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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

OR

o **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: 001-40590

Cue Health Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**27-1562193**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4980 Carroll Canyon Rd. Suite 100 San Diego, CA 92121	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 412-8151

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 $0.00001 per share	**HLTH**	**Nasdaq Global Stock 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 o No x

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 x No o

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	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	o
		Emerging growth company	x

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. o

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

As of November 5, 2021 the registrant had 146,362,598 shares of common stock, $0.00001 par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements generally relate to future events or our future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential," or "continue" or the negative of these words, variations of these words or other similar terms or expressions that concern our expectations, strategy, plans, or intentions. Such forward-looking statements are subject to certain risks, uncertainties and assumptions relating to factors that could cause actual results to differ materially from those anticipated in such statements, including, without limitation, the following:

- our expectations regarding our revenue, expenses and other operating results;
- the extent and duration of the COVID-19 pandemic and the impact of the end of the COVID-19 pandemic on our business and our expectations regarding customer and user demand for our COVID-19 test;
- our ability to increase demand for, and the rate of market adoption of, the Cue Health Monitoring System and our platform, tests and other products generally, including with consumers, healthcare professionals, enterprises, insurers and other payors and public health officials;
- our ability to effectively scale our manufacturing capacity and other operations in a timely manner in order to meet contractual obligations, market demand and to be able to successfully operate our business;
- our ability to meet our contractual obligations under our agreement with the U.S. Department of Defense (the "U.S. DoD") or other customers;
- our ability to successfully develop and commercialize additional tests and other products for use with our Cue Integrated Care Platform;
- our expectations of the reliability, accuracy and performance of our products and services, as well as expectations of the benefits to patients, clinicians and providers of our products and services;
- our ability to obtain and maintain regulatory authorizations, clearances or approvals for our tests, including our existing FDA EUAs for our COVID-19 test;
- our ability to accurately forecast demand for the Cue Health Monitoring System, our tests and other products;
- our ability to successfully build out our sales and marketing infrastructure, the costs and success of our marketing efforts, and our ability to promote our brand;
- our ability to increase demand for our products and services, obtain favorable coverage and reimbursement determinations from third-party payors and expand geographically;
- our intellectual property position and our expectations regarding our ability to obtain and maintain intellectual property protection;
- our ability to effectively manage our growth, including our ability to retain and recruit personnel, and maintain our culture;
- the impact of U.S. and international laws and regulations;
- our competitive position and expectations regarding developments and projections relating to our competitors and any competing products and services;
- future investments in our business, our anticipated capital expenditures and our estimates regarding our capital requirements, future revenue, expenses, the ability to obtain reimbursement for our products and any needs for additional financing;
- our expectations regarding technology trends and developments in the healthcare industry and our ability to address those trends and developments with our offerings;
- our expectations concerning relationships with third parties, including healthcare professionals, enterprises, insurance companies and other payors, public health officials and other stakeholders in the healthcare system;
- the degree to which we are able to help bring about a new healthcare paradigm, and be a significant participant in any such new paradigm;
- our ability to grow our business internationally, in addition to within the United States;
- our ability to implement, maintain and improve effective internal controls and remediate material weaknesses; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Quarterly Report on Form 10-Q primarily on our current expectations and projections about future events and trends that we believe may affect our business, results of operations, financial condition, and prospects.

The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in the section titled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report on Form 10-Q. We cannot assure you that the results, events, and circumstances

reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this Quarterly Report on Form 10-Q relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Quarterly Report on Form 10-Q to reflect events or circumstances after the date of this report or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments we may make. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. 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 are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Cue Health Inc.

CONDENSED BALANCE SHEETS
(Unaudited)
(In thousands, except share amounts and share data)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 446,589	$ 121,578
Restricted cash	12,000	6,000
Accounts receivable, net	90,190	4,168
Inventory	70,739	36,842
Prepaid expenses	47,922	13,847
Other current assets	2,088	1,263
Total current assets	669,528	183,698
Restricted cash, non-current	—	1,677
Property and equipment, net	168,642	103,683
Prepaid rent	161	16,771
Operating lease right-of-use assets	78,555	8,281
Intangible assets, net	3,691	2,038
Other non-current assets	1,407	180
Total assets	$ 921,984	$ 316,328
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 35,148	$ 23,847
Accrued liabilities and other current liabilities	26,212	8,822
Income taxes payable	37,365	—
Deferred revenue, current	76,341	115,747
Debt, current	—	5,434
Operating lease liabilities, current	3,960	797
Finance lease liabilities, current	2,603	1,249
Total current liabilities	181,629	155,896
Redeemable convertible preferred stock warrant liabilities	—	1,331
Deferred revenue, net of current portion	31,225	67,349
Operating leases liabilities, net of current portion	50,027	10,472
Finance lease liabilities, net of current portion	3,841	1,857
Other non-current liabilities	884	4,500
Total liabilities	267,606	241,405
Commitments and contingencies (Note 16)		

Redeemable Convertible Preferred Stock		
Series A redeemable convertible preferred stock, $0.00001 par value; 8,721,437 shares authorized, no shares issued and outstanding at September 30, 2021 and 8,350,743 issued and outstanding at December 31, 2020; liquidation preference of $0 at September 30, 2021 and $7,660 at December 31, 2020	—	7,519
Series B redeemable convertible preferred stock, $0.00001 par value; 46,213,620 shares authorized no shares issued and outstanding at September 30, 2021 and, 46,176,715 issued and outstanding at December 31, 2020; liquidation preference of $0 September 30, 2021and $66,240 at December 31, 2020	—	66,186
Series C-1 redeemable convertible preferred stock, $0.00001 par value; 27,308,229 shares authorized, no shares issued and outstanding at September 30, 2021 and 27,308,227 issued and outstanding at December 31, 2020; liquidation preference of $0 September 30, 2021 and $100,000 at December 31, 2020	—	96,436
Series C-2 redeemable convertible preferred stock, $0.00001 par value; 1,690,380 shares authorized, no shares issued and outstanding at September 30, 2021 and 1,690,380 issued and outstanding at December 31, 2020; liquidation preference of $0 September 30, 2021 and $5,571 at December 31, 2020	—	6,182
Total redeemable convertible preferred stock	—	176,323
Stockholders' Equity (Deficit)		
Preferred stock, $0.00001 par value; 50,000,000 and no shares authorized, no shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.00001 par value; 500,000,000 and 129,030,355 shares authorized, 146,362,598 and 27,995,780 issued and outstanding at September 30, 2021 and December 31, 2020, respectively	1	—
Additional paid-in-capital	712,625	9,036
Accumulated deficit	(58,248)	(110,436)
Total stockholders' equity (deficit)	654,378	(101,400)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 921,984	$ 316,328

The accompanying notes are an integral part of these condensed financial statements.

Cue Health Inc.

CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenue				
Product revenue	$ 222,594	$ 2,128	$ 424,516	$ 2,128
Grant and other revenue	1,085	2,602	1,085	7,562
Total revenue	223,679	4,730	425,601	9,690
Operating costs and expenses:				
Cost of product revenue	88,569	2,641	173,746	2,641
Sales and marketing	5,572	19	7,531	64
Research and development	9,079	6,878	21,150	26,558
General and administrative	33,084	3,694	56,336	7,458
Total operating costs and expenses	136,304	13,232	258,763	36,721
Income (loss) from operations	87,375	(8,502)	166,838	(27,031)
Other income (expense):				
Interest expense	(1,786)	514	(9,752)	(274)
Change in fair value of redeemable convertible preferred stock warrants	243	20	53	—
Change in fair value of convertible notes	(36,306)	—	(59,560)	—
Loss on extinguishment of debt	—	(610)	(1,998)	(610)
Other income (expense), net	(80)	40	(19)	99
Net income (loss) before income taxes	49,446	(8,538)	95,562	(27,816)
Income tax expense	30,098	—	43,374	—
Net income (loss)	$ 19,348	$ (8,538)	$ 52,188	$ (27,816)
Net income (loss) per share attributable to common stockholders – basic	$ 0.14	$ (0.52)	$ 0.37	$ (1.72)
Weighted-average number of shares used in computation of net income (loss) per share attributable to common stockholders – basic	31,554,720	16,556,343	22,997,311	16,126,647
Net income (loss) per share attributable to common stockholders – diluted	$ 0.13	$ (0.52)	$ 0.35	$ (1.72)
Weighted-average number of shares used in computation of net income (loss) per share attributable to common stockholders – diluted	39,304,978	16,556,343	30,747,569	16,126,647

The accompanying notes are an integral part of these condensed financial statements.

Cue Health Inc.

CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(Unaudited)
(In thousands, except share data)

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at June 30, 2021	8,350,743	$ 7,519	46,176,715	$ 66,186	28,998,607	$ 102,618	29,128,604	$ —	$ 16,264	$ (77,596)	$ (61,332)
Exercise of redeemable convertible preferred stock warrants	48,513	831	31,369	537	—	—	—	—	—	—	—
Conversion of redeemable convertible preferred stock	(8,399,256)	(8,350)	(46,208,084)	(66,723)	(28,998,607)	(102,618)	83,605,947	1	177,690	—	177,691
Conversion of convertible notes into common stock	—	—	—	—	—	—	18,611,914	—	297,792	—	297,792
Issuance of common stock at public offering, net of issuance costs of $24.7 million	—	—	—	—	—	—	14,375,000	—	205,293	—	205,293
Exercise of common stock options	—	—	—	—	—	—	436,576	—	159	—	159
Vesting of early exercised stock options	—	—	—	—	—	—	—	—	46	—	46
Tax withholding on exercise of stock options and restricted stock units	—	—	—	—	—	—	—	—	(4,586)	—	(4,586)
Common stock issued to outgoing directors	—	—	—	—	—	—	128,000	—	—	—	—
Vesting of restricted stock units	—	—	—	—	—	—	76,557	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	19,967	—	19,967
Net income	—	—	—	—	—	—	—	—	—	19,348	19,348
Balance at September 30, 2021	—	$ —	—	$ —	—	$ —	146,362,598	$ 1	$ 712,625	$ (58,248)	$ 654,378

Cue Health Inc.

CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(Unaudited)
(In thousands, except share data)

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at June 30, 2020	8,350,743	$ 7,519	46,176,715	$ 66,186	28,998,607	$ 103,145	20,224,118	$ —	$ 5,771	$ (82,362)	$ (76,591)
Exercise of common stock options	—	—	—	—	—	—	398,499	—	—	—	—
Issuance of common stock per restricted stock purchase agreements	—	—	—	—	—	—	7,373,163	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	145	—	145
Net loss	—	—	—	—	—	—	—	—	—	(8,538)	(8,538)
Balance at September 30, 2020	8,350,743	$ 7,519	46,176,715	$ 66,186	28,998,607	$ 103,145	27,995,780	$ —	$ 5,916	$ (90,900)	$ (84,984)

Cue Health Inc.

CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(Unaudited)
(In thousands, except share data)

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	8,350,743	$ 7,519	46,176,715	$ 66,186	28,998,607	$ 102,618	27,995,780	$ —	$ 9,036	$ (110,436)	$ (101,400)
Exercise of redeemable convertible preferred stock warrants	48,513	831	31,369	537	—	—	—	—	—	—	—
Conversion of redeemable convertible preferred stock	(8,399,256)	(8,350)	(46,208,084)	(66,723)	(28,998,607)	(102,618)	83,605,947	1	177,690	—	177,691
Exercise of common stock options	—	—	—	—	—	—	1,485,282	—	417	—	417
Conversion of convertible notes into common stock	—	—	—	—	—	—	18,611,914	—	297,792	—	297,792
Stock-based compensation expense from issuance of a fully vested warrant to vendor	—	—	—	—	—	—	—	—	1,239	—	1,239
Issuance of common stock at public offering, net of issuance costs of $24.7 million	—	—	—	—	—	—	14,375,000	—	205,293	—	205,293
Exercise of common stock warrants	—	—	—	—	—	—	84,118	—	77	—	77
Vesting of early exercised stock options	—	—	—	—	—	—	—	—	109	—	109
Tax withholding on exercise of stock options and restricted stock units	—	—	—	—	—	—	—	—	(4,586)	—	(4,586)
Common stock issued to outgoing directors	—	—	—	—	—	—	128,000	—	—	—	—
Vesting of restricted stock units	—	—	—	—	—	—	76,557	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	25,558	—	25,558
Net income	—	—	—	—	—	—	—	—	—	52,188	52,188
Balance at September 30, 2021	—	$ —	—	$ —	—	$ —	146,362,598	$ 1	$ 712,625	$ (58,248)	$ 654,378

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2019	8,350,743	$ 7,519	46,176,715	$ 66,186	—	$ —	18,704,118	$ —	$ 4,945	$ (63,084)	$ (58,139)
Issuance of Series C-1 preferred stock	—	—	—	—	27,308,227	96,963	—	—	—	—	—
Conversion of convertible notes to Series C-2 preferred stock	—	—	—	—	1,690,380	6,182	—	—	—	—	—
Exercise of common stock options	—	—	—	—	—	—	1,918,499	—	—	—	—
Vesting of early exercised stock options	—	—	—	—	—	—	—	—	729	—	729
Issuance of common stock per restricted							7,272,162				

per restricted stock purchase agreements	—	—	—	—	—	—	7,375,165	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	242	—	242
Net loss	—	—	—	—	—	—	—	—	—	(27,816)	(27,816)
Balance at September 30, 2020	8,350,743	$ 7,519	46,176,715	$ 66,186	28,998,607	$ 103,145	27,995,780	$ —	$ 5,916	$ (90,900)	$ (84,984)

The accompanying notes are an integral part of these condensed financial statements.

Cue Health Inc.

CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(Unaudited)
(In thousands, except share data)

Cue Health Inc.

CONDENSED STATEMENT OF CASH FLOWS
(Unaudited)
(In thousands, except share data)

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities		
Net income (loss)	$ 52,188	$ (27,816)
Adjustments to reconcile net income (loss) to net cash, cash equivalents and restricted cash used in operations		
Depreciation and amortization	26,079	4,367
Inventory reserve	286	—
Change in fair value of redeemable convertible preferred stock warrant liabilities	(53)	—
Change in fair value of convertible notes	59,560	—
Stock-based compensation expense	25,558	242
Loss on extinguishment of debt	1,998	610
Non-cash lease expense	3,462	421
Convertible notes issuance costs	6,000	—
Deferred income taxes	883	—
Interest on finance leases	154	65
Stock-based compensation expense from issuance of fully vested warrant to vendor	1,239	—
Non-cash interest expense	1,857	16
Changes in operating assets and liabilities:		
Accounts receivable	(86,022)	(2,564)
Inventory	(34,183)	(11,485)
Prepaid expenses and other current assets	(25,487)	(24,781)
Other non-current assets	(3,871)	40
Accounts payable, accrued liabilities and other current liabilities	5,270	1,759
Income taxes payable	37,365	—
Deferred revenue	(75,529)	—
Operating lease liabilities	(15,052)	(119)
Net cash, cash equivalents and restricted cash used in operating activities	(18,298)	(59,245)
Cash flows from investing activities		
Purchase of property and equipment	(74,637)	(6,123)
Expenditures for software development	(3,524)	(885)
Net cash, cash equivalents and restricted cash used in investing activities	(78,161)	(7,008)
Cash flows from financing activities		
Proceeds for Series C-1 redeemable convertible preferred stock	—	100,000
Proceeds from convertible notes	235,480	5,563
Payments for issuance costs of Series C-1 redeemable convertible preferred stock	—	(3,037)
Proceeds from exercise of redeemable convertible preferred stock warrant	89	—
Payments of issuance costs of convertible notes	(6,000)	—
Proceeds from exercise of common stock options	418	729
Proceeds from exercise of common stock warrant	77	—
Proceeds from issuance of common stock at public offering	230,000	—
Payments of issuance costs of public offering	(22,062)	—

Proceeds from debt	82,250	1,658
Tax withholding on exercise of stock options	(4,586)	—
Debt issuance and prepayment costs	(781)	—
Repayment of debt	(87,684)	(1,929)
Payments for finance leases	(1,408)	(385)
Net cash, cash equivalents and restricted cash provided by financing activities	425,793	102,599
Net increase in cash, cash equivalents and restricted cash	329,334	36,346
Cash, cash equivalents and restricted cash, beginning balance	129,255	14,505
Cash, cash equivalents and restricted cash, ending balance	$ 458,589	$ 50,851
Reconciliation of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	$ 446,589	$ 49,174
Restricted cash, current	12,000	—
Restricted cash, non-current	—	1,677
Total cash, cash equivalents and restricted cash	$ 458,589	$ 50,851
Supplemental disclosure for cash flow information		
Cash paid for taxes	$ 5,100	$ —
Cash paid for interest	$ 760	$ 106
Supplemental disclosure for non-cash investing and financing matters		
Early exercised stock options liability	$ 109	$ —
Right-of-use assets obtained in exchange for lease obligations	$ 47,611	$ 9,738
Prepaid rent reclassified to right-of-use assets	$ 15,966	$ —
Purchase of property and equipment included in accounts payable	$ 18,708	$ 13,208
Conversion of preferred shares into common stock	$ 176,322	$ —
Conversion of convertible notes	$ 297,792	$ —
Initial public offering costs included in accounts payable	$ 2,644	$ —

The accompanying notes are an integral part of these condensed financial statements.

Cue Health Inc.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share data)

NOTE 1. BUSINESS AND BASIS OF ACCOUNTING

Organization and Description of Business

Cue Health Inc. (the "Company") was originally formed in the State of California on January 26, 2010, prior to being incorporated in the State of Delaware on December 14, 2017. The Company is a healthcare technology company committed to revolutionizing the healthcare experience by providing individuals with a convenient and connected diagnostic platform that bridges the physical and virtual care continuum. The Company's proprietary platform, the Cue Health Monitoring System, comprised of the Cue Reader and Cue Test Kit, enables lab-quality diagnostics-led care at home, at work or at the point of care. This platform is designed to empower stakeholders across the healthcare ecosystem, including individuals, enterprises, healthcare providers and payors, and public health agencies with paradigm-shifting access to diagnostic and health data to inform care decisions. The Company's headquarters are located in San Diego, California.

