Record Owners. The Corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends, and to vote as such owner, and to hold liable for calls and assessments a person registered on its books as the owner of shares, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person, whether or not it shall have express or other notice thereof, except as otherwise required by law.

Section 4.4. Transfer and Registry Agents. The Corporation may from time to time maintain one or more transfer offices or agencies and registry offices or agencies at such place or places as may be determined from time to time by the Board.

ARTICLE V

MISCELLANEOUS

Section 5.1. Contracts. The Board may authorize any officer or officers or any agent or agents to enter into any contract or execute and deliver any instrument or other document in the name of and on behalf of the Corporation, and such authority may be general or confined to specific instances.

Section 5.2. Disbursements. All checks or demands for money and notes of the Corporation shall be signed by such officer or officers or such other person or persons as the Board may from time to time designate.

Section 5.3. Fiscal Year. The fiscal year of the Corporation shall end on the 31st day of December in each year or on such other day as may be fixed from time to time by resolution of the Board.

Section 5.4. Corporate Seal. The corporate seal shall have inscribed thereon the name of the Corporation, the year of its organization and the words "Corporate Seal, Delaware." The seal may be used by causing it or a facsimile thereof to be impressed or affixed or otherwise reproduced.

Section 5.5. Offices. The Corporation shall maintain a registered office inside the State of Delaware and may also have other offices outside or inside the State of Delaware. The books of the Corporation may be kept (subject to any applicable law) outside the State of Delaware at the principal executive offices of the Corporation or at such other place or places as may be designated from time to time by the Board.

Section 5.6. Waiver of Notice. Whenever any notice is required to be given to any stockholder or director of the Corporation under the provisions of the DGCL or these Bylaws, a waiver thereof in writing, signed by the person or persons entitled to such notice, or a waiver by electronic transmission by the person or persons entitled to such notice, whether before or after the time stated therein, shall be deemed equivalent to the giving of such notice. Neither the business to be transacted at, nor the purpose of, any annual or special meeting of the stockholders or any regular or special meeting of the Board or committee thereof need be specified in any waiver of notice of such meeting unless so required by law.

ARTICLE VI
AMENDMENTS

Subject to Section 7.5 below, these Bylaws may be adopted, amended, altered or repealed by the Board or by the stockholders of the Corporation by the affirmative vote of the holders of at least a majority of the voting power of all then outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class; provided, however, that, in the case of any adoption, amendment, alteration or repeal of these Bylaws by the stockholders of the Corporation, notwithstanding any other provision of these Bylaws, and in addition to any other vote that may be required by law or the terms of any series of preferred stock, the affirmative vote of the holders of at least sixty six and two-thirds percent (66 2/3%) of the voting power of all of the then outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to amend, alter, repeal or adopt any provision inconsistent with Section 1.7(b), 1.16, 1.17, or 2.14 or Article VI of these Bylaws.

ARTICLE VII
EMERGENCY BYLAWS

Section 7.1 Emergency Bylaws. This Article VII shall be operative during any emergency, disaster or catastrophe, as referred to in Section 110 of the DGCL, or other similar emergency condition (including, without limitation, a pandemic), as a result of which a quorum of the Board or a committee thereof cannot readily be convened for action (each, an "***Emergency***"), notwithstanding any different or conflicting provision of the preceding Sections of these Bylaws or in the Certificate of Incorporation. To the extent not inconsistent with the provisions of this Article VII, the preceding Sections of these Bylaws and the provisions of the Certificate of Incorporation shall remain in effect during such Emergency, and upon termination

of such Emergency, the provisions of this Article VII shall cease to be operative unless and until another Emergency shall occur.

Section 7.2 Meetings; Notice. During any Emergency, a meeting of the Board or any committee thereof may be called by any member of the Board or such committee or the Chair of the Board, the Chief Executive Officer, the President or the Secretary of the Corporation. Notice of the place, date and time of the meeting shall be given by any available means of communication by the person calling the meeting to such of the directors or committee members and Designated Officers (as defined below) as, in the judgment of the person calling the meeting, it may be feasible to reach. Such notice shall be given at such time in advance of the meeting as, in the judgment of the person calling the meeting, circumstances permit.

Section 7.3 Quorum. At any meeting of the Board called in accordance with Section 7.2 above, the presence or participation of one director shall constitute a quorum for the transaction of business, and at any meeting of any committee of the Board called in accordance with Section 7.2 above, the presence or participation of one committee member shall constitute a quorum for the transaction of business. In the event that no directors are able to attend a meeting of the Board, or any committee thereof, then the Designated Officers in attendance shall serve as directors, or committee members, as the case may be, for the meeting, without any additional quorum requirement and will have full powers to act as directors, or committee members, as the case may be, of the Corporation.

Section 7.4 Liability. No officer, director or employee of the Corporation acting in accordance with the provisions of this Article VII shall be liable except for willful misconduct.

Section 7.5 Amendments. At any meeting called in accordance with Section 7.2 above, the Board, or any committee thereof, as the case may be, may modify, amend or add to the provisions of this Article VII as it deems it to be in the best interests of the Corporation so as to make any provision that may be practical or necessary for the circumstances of the Emergency.

Section 7.6 Repeal or Change. The provisions of this Article VII shall be subject to repeal or change by further action of the Board or by action of the stockholders, but no such repeal or change shall modify the provisions of Section 7.4 above with regard to action taken prior to the time of such repeal or change.

Section 7.7 Definitions. For purposes of this Article VII, the term "***Designated Officer***" means an officer identified on a numbered list of officers of the Corporation who shall be deemed to be, in the order in which they appear on the list up until a quorum is obtained, directors of the Corporation, or members of a committee of the Board, as the case may be, for purposes of obtaining a quorum during an Emergency, if a quorum of directors or committee members, as the case may be, cannot otherwise be obtained during such Emergency, which officers have been designated by the Board from time to time but in any event prior to such time or times as an Emergency may have occurred.

* * *

Adopted as of: October 14, 2020, subject to and effective upon the closing of the Corporation's initial public offering on its Registration Statement on Form S-1.

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, Scott Hutton, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Biodesix, 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(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) 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

   (d) 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(s) 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: December 10, 2020

By: /s/ Scott Hutton

Scott Hutton

Chief 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, Robin Harper Cowie, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Biodesix, 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(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) 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

   (d) 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(s) 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: December 10, 2020

By: /s/ Robin Harper Cowie

Robin Harper Cowie

Chief Financial 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 of Biodesix, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: December 10, 2020

By: /s/ Scott Hutton

Scott Hutton

Chief Executive Officer

Exhibit 32.2

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 of Biodesix, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: December 10, 2020

By: /s/ Robin Harper Cowie

Robin Harper Cowie

Chief Financial Officer