Initial Public Offering

The Company's registration statement related to its initial public offering ("IPO") was declared effective on September 23, 2021, and the Company's common stock began trading on the Nasdaq Global Stock Market ("Nasdaq") on September 24, 2021. On September 28, 2021, the Company completed its IPO of 14,375,000 shares of the Company common stock at an offering price of $16.00 per share, including 1,875,000 shares purchased by the IPO underwriters. The Company received aggregate net proceeds of approximately $205.3 million after deducting underwriting commissions and legal, accounting, and consulting fees related to the IPO.

Upon completion of the IPO, Convertible Notes outstanding in the principal amount of $235.5 million and accrued interest of $2.7 million were automatically converted into 18,611,914 shares of common stock. All outstanding shares of the Company's redeemable convertible preferred stock were converted into 83,605,947 shares of common stock. Immediately prior to the IPO, all of the Company's outstanding warrants to purchase redeemable convertible preferred stock were converted into the redeemable convertible preferred stock and the related warrant liabilities were reclassified to additional paid-in capital.

Basis of Presentation

The accompanying unaudited interim condensed financial statements should be read in conjunction with the audited annual financial statements and notes thereto for the year ended December 31, 2020. The unaudited interim condensed balance sheet as of December 31, 2020 included herein was derived from the audited financial statements as of that date. The results of operations for the three and nine months ended September 30, 2021 are not necessarily indicative of the results for the fiscal year ending December 31, 2021 or any future interim period. The Company's financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"), applicable rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for interim reporting and, in the opinion of management, include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented. All such adjustments are of a normal, recurring nature. Certain disclosures have been condensed or omitted from the interim condensed financial statements. The preparation of the accompanying financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, income and expenses as well as the related disclosure of contingent assets and liabilities.

Use of Estimates

The preparation of the accompanying financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could materially differ from those estimates.

Significant estimates and assumptions made in the accompanying financial statements include, but are not limited to revenue recognition, net accounts receivable, equity-based compensation expense, product warranty reserve, the

recoverability of its long-lived assets, net deferred tax assets (and related valuation allowance) and the fair value of Company's common warrants, Convertible Notes and common stock prior to Company's IPO. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

Segment Reporting

Operating segments are identified as components of an enterprise about which discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. In addition, the guidance for segment reporting indicates certain quantitative materiality thresholds. The Company views its operations and manages its business in one operating segment which is consistent with how the Chief Executive Officer, who is the chief operating decision maker, reviews the business, makes investment and resource allocation decisions, and assesses operating performance. All revenue to date is from customers located in the United States and all long-lived assets are located in the United States.

COVID-19 Impact

The novel coronavirus ("COVID-19") that was declared a global pandemic by the World Health Organization in March 2020 adversely impacted global commercial activity but served as a catalyst to accelerating the Company's product pipeline. The Company's first commercially available diagnostic test for the Cue Health Monitoring System is the Cue COVID-19 test for ribonucleic acid of SARS-CoV-2, the virus that causes COVID-19. The Company began selling and recording product revenues for its Cue COVID-19 test in August 2020 after obtaining an Emergency Use Authorization ("EUA") from the Federal Drug Administration ("FDA") in June 2020. Currently, 100% of the Company's product revenues are derived from the Cue COVID-19 test. Given the unpredictable nature of the COVID-19 pandemic, the development and potential size of the COVID-19 diagnostic testing market is highly uncertain.

The FDA issued emergency use authorizations for two COVID-19 vaccines and in February 2021, the FDA issued a third EUA for a COVID-19 vaccine. The widely administered use of an efficacious vaccine or new therapeutic treatment for COVID-19 may reduce the demand for the Cue COVID-19 test and, as a result, the COVID-19 diagnostic testing market may not develop or grow substantially. Given the rapid development of events surrounding the pandemic, there is uncertainty to the Company's future results and performance.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Cash and Cash Equivalents

Cash and cash equivalents consist of bank deposits. The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents.

Restricted Cash

Restricted cash consists primarily of cash that serves as collateral for the Company's standby letters of credit. Any cash that is legally restricted from use is classified as restricted cash. If the purpose of restricted cash relates to acquiring long-term assets, liquidating a long-term liability, or is otherwise unavailable for a period longer than one year from the balance sheet date, the restricted cash is classified as a long-term asset. Otherwise, restricted cash is presented in current assets in the balance sheets. As of September 30, 2021, the Company had $12.0 million of restricted cash included in current assets on the balance sheet.

Accounts Receivable

The Company grants credit to customers in the normal course of business and the resulting accounts receivables are stated at their net realizable value. The allowance for doubtful accounts represents the Company's estimate of probable credit losses relating to accounts receivables and is determined based on historical experience and other specific account data. Amounts are written off against the allowances for doubtful accounts when the Company determines that a customer account is uncollectible. As of September 30, 2021, the Company's allowance for bad debt was $0.3 million.

Inventories

Inventory is valued at lower of cost or net realizable value on a first in, first out basis. Work-in-process and finished goods inventories consist of materials, labor and manufacturing overhead. Inventory owned by the Company that is on hand with contract manufacturers is disclosed as inventory on consignment. Provisions for excess and obsolete inventory are

primarily based on the Company's estimates of forecasted sales, usage levels, and expiration dates, as applicable for certain disposable products, and assumptions about obsolescence. Unabsorbed manufacturing costs are treated as expense in the period incurred.

Product Warranty Reserve

The Company provides its customers with the right to receive a replacement of defective or nonconforming Cue Readers for a period of up to twelve months from the date of shipment. Although no explicit warranty is provided for Cue Cartridges, the Company may replace Cue Cartridges that result in invalid test results. All warranties are classified as current liabilities and within the accrued liabilities and other current liabilities on the balance sheet. Provisions for estimated expenses related to product warranty are made at the time products are sold. These estimates are determined historical information that includes test failure rates, replacement frequency, and the overall replacement cost. The Company evaluates the reserve on a quarterly basis and makes adjustments when appropriate. Changes to test failure rates and overall replacement rates could have a material impact on our estimated liability. The product warranty reserve is recorded within accrued liabilities and other current liabilities on the balance sheets and in costs of product revenue in the statements of operations.

The following table provides a reconciliation of the change in estimated warranty liabilities:

	Amount
Balance, December 31, 2020	$ —
Provision for warranties	7,063
Settlements	(834)
Balance, September 30, 2021	$ 6,229

Fair Value Measurements and Financial Instruments

The carrying value of the Company's cash and cash equivalents, accounts receivables and accounts payable approximate fair value due to the short-term nature of these items. Based on the borrowing rates currently available to the Company for debt with similar terms and consideration of default and credit risk, the carrying value of the Company's long-term borrowings approximates its fair value.

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

Level 1 — Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 — Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The Company records subsequent adjustments to reflect the increase or decrease in estimated fair value at each reporting date in current period earnings.

Property and Equipment, Net

Property and equipment, net, which consist of manufacturing equipment, laboratory equipment, computers and software, office equipment and leasehold improvements, are stated at cost less depreciation. Leasehold improvements are amortized on a straight-line basis over the shorter of their useful life or the remaining lease term, including any renewal periods that the Company is reasonably certain to exercise. Repair and maintenance costs that do not improve service potential or extend economic life are expensed as incurred.

The estimated useful lives are as follows:

	Years
Leasehold improvements	Shorter of the estimated useful life or lease term
Machinery and equipment	3-7 years
Furniture and fixtures	7

The Company completed a review of the estimated useful lives of its assets upon receiving FDA EUAs of the Company's Cue COVID-19 Test in June 2020. This review, based on expected technological advances and demand expectations, reduced the useful life of laboratory equipment from seven to five years and the useful life of manufacturing equipment from seven to three years. The change in useful lives was accounted for as a change in accounting estimate on a prospective basis effective June 1, 2020. For the nine months ended September 30, 2020, the change in estimate resulted in an increase in depreciation and amortization expense of $2.2 million, an increase in net loss of $2.2 million and an increase in basic and diluted net loss per share of $0.14 .

Intangible Assets

Intangible assets are recorded at cost and amortized on a straight-line basis over their estimated useful lives. Intangible assets consist of capitalized software costs incurred in the development of the Cue Health App (the "App"). The Company determined that costs incurred during the application development stage that are directly related to the actual development of the software application are capitalized, while costs incurred in the preliminary project and post implementation stage are expensed as incurred. Additionally, indirect costs related to the software development during the application development stage are expensed as incurred. As the App is constantly updated to the next version once it has reached technological feasibility, the Company separates costs on a reasonable basis between maintenance and upgrades that extend the functionality and useful life of the App. The maintenance costs are expensed as incurred. The Company has concluded that given the rapid changes in technology, the software has a relatively short useful life of three years and is amortized on a straight-line basis. Amortization expense related to the App is recorded in cost of product revenue.

Leases

The Company determines if an arrangement is a lease at inception and if so, determines whether the lease qualifies as an operating or finance lease. Lease balances are included in the balance sheets as right-of-use assets and lease liabilities.

Right-of-use assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Right-of-use assets and liabilities are recognized at lease commencement date based on the present value of lease payments over the lease term. When the Company's leases do not provide an implicit rate, an incremental borrowing rate is used based on the information available at commencement dates in determining the present value of lease payments. The incremental borrowing rate is the rate of interest that the Company would expect to pay to borrow over a similar term, and on a collateralized basis, an amount equal to the lease payments in a similar economic environment. The Company's lease terms may include options to extend or terminate the lease when the Company is reasonably certain that it will exercise such options. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the financing, these costs are recorded as a reduction of the proceeds received from the equity financing. If a planned equity financing is abandoned, the deferred offering costs are expensed immediately as a charge to operating expenses in the condensed statements of operations. There were no deferred offering costs recorded in the Company's balance sheets as of December 31, 2020. As of September 30, 2021, the deferred offering costs were offset against the proceeds received upon the completion of the IPO.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset or an asset group may not be recoverable. If such triggering event is determined to have occurred, the asset's or asset group's carrying value is compared to the future undiscounted cash flows expected to be generated. If the carrying value exceeds the undiscounted cash flows of the asset, then an impairment exists. An impairment loss is

measured as the excess of the asset's carrying value over its fair value. There were no impairment indicators and no impairment was recorded for the nine months ended September 30, 2021 and the year ended December 31, 2020.

Common Stock Warrants

Common stock warrants are measured at their estimated fair value upon issuance and recorded in additional paid-in capital. Common stock warrants are classified as equity and no subsequent remeasurement is required.

Redeemable Convertible Preferred Stock Warrants

The Company accounts for its redeemable convertible preferred stock warrants as liabilities based upon the characteristics and provisions of each instrument. The redeemable convertible preferred stock warrants classified as liabilities are recorded on the Company's balance sheets at their fair values on the date of issuance and are revalued on each subsequent balance sheet date, with fair value changes recognized as increases or reductions in the statement of operations. All of the Company's outstanding redeemable convertible preferred stock warrants were exercised and converted into shares of Series A and Series B redeemable convertible preferred stock prior to the IPO.

Convertible Notes

The Company elected to account for Convertible Notes issued in May 2021 using the fair value option. Such instruments are recognized at estimated fair value, with changes in estimated fair value recorded as a component of earnings in the statements of operations unless the change is a result of a change in credit risk, in which case such change in estimated fair value is recorded within other comprehensive income. Direct issuance costs are expensed as incurred and are included in interest expense in the statements of operations.

Increases or decreases in the fair value of the Convertible Notes can result from updates to assumptions such as the expected timing or probability of a qualified financing event, or changes in discount rates. Judgment is used in determining these assumptions as of the initial valuation date and at each subsequent reporting period. Updates to assumptions could have a significant impact on the Company's results of operations in any given period.

Upon completion of the IPO, outstanding Convertible Notes in the principal amount of $235.5 million and accrued interest of $2.8 million were automatically converted into 18,611,914 shares of commons stock, based on interest accrued through September 27, 2021 and a 20% discount to the IPO price of $16.00 per share. The Company no longer has Convertible Notes outstanding as of September 30, 2021.

Redeemable Convertible Preferred Stock

Prior to the completion of the IPO, the Company had multiple classes of redeemable convertible preferred stock, all of which were classified as temporary equity in the accompanying condensed balance sheet as the redemption of the shares were outside of the Company's control.

In connection with the completion of the IPO in September 2021, all outstanding shares of redeemable convertible preferred stock were automatically converted into an aggregate of 83,605,947 shares of common stock.

Revenue Recognition

Product Revenue

The Company generates revenue from the sale of its Cue Health Monitoring System to government entities, healthcare providers, commercial customers, and through agreements with distributors. See Note 3, Revenue Recognition, for details.

The Company considers purchase orders, which are governed by agreements with customers, to be a contract with a customer. The contract terms with customers range in length, from one-time purchases to six-month or twelve-month commitments on a subscription basis where customers purchase a fixed number of products on a monthly basis. The timing of revenue recognition is based on the satisfaction of performance obligations promised to the customer. Cue Readers, Cue Enterprise Dashboards, and Cue Test Kits, composed of Cue Cartridges and Cue Wands, are considered distinct performance obligations. The App is integral to the functionality of the Cue Reader and these components form a single performance obligation. Revenue allocated to Cue Readers and Cue Test Kits is recognized when control of the promised goods has transferred to customers, generally upon shipment, in an amount that reflects the consideration the Company expects to receive in exchange for those goods. Revenue allocated to Cue Enterprise Dashboards is recognized

ratably over the term of the service. The Company's contracts with its customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product. The Company estimates returns of products due to defective or nonconforming products and records a provision for estimated expenses related to product warranty at the time products are sold. The transaction price is measured as the amount of consideration the Company expects to receive in exchange for the goods transferred to customers. A contract's transaction price is allocated to each distinct performance obligation on a relative standalone selling price basis. The Company estimates standalone selling prices for groups of customers with similar circumstances and characteristics.

The Company recognizes receivables when there is an unconditional right to payment, which represents the amount the Company expects to collect in a transaction and is most often equal to the transaction price in the contract. Payment terms are typically 30 to 45 days.

The Company excludes from the measurement of the transaction price all taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction and collected by the entity from a customer.

See Note 3, *Revenue Recognition*, for details regarding disaggregation of product revenue by type of customer for the three and nine months ended September 30, 2021 and 2020.

Deferred Revenue

In October 2020, the Company received a $184.6 million upfront payment ("U.S. DoD Advance") from the U.S. DoD to increase production capacity of its Cue COVID-19 Test. The Company concluded that the activities related to increasing production do not represent a performance obligation as those activities do not transfer a product or service to the customer. Instead, the upfront payment is an advanced payment for future goods or services because the agreement with the U.S. government included an option to renew the contract which included a material right to obtain products in a future contract at a specified discount, subject to a price floor, from prices offered to commercial customers with similar volume of purchases.

Deferred revenue is recognized upon satisfaction of performance obligations by reference to the total goods or services expected to be provided to the customer, including an estimate of future performance obligations under expected contract renewals, and the corresponding expected consideration.

Grant and Other Revenue

Arrangements under which the Company receives grants or contracts to conduct research and development activities constitute non-exchange transactions. Revenue from such is recognized to the extent of costs incurred in the period during which the related costs are incurred, provided that the conditions under which the grants and contracts were provided have been met and only perfunctory performance obligations are outstanding. Costs are included in research and development expenses.

The Company may enter into collaboration agreements with third parties to conduct research and development activities. The Company evaluates its collaboration agreements for proper classification in its statements of operations based on the nature of the underlying activity. When the Company has concluded that it has a customer relationship with one of its collaborators, the Company follows the guidance in ASC Topic 606, *Revenue from Contracts with Customers*.

See Note 3, *Revenue Recognition*, for details regarding the Company's agreements with the Biomedical Advanced Research and Development Authority ("BARDA") and Janssen.

Contract Assets and Liabilities

Contract assets primarily relate to the Company's conditional right to consideration for work completed but not billed at the reporting date. Contract assets at the beginning of and end of the year ended December 31, 2020, as well as changes in the balance, were not material.

Contract liabilities primarily relate to the U.S. DoD Advance and were recorded in current and non-current deferred revenue on the balance sheets. See Note 3, *Revenue Recognition*, for details regarding the activity related to contract liabilities for the nine months ended September 30, 2021.

Revenue Contracts

In the second quarter of 2021, the Company entered into a purchase agreement to provide a customer with Cue Readers and in excess of 1,000,000 Cue Test Kits between the effective date of the agreement and December 2021 based on a pre-defined monthly delivery schedule. In the third quarter of 2021, the customer increased its order of Cue Readers and Cue COVID-19 Test Kits. The customer may change the quantities ordered and may terminate the order and/or agreement with a 45 days' notice.

In May 2021, the Company entered into a purchase agreement to provide a customer a one-time order of 1,000 Cue Readers and 300,000 Cue COVID-19 Test Kits on a monthly basis during the 12-month period following the agreement execution date. In August 2021, the Company and customer amended the purchase agreement to reduce the number of Cue COVID-19 Test Kits to 10,000 test kits on a monthly basis until the agreement expiration date. The agreement may be terminated for cause by either party with a 30 days' notice.

In September 2021, the contract with the U.S. Department of Defense ("U.S. DoD Agreement") was amended to extend delivery of the 6,000,000 Cue Test Kits and other deliverables to December 31, 2021.

Cost of Product Revenue

Cost of product revenue includes the cost of materials, direct labor, inclusive of salaries and other related costs, including stock-based compensation, depreciation, and manufacturing overhead costs used in the manufacturing of the Cue Test Kits as well as contract manufacturing costs associated with production of the Cue Readers. Cost of product revenue also includes amortization of intangible assets.

Shipping and Handling Costs

The Company elected to account for shipping and handling as activities to fulfill the promise the goods and records them as cost of product revenue.

Sales and Marketing Expenses

Sales and marketing expense consist primarily of salaries and other related costs, including stock-based compensation, for personnel in sales and marketing, customer support and business development functions.

Research and Development Expenses

Research and development expenses are expensed as incurred. Research and development expenses are primarily comprised of costs and expenses for salaries and other related costs, including stock-based compensation, associated with research and development personnel, contract services, laboratory supplies, facilities, depreciation, and outside services. Costs associated with the Company's grant and collaboration agreements as well as costs associated with products produced for research and development purposes are recorded within research and development expenses.

Accrued Research and Development Costs

The Company records accrued expenses for estimated costs of its research and development activities conducted by third-party service providers, which include clinical trial activities, based on the estimated amount of services or supplies provided but not yet invoiced and include these costs in accrued liabilities in the balance sheets and within research and development expense in the statements of operations. Any payments made in advance of services or supplies provided are recorded as prepaid assets, which are expensed as the services or supplies are received.

The Company estimates the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. Significant judgments and estimates are made in determining the accrued balance in each reporting period. As actual costs become known, the Company adjusts its accrued estimates.

General and Administrative Expenses

The Company's general and administrative expense consists primarily of salaries and other related costs, including stock-based compensation, for personnel in its executive, finance, corporate and business development and administrative functions. General and administrative expense also includes professional fees for legal, patent, accounting, information

technology, depreciation, auditing, tax and consulting services, travel expenses and facility-related expenses, which include allocated expenses for rent and maintenance of facilities and other operating costs.

Patent Costs

Costs related to filing and pursuing patent applications are expensed as incurred, as recoverability of such expenditures is uncertain. These costs are included in general and administrative expenses.

Fair Value of Common Stock

Prior to the IPO, the fair value of the shares of common stock underlying the Company's stock-based awards was estimated on each grant date by its board of directors. In order to determine the fair value of its common stock underlying option grants, the Company's board of directors considered, among other things, valuations of its common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation.

Stock-Based Compensation

The Company estimates the fair value of stock options using the Black-Scholes-Merton ("BSM") option pricing model on the date of grant. The fair value of equity instruments expected to vest are recognized and amortized on a straight-line basis over the requisite service period of the award, which is generally three to four years; however, the Company's equity compensation plans provide for any vesting schedule as the Company's Board of Directors may deem appropriate. The Company recognizes forfeitures as incurred.

The BSM option pricing model incorporates various estimates, including the fair value of the Company's common stock, expected volatility, expected term and risk-free interest rates. The weighted-average expected term of options was calculated using the simplified method. This decision was based on the lack of relevant historical data due to the Company's limited historical experience. In addition, due to the Company's limited historical data, the estimated volatility incorporates the historical volatility over the expected term of the award of comparable companies whose share prices are publicly available. The risk-free interest rate for periods within the contractual term of the option is based on the U.S. Treasury yield in effect at the time of grant. The dividend yield was zero, as the Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

For stock-based compensation awards with both performance and market-condition vesting, such as restricted stock units, cost is measured at the grant date, based on the fair value of the award considering the market conditions, and recorded over the requisite service period if the performance condition is probable. The Company estimates the fair value of stock-based payment awards considering the market conditions on the date of grant using a Monte Carlo simulation model.

Comprehensive Income

Comprehensive income is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. There have been no items qualifying as other comprehensive income and, therefore, the Company's comprehensive income was the same as its reported net income.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the bases of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would adjust the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Out-of-period Correction

Certain immaterial cost of product revenue expenses of $3.0 million were not recognized by the Company in the three and six months ended June 30, 2021. This immaterial prior period error was recognized as an out-of-period adjustment to cost of product revenue in the statements of operations for the three and nine months ended September 30, 2021.

Recent Accounting Pronouncements

In September 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326) – Measurement of Credit Losses on Financial Instruments. The standard provides guidance for estimating credit losses on certain types of financial instruments, including trade receivables, by introducing an approach based on expected losses. The expected loss approach will require entities to incorporate considerations of historical information, current information and reasonable and supportable forecasts. ASU 2017-13 also amends the accounting for credit losses on available-for-sale debt securities and purchased financial assets with credit deterioration. The FASB has issued several amendments to the standard. In November 2019, the FASB amended the standard with the issuance of ASU 2019-10, Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates. The amendment revised the effective date of ASU 2016-13 to fiscal years beginning after December 15, 2022. The Company is currently evaluating the impact of ASU 2016-13 on its financial statements.

In August 2020, the FASB issued ASU No. 2020-06, Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"). The ASU simplifies the accounting for convertible instruments by removing certain models in Subtopic 470-20 and revises the guidance in Subtopic 815-40 to simplify the accounting for contracts in an entity's own equity. ASU 2020-06 is effective for reporting periods beginning after December 15, 2023 with early adoption permitted for reporting periods beginning after December 15, 2020. The amendment is to be adopted through either a modified retrospective or fully retrospective method of transition. The Company is currently evaluating the impact of ASU 2020-06 on its financial statements and its adoption method.

NOTE 3. REVENUE

Product Revenue

For the three and nine months ended September 30, 2021, product revenue from public sector entities primarily relates to a $480.9 million agreement the Company entered into with the U.S. government for the purchase of its Cue COVID-19 Test in October 2020 ("the U.S. DoD Agreement"). The U.S. DoD Agreement provided a $184.6 million U.S. DoD Advance to facilitate the scaling of the Company's manufacturing capacity, which was received upon signing the contract. The remainder of the agreement is for the sale of the Company's products. Product revenue from private sector customers represented 42% of product revenue in the three months ending September 30, 2021, 24% in the three months ending June 30, 2021 and 4% in the three months ending March 31, 2021.

Disaggregation of the product revenue by type of customer for the three and nine months ended September 30, 2021 and 2020, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Public sector entities	$ 128,587	$ 1	$ 295,708	$ 1
Private sector customers	94,007	2,127	128,808	2,127
Total product revenue	$ 222,594	$ 2,128	$ 424,516	$ 2,128

Product revenue from public sector entities primarily relates to the U.S. DoD Agreement.

The following table sets forth the Company's product gross profit and product gross profit margin for the three and nine months ended September 30, 2020 and 2021:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Product revenue	$ 222,594	$ 2,128	$ 424,516	$ 2,128
Cost of product revenue	88,569	2,641	173,746	2,641
Product gross profit	$ 134,025	$ (513)	$ 250,770	$ (513)
Product gross profit margin	60 %	(24)%	59 %	(24)%

Contract Assets and Liabilities

Contract assets primarily relate to the Company's conditional right to consideration for work completed but not billed at the reporting date.

Contract liabilities primarily relate to the U.S. DoD Advance and were recorded in current and non-current deferred revenue on the balance sheets. The activity related to contract liabilities for the nine months ended September 30, 2021 is as follows:

	Amount
Balance at December 31, 2020	$ 183,096
Recognition of U.S. DoD Advance	(74,726)
Recognition of non-refundable customer deposits	(804)
Balance at September 30, 2021	$ 107,566

Grant and Other Revenue

Grant and other revenue relate to a cost reimbursement agreement with the Biomedical Advanced Research and Development Authority ("BARDA") and a collaboration agreement with Janssen Pharmaceuticals, Inc. ("Janssen"). The Company generated $2.6 million and $7.6 million of revenue related to the agreement with BARDA during the three and nine months ended September 30, 2020, respectively. The Company generated $0.9 million of revenue related to the agreement with BARDA during the three and nine months ended September 30, 2021.

NOTE 4. INVENTORIES

As of September 30, 2021, and December 31, 2020, the Company's inventories consisted of the following:

	September 30, 2021	December 31, 2020
Raw materials	$ 34,164	$ 29,948
Work-in-process	10,643	4,957
Finished goods	21,216	1,645
Inventory on consignment	5,791	1,081
Reserve	(1,075)	(789)
Total inventories	$ 70,739	$ 36,842

Inventory on consignment represents inventory owned by the Company that is on hand with contract manufacturers. The inventory reserve relates to excess and obsolete inventory as a result of ongoing assessments of inventory on hand and the continuous improvement and innovation of its products.

NOTE 5. PREPAID EXPENSES

As of September 30, 2021, and December 31, 2020, the Company's prepaid expenses consisted of the following:

	September 30, 2021	December 31, 2020
Prepaid expense	$ 33,476	$ 5,152
Prepaid inventory	14,446	8,695
Total prepaid expenses	$ 47,922	$ 13,847

NOTE 6. PROPERTY AND EQUIPMENT, NET

As of September 30, 2021, and December 31, 2020, the Company's property and equipment, net consisted of the following:

	September 30, 2021	December 31, 2020
Construction in progress	$ 861	$ 83,353
Machinery and equipment	175,961	26,972
Leasehold improvements	26,172	2,897
Furniture and fixtures	1,008	683
Property and equipment	204,002	113,905
Accumulated depreciation and amortization	(35,360)	(10,222)
Total property and equipment, net	$ 168,642	$ 103,683

Depreciation and amortization expense related to property and equipment was $11.4 million and $1.0 million for the three months ended September 30, 2021 and 2020, respectively. Depreciation and amortization expense related to property and equipment was $24.2 million and $4.4 million for the nine months ended September 30, 2021 and 2020, respectively. The carrying value of assets under finance leases within property and equipment as of September 30, 2021 and December 31, 2020 and was $10.3 million and $4.8 million, respectively.

NOTE 7. INTANGIBLE ASSETS

As of September 30, 2021, and December 31, 2020, the Company's intangible assets consisted of the following:

	September 30, 2021	December 31, 2020
Capitalized software	$ 5,638	$ 2,114
Accumulated amortization	(1,947)	(76)
Total intangible assets	$ 3,691	$ 2,038

Amortization expense related to intangible assets was $0.2 million and $1.9 million for the three and nine months ended September 30, 2021, respectively. Estimated amortization expense for each of the years ending December 31 is as follows:

2021 (excluding the nine months ended September 30, 2021)	$ 352
2022	1,409
2023	1,362
2024	568
Total amortization expense	$ 3,691

NOTE 8. LEASES

In September 2020, the Company entered into an agreement to lease a 63,700 square-foot building to be used as manufacturing facility in San Diego, California ("Waples Lease"). The Waples Lease has an initial term of ten years with a renewal option to extend the lease which the Company is not reasonably certain to exercise. The Waples Lease commenced in May 2021 when the Company was granted a temporary certificate of occupancy to install the manufacturing equipment.

The Company paid $12.5 million for a landlord-owned improvements recorded as a prepaid rent until the commencement date when those were reclassified into the right-of-use asset. The Company recognized an operating lease right-of use asset of approximately $32.4 million and operating lease liabilities of $19.9 million related to the Waples Lease as of commencement date.

In October 2020, the Company entered into an agreement to lease a 197,000 square-foot building to be used as a manufacturing facility in Vista, California ("Vista Lease"). The Vista Lease has an initial term of five years and the Company is reasonably certain to exercise a renewal option to extend the lease term for an additional five years. The Vista Lease commenced in January 2021 when the Company was permitted to install its tenant improvements and manufacturing equipment. The Company recognized an operating lease right-of use asset of approximately $20.5 million and operating lease liabilities of $17.1 million related to the Vista Lease. The Company will receive a tenant reimbursement allowance of $1.6 million to cover a portion of the construction of tenant improvements that began in October 2020. As of September 30, 2021, this reimbursement is recorded in other current assets.

Subsequent to the commencement dates of the Waples and Vista leases, the Company made cash payments of $12.7 million related to the ongoing construction of landlord-owned assets. This is presented in operating lease liabilities in the statements of cash flows.

In January 2021, the Company entered into a lease agreement for approximately 8,010 square feet in an industrial building in San Diego, California. The initial lease term is three years without any renewal option. This lease was classified as operating lease and recognized in the right of use asset and liability during the period.

In August 2021, the Company amended an existing lease agreement to include two additional suites containing approximately 6,932 square feet and 4,976 square feet of rentable area, respectively, in San Diego, California. The lease term is subject to the existing lease agreement expiration date of April 2030, without any renewal option. This lease was classified as an operating lease and recognized in right-of-use asset and lease liabilities during the period.

The Company made payments of $0.2 million related to deposits for equipment leases that had not commenced as of September 30, 2021. The payments have been capitalized in prepaid rent and will be reflected in right-of-use assets upon commencement of the leases.

The right-of-use assets and lease liabilities recognized on the Company's balance sheet as of September 30, 2021 were as follows:

		September 30, 2021	
	Balance Sheet Location	**Operating Leases**	**Finance Leases**
Assets			
Right-of-use assets operating leases	*Operating lease right-of-use assets*	$ 78,555	
Right-of-use assets finance leases	*Property and equipment, net*		$ 10,316
Liabilities			
Operating lease liabilities (current)	*Operating lease liabilities, current*	3,960	
Finance lease liabilities (current)	*Finance lease liabilities, current*		2,603
Operating lease liabilities (non-current)	*Operating lease liabilities, net of current portion*	50,027	
Finance lease liabilities (non-current)	*Finance lease liabilities, net of current portion*		3,841

The components of lease expense for the three and nine months ended September 30, 2021 and 2020 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating lease cost	$ 2,398	$ 393	$ 5,365	$ 1,159
Finance lease cost:				
Amortization of right-of-use assets	509	153	1,215	297
Interest on lease liabilities	54	26	154	65
Total lease cost	$ 2,961	$ 572	$ 6,734	$ 1,521

NOTE 9. CONVERTIBLE NOTES

In May 2021, the Company issued and sold convertible promissory notes (“Convertible Notes”) with a principal amount of $235.5 million and incurred $6.0 million of debt issuance costs that have been recorded in interest expense in the statements of operations. The Convertible Notes accrue interest at a simple rate of 3.0% per annum during the first 12-month period and will accrue at a simple rate of 9.0% per annum thereafter.

The Convertible Notes are only convertible upon a qualified conversion event or corporate transaction.

The Convertible Notes were converted into shares of the Company’s common stock at the then effective conversion price in the case of a qualified going public transaction: (a) an IPO resulting in at least $50.0 million in proceeds, (b) a SPAC combination, or (c) a direct listing. If the Company closes an equity financing with gross proceeds of not less than $50.0 million, then the Convertible Notes, unless previously converted into shares of our common stock, will automatically convert into shares of the same class and series of capital stock of the Company issued to investors in such equity financing. The conversion price with respect to a qualified conversion event, which would be a qualified going public transaction or an equity financing, will incorporate the applicable discount: (i) a 20.0% discount if the qualified conversion event is consummated on or prior to September 30, 2021, and (ii) a 25.0% discount if the qualified conversion event is consummated after September 30, 2021.

In the event of certain corporate transactions prior to the conversion of the Convertible Notes or the repayment of the Convertible Notes, each purchaser, in its discretion, shall have the right either (a) to convert, effective immediately prior to the closing of the corporate transaction, all, but not less than all, of the outstanding principal amount of a Convertible Note and all accrued and unpaid interest on such May 2021 Note immediately prior to the closing of a corporate transaction into shares of common stock at the then effective conversion price, or (b) be paid an amount equal to the sum of 1.75 times the outstanding principal amount of a Convertible Notes and all accrued and unpaid interest of such Convertible Notes immediately prior to the closing of a corporate transaction

The Convertible Notes include customary events of default. In the event of any default under the Convertible Notes, the interest rate then in effect shall be increased by 3.0%, and then by an additional 3.0% each year thereafter, so long as such event of default continues. Unless earlier converted immediately prior to the qualified conversion event, the Convertible Notes and any unpaid accrued interest will become due in May 2023.

The Company elected to account for the Convertible Notes at estimated fair value pursuant to the fair value option and records the change in estimated fair value in the statement of operations. The Company recorded a loss of $36.3 million and $59.6 million related to the change in estimated fair value of the Convertible Notes in its statement of operations for the three and nine months ended September 30, 2021, respectively.

All of the Convertible Notes were converted upon the IPO, which was a qualified conversion event. The Convertible Notes’ principal of $235.5 million and accrued interest of $2.8 million was converted into 18,611,914 shares of common stock at a fair value of $297.8 million using a 20% discount to the initial public offing price of $16.00 per share. The Company no longer had outstanding Convertible Notes as of September 30, 2021.

NOTE 10. DEBT

On February 5, 2021, the Company entered into a Loan and Security Agreement (“Revolving Credit Agreement”) with group of lenders with East West Bank, acting as administrative agent and Collateral Agent for the lenders. In connection

with entering into the Revolving Credit Agreement, the Company repaid outstanding amounts of $5.4 million and terminated the prior Loan and Security Agreement with Comerica Bank ("2015 Credit Agreement") that was initially entered into in May 2015. The 2015 Credit Agreement, as amended, provided for a revolving line with a credit extension of up to $4.0 million and a Growth Capital A Line with a credit extension of up to $6.0 million. The Revolving Credit Agreement provided a revolving credit facility with an aggregate maximum principal amount of $130.0 million and a letter of credit subfacility of $20.0 million. In May 2021, the Company repaid $63.2 million of debt outstanding under the Revolving Credit Agreement with a portion of the net proceeds from the issuance and sale of Convertible Notes.

In June 2021, the Company terminated the Revolving Credit Agreement and was required to pay a fee of $1.3 million, equal to 1.00% of the amount of the outstanding revolving commitment. The Company also wrote-off issuance costs of $0.7 million for a total loss on extinguishment of debt of $2.0 million. These amounts were recorded in loss on extinguishment of debt in the statement of operations during the nine months ended September 30, 2021. Upon agreement with East West Bank and the other lenders to the Revolving Credit Agreement, the Company kept in place its outstanding letter of credit in the amount of $6.0 million, which has been cash collateralized. The letter of credit was increased to $12.0 million in July 2021. All other obligations under the Revolving Credit Agreement have otherwise been terminated.

NOTE 11. CAPITAL STOCK

Amended and Restated Certificate of Incorporation

In September 2021, the Company's board of directors approved and the Company filed its restated amended certificate of incorporation, which authorized the issuance of up to 550,000,000 shares consisting of 500,000,000 shares of common stock and 50,000,000 shares of preferred stock with a par value of $0.00001 per share, respectively.

Redeemable Convertible Preferred Stock

In connection with the closing of the IPO, all outstanding shares of redeemable convertible preferred stock were converted into 83,605,947 shares of common stock.

Redeemable Convertible Preferred Stock Warrants

Prior to September 2021, the Company had outstanding warrants to purchase 79,882 redeemable convertible preferred shares. These warrants were classified as liabilities, with changes in fair value recorded through earnings, as the underlying redeemable convertible preferred shares could be redeemed by the holders of these shares upon the occurrence of certain events that are outside of the control of the Company. Immediately prior to the IPO in September 2021 all outstanding warrants were exercised and converted into shares of Series A and Series B redeemable convertible preferred stock prior to the IPO. The related liability was derecognized upon exercise and recorded in temporary equity.

Common Stock Warrants

As of September 30, 2021, the Company had an outstanding warrant to purchase 75,744 shares of common stock at a purchase price of $0.40 per share. The warrant was issued on August 22, 2017 and expires on August 22, 2027. All shares subject to the warrant have vested as of December 31, 2020.

NOTE 12. FAIR VALUE MEASUREMENTS

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis within the fair value hierarchy:

There are no instruments that were measured at fair value on a recurring basis as of September 30, 2021.

December 31, 2020	**Recurring Fair Value Measurements**			
	Level 1	**Level 2**	**Level 3**	**Total**
Redeemable convertible preferred stock warrant liabilities	$ —	$ —	$ 1,331	$ 1,331

There were no transfers between Level 1, Level 2 and Level 3 categories of the fair value hierarchy during the nine months ended September 30, 2020 and 2021.

In May 2021, the Company issued and sold Convertible Notes with a principal amount of $235.5 million (See Note 9, *Convertible Notes*). The Company elected the fair value option to account for the Convertible Notes and recognized their estimated fair value, with changes in estimated fair value recorded as a component of earnings in the statements of operations. The fair value of the notes was determined based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy.

The Convertible Notes were valued using a scenario-based analysis. Three primary scenarios were considered and assigned a probability weighted to arrive at the estimated fair value. The first scenario considered the value impact of conversion at the 20.0% discount to the issue price if the Company had a qualified conversion event of (a) an IPO, (b) a SPAC combination, (c) or a direct listing, or (d) an equity financing with gross proceeds of not less than $50.0 million, before or on September 30, 2021. The second scenario considered the value impact of conversion at the 25.0% discount to the issue price if the Company had a qualified conversion event of (a) an IPO, (b) a SPAC combination, (c) or a direct listing, or (d) an equity financing with gross proceeds of not less than $50.0 million, after September 30, 2021. The third scenario assumed that a qualified conversion event did not occur, and the Convertible Notes and any unpaid accrued interest are repaid in May 2023.

The closing of the IPO was considered a qualified conversion event per the terms of convertible notes. As a result, the Convertible Notes, $235.5 million of principal and $2.8 million of accrued interest through September 27, 2021, were converted into 18,611,914 shares of common stock at 20% discount to the initial public offing price of $16.00 per share. The Company recognized a loss of $36.3 million resulting from the conversion which was recorded in change in fair value of convertible notes in the statements of income for the three months ended September 30, 2021.

The following table provides a rollforward of the fair value of the Company's Convertible Notes and redeemable convertible preferred stock warrant liabilities measured on a recurring basis and classified within Level 3 fair value hierarchy:

	Redeemable Convertible Preferred Stock Warrants	Convertible Notes
Balance, December 31, 2020	$ 1,331	$ —
Issuance	—	235,480
Remeasurement	(53)	59,559
Accrued interest	—	2,753
Exercise of redeemable convertible preferred stock warrants	(1,278)	—
Conversion into common stock	—	(297,792)
Balance, September 30, 2021	$ —	$ —

No redeemable convertible preferred stock warrants were outstanding as of September 30, 2021.

NOTE 13. STOCK-BASED COMPENSATION

Stock Incentive Plans

2014 Equity Incentive Plan

In August 2014, the Company adopted the 2014 Equity Incentive Plan ("2014 Plan") under which employees, non-employee directors and consultants of the Company may be granted either incentive stock options or non-qualified stock options to purchase shares of the Company's common stock. In January 2021, the Company increased the number of shares of common stock available for issuance under the 2014 Plan from 20,399,691 to 22,399,691. The Company granted 128,000 shares with a one year restriction to certain non-employee directors effective immediately prior to effectiveness of the registration statement.

As of September 30, 2021, and December 31, 2020, shares available for future grant under the 2014 Plan were 0 and 2,950,871, respectively.

2021 Stock Incentive Plan

In September of 2021, the Company adopted the 2021 Stock Incentive Plan ("2021 Plan") under which employees, officers and directors, as well as consultants and advisors to the Company are eligible to be granted awards under the 2021 Plan. The authorized number of shares includes 14,173,771 common shares plus such additional number of shares of Common Stock up to 22,399,691 as equal to the number shares reserved in the 2014 Plan above. The 2021 Plan has an annual increase to be added on the first day of each fiscal year commencing January 1, 2022 until and including January 1, 2031 equal to at least 5% of outstanding shares on such date and the number of shares of common stock determined by the board. Up to 56,695,085 shares of common stock is available for issuance under the 2021 Plan may be issued as incentive stock options under the 2021 Plan.

As of September 30, 2021, there have been 9,820,216 shares issued and 8,900 shares that have vested.

2021 Employee Stock Purchase Plan

In September 2021, the Company adopted the 2021 Employee Stock Purchase Plan ("2021 ESPP") under which employees of the Company can purchase shares of the Company's common stock commencing on such time and such dates as the board of directors of the Company determine. The number of shares of common stock that have been approved for the purpose is 2,834,754 shares of common stock plus an annual increase to be added on the first day of each fiscal year commencing January 1, 2022 and continuing for each fiscal year until and including January 1, 2032. The annual increase is equal to the least of 8,504,263 shares of common stock, 1% of outstanding shares on such date, and a number of shares of common stock determined by the board of directors.

Stock-Based Compensation

Stock-based compensation expense related to awards issued under the Company's incentive compensation plans for the three and nine months ended September 30, 2021 and 2020, was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of revenues	$ 302	$ —	$ 1,500	$ —
Sales and marketing	11	—	37	—
Research and development	294	41	884	59
General and administrative	19,359	104	23,136	183
Total stock-based compensation expense	$ 19,967	$ 145	$ 25,558	$ 242

In total, $0.3 million and $1.5 million of stock-based compensation expense was capitalized to inventory during the manufacturing process during the three and nine months ended September 30, 2021, respectively.

Stock Options

A summary of stock option activity and related information for three and nine months ended September 30, 2021 was as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at January 1, 2021	8,344,752	0.61	6.44
Granted	2,975,821	15.61	
Exercised	(1,698,265)	0.30	
Forfeited	(310,816)	10.31	
Expired	(107,792)	0.37	
Outstanding at September 30, 2021	9,203,700	4.99	4.88
Exercisable at September 30, 2021	5,775,902	1.02	5.79
Vested and expected to vest at September 30, 2021	9,260,605	4.49	6.49

The estimated fair value of each stock option award granted to employees was determined on the date of grant using the BSM option pricing model with the following assumptions for stock option grants for three months ended September 30, 2020 and 2021:

	2021	2020
Expected volatility	40.9%	39.6%
Expected term (years)	7.71	7.04
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	0.83%	0.41%
Grant date fair value	$ 6.93	$ 0.57

As of September 30, 2021, there was $12.6 million of unamortized compensation cost related to unvested stock option awards, which is expected to be recognized over a remaining weighted-average vesting period of 3.16 years, on a straight-line basis.

Restricted Stock Units

Restricted stock units (“RSUs”) are generally subject to a 4-year vesting period, with 25% of the shares vesting one year from the vesting commencement date and quarterly thereafter over the remaining vesting term. Compensation expense is recognized over the requisite service period.

In February and March 2021, the Company issued a total of 1,049,043 restricted stock units to certain executives under the 2014 Plan with the right to receive common stock shares upon vesting schedule per agreements with certain executives. No additional grants of RSUs are expected under the 2014 Plan. One of the grants to an executive accelerated upon the completion of the IPO, resulting in the vesting of 137,375 restricted stock units.

In September 2021 issued an aggregate of 6,707,320 RSUs to certain executives. Approximately 75% or 4,932,573 RSUs, of these grants vest based on the satisfaction of both a continued employment condition and the achievement of certain performance goals, referred to as the performance-vesting RSUs, and approximately 25% or 1,774,747 RSUs vest solely

based on the satisfaction of a continued employment condition, referred to as the time-vesting RSUs. The Company also issued 3,240,896 RSUs to other employees, all of which are time-vesting RSUs.

Time-vesting RSUs will vest as to 12.5% of the shares of common stock subject to the award on the six-month anniversary of three-month period thereafter until the award is fully vested on the fourth anniversary of the grant date.

Performance-vesting RSUs vest upon the achievement of certain stock price performance goals (approximately 70% of the performance-vesting RSUs), target revenue performance goals (approximately 20% of the performance-vesting RSUs), and a product milestone goal.

A summary of RSU activity and related information for the nine months ended September 30, 2021 was as follows:

	Underlying Shares	Weighted-average Grant Date Fair Value	Aggregate Fair Value
Outstanding, January 1, 2021	—	$ —	$ —
Granted	10,869,259	19.58	212,833
Vested	(146,274)	17.80	(2,604)
Outstanding, September 30, 2021	10,722,985	$ 19.63	$ 210,457

In addition to the RSU activity above, an award of 128,000 fully vested shares of common stock to outgoing members of the board of directors. Recipients are prohibited from selling or otherwise transferring the shares for one year after the date of grant.

Restricted Stock Purchase Agreements with Executives

In 2018 and 2020, the Company issued shares of common stock pursuant to Restricted Stock Purchase Agreements with its Chief Executive Officer and Chief Product Officer in exchange for nonrecourse promissory notes to finance the entire cost of the shares. These shares are legally issued and outstanding and included on the balance sheet, but they are not treated as outstanding common stock for accounting purposes as they are deemed to be common stock options. As of December 31, 2020, 9,872,293 shares were subject to the Restricted Stock Purchase Agreements.

In September, 2021 the Company's board of directors approved the forgiveness of the Chief Executive Officer's 2018 promissory notes under which $1.3 million of principal and accrued interest was outstanding for the purchase of 2,444,130 common stock shares. The Company's board of directors also approved the forgiveness of the Chief Executive Officer's 2020 promissory notes for the purchase of 4,915,442 shares of common stock under which $7.0 million of principal and accrued interest was outstanding.

On September 1, 2021 the Company's board of directors approved the forgiveness of the Chief Product Officer's 2020 promissory notes under which $3.5 million of principal and accrued interest was outstanding for the purchase of 2,457,721 common stock shares. The Chief Product Officer's 2018 promissory note was forgiven in prior periods.

The forgiveness of the promissory notes were deemed to be an option modification. The unrecognized grant date fair value and the incremental fair value from the modification resulting from the forgiveness of the promissory notes related to vested shares was recognized in stock-based compensation expense during the nine months ended September 30, 2021 and the unvested portion thereof will be recognized as stock-based compensation expense over the remaining vesting period. This modification resulted in $12.9 million in additional stock-based compensation expense for the three and nine months ended September 30, 2021.

Early Exercise Liability

The unvested shares of the early-exercised options are held in escrow until the stock option becomes fully vested or until the employee's termination, whichever occurs first. The right to repurchase these shares lapses over the four-year vesting period. As of September 30, 2021, the early exercise liability was not material and is included in accrued liabilities in the balance sheets. For accounting purposes, the early exercise of options is not considered to be a substantive exercise until the underlying awards vest.

The following table summarizes the activity of the unvested common stock issued pursuant to an early exercise of stock option awards during the nine months ended September 30, 2021:

	Number of Shares
Unvested at December 31, 2020	316,666
Early exercised stock options during period	—
Vested or cancelled	(284,998)
Unvested at September 30, 2021	31,668

NOTE 14. INCOME (LOSS) PER SHARE

Basic net income (loss) per share is computed by dividing net income (loss) attributable to common stockholders by the weighted-average common shares outstanding during the period. Diluted net income (loss) per share attributable to common stockholders is computed based on the weighted-average common shares outstanding plus the effect of dilutive potential common shares outstanding during the period calculated using the treasury stock method and the if-converted method. Dilutive potential common shares include stock options, non-vested shares, redeemable convertible preferred shares, restricted stock and similar equity instruments granted by the Company. Potential common share equivalents have been excluded where their inclusion would be anti-dilutive.

Basic and diluted net income (loss) attributable to common holders per share is presented in conformity with the two- class method required for participating securities as the redeemable convertible preferred stock, common stock subject to restricted stock purchase agreements, early exercised options, and restricted shares are considered participating securities. Under the two-class method, distributed and undistributed income allocated to participating securities are excluded from net income (loss) attributable to common stockholders for purposes of calculating basic and diluted income (loss) per share. The Company’s participating securities do not have a contractual obligation to share in the Company’s losses, so the net loss for the nine months ended September 30, 2020 was attributed entirely to common stockholders and there is no difference in the number of shares used to calculate basic and diluted shares outstanding.

The following table reconciles net income and the weighted-average shares used in computing basic and diluted earnings per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net income (loss)	$ 19,348	$ (8,538)	$ 52,188	$ (27,816)
Minus: Income allocated to participating securities	14,926	—	43,670	—
Net income (loss) attributable to common stockholders – basic	$ 4,422	$ (8,538)	$ 8,518	$ (27,816)
Plus: Income allocated to non-participating securities	701	—	2,142	—
Net income (loss) attributable to common stockholders - diluted	$ 5,123	$ (8,538)	$ 10,660	$ (27,816)
Denominator:				
Basic weighted-average common shares outstanding	31,554,720	16,556,343	22,997,311	16,126,647
Dilutive potential common stock issuable:				
Common stock warrants	89,551	—	89,551	—
Stock options	7,660,707	—	7,660,707	—
Diluted weighted-average shares outstanding	39,304,978	16,556,343	30,747,569	16,126,647
Net income (loss) attributable to common stockholders per share				
Basic	$ 0.14	$ (0.52)	$ 0.37	$ (1.72)
Diluted	$ 0.13	$ (0.52)	$ 0.35	$ (1.72)

In periods of net losses, potentially dilutive securities are not included in the calculation of diluted net income (loss) per share because to do so would be anti-dilutive.

Outstanding anti-dilutive securities not included in the diluted net income (loss) per share attributable to common stockholders calculations were as follows (in common stock equivalent shares):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Redeemable convertible preferred stock	—	83,526,065	—	83,526,065
Stock options	2,767,821	8,244,751	2,767,821	8,244,751
Restricted stock units	9,747,566	—	9,747,566	—
Common stock subject to restricted stock purchase agreements	—	9,872,293	—	9,872,293
Common stock warrants	—	75,744	—	75,744
Redeemable convertible preferred stock warrants	—	79,882	—	79,882
Total	12,515,387	101,798,735	12,515,387	101,798,735

NOTE 15. INCOME TAXES

The Company’s effective income tax rate for the nine months ended September 30, 2021 was 45% compared to 0% in the corresponding period in the prior year. The increase in our provision and effective tax rate was primarily due to the current tax liability arising from an increase in income from operations which exceeded available net operating loss carryforwards.

Income taxes for the three months and nine months ended September 30, 2021 include state income taxes in jurisdictions for which the Company does not have available tax attributes. The Company remains under a full valuation allowance with the exception of deferred tax liabilities arising for accelerated depreciation deductions for United States federal tax purposes. The effective tax rate for the three months and nine months ended September 30, 2021 differed from the statutory tax rate primarily due to the non-tax deductible items including the charges related to the Convertible Notes and the forgiveness of the promissory notes. The deduction related to the forgiveness of the promissory notes has limitations applied under Section 162(m) of the Internal Revenue Code. The effective tax rate for the three months and nine months ended September 30, 2020 differed from the statutory tax rate primarily due to the Company maintaining a full valuation allowance against its loss from continuing operations.

The Company recorded a valuation allowance against all of its United States federal and state deferred tax assets as of December 31, 2020. At each interim period, the Company evaluates both the positive and negative evidence, which includes, projected future taxable income, scheduled reversals of deferred tax liabilities, prudent tax planning strategies, and recent financial operations, as to whether changes to the valuation assessment are needed.

As of September 30, 2021, the Company recorded $0.9 million of deferred tax liability to reflect the expected reversal of deferred tax liabilities in excess of deferred tax assets in certain future tax years. The Company continues to maintain a full valuation allowance on the remaining net deferred tax asset until there is sufficient evidence to support the reversal of all or an additional portion of the allowance.

On March 11, 2021, the American Rescue Plan Act H.R. 1319 (ARPA) was enacted and signed into law in the United States. ARPA is a follow up to the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The bill includes provisions on taxes, health care, unemployment benefits, direct payments, state and local funding, and other issues. ARPA did not have a significant impact on the Company's financial statements for the nine months ended September 30, 2021.

In April 2021, the Company was awarded a California Competes Tax Credit (CCTC) totaling $20.0 million for a five-year agreement. The CCTC is a competitive income tax credit available to businesses across various industries that want to locate or expand in California. The CCTC can offset California corporate income tax liability and is non-refundable.

The credit is allocated in equal increments of $4.0 million over five years for a total of $20.0 million as documented in the CCTC Agreement. The Agreement covers tax years 2021-2025 and is awarded after the completion of each year.

The credit is earned on an annual basis and certain milestones are required to be achieved. If the credit earned in a given year exceeds the Company's California corporate income tax liability, the balance can be carried over for up to six years if necessary, until exhausted. The California Competes Tax Credit will be reflected as a benefit when certified annually which did not occur during the three months ended September 30, 2021.

NOTE 16. COMMITMENTS AND CONTINGENCIES

Product Liability

The Company's business exposes it to liability risks from its potential medical diagnostic products. Product liability claims could result in the payment of significant amounts of money and divert management's attention from running the business. The Company may not be able to maintain insurance on acceptable terms, or the insurance may not provide adequate protection in the case of a product liability claim. To the extent that product liability insurance, if available, does not cover potential claims, the Company would be required to self-insure the risks associated with such claims. The Company believes it carries reasonably adequate insurance for product liability.

Standby Letters of Credit

As of December 31, 2020, the Company was party to certain letters of credit ("LOC"), primarily related to an LOC with Comerica Bank as collateral required by one of the Company's vendors. During the nine months ended September 30, 2021, the Company entered into a Revolving Credit Agreement with a capacity of $130.0 million and all but one of the LOCs were no longer required by the counterparties. The one LOC, totaling $6.0 million, has been re-issued under the Revolving Credit Agreement.

In May 2021, the Company repaid the debt outstanding under the Revolving Credit Agreement and terminated the agreement in September 2021. Upon agreement with East West Bank and the other lenders to the Revolving Credit Agreement, the Company kept in place its outstanding LOC in the amount of $6.0 million, which has been cash collateralized. The letter of credit was increased to $12.0 million in July 2021.

Legal Settlement

In March 2021, the Company reached a settlement pursuant to a consulting agreement for services rendered during the year ended December 31, 2020, related to the advancement of the Company's diagnostic platform and identification of funding opportunities. The Company agreed to pay $9.0 million, payable in four equal installments over eighteen months, starting on April 1, 2021. The amount was included in the statements of operations in general and administrative expenses for the year ended December 31, 2020. As of September 30, 2021, $4.5 million of this amount was included in accrued liabilities and other current liabilities in the balance sheets.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and the related notes and the discussion under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" for the fiscal year ended December 31, 2020 included in our final prospectus, or the Final Prospectus, that forms a part of the Registration Statement on Form S-1 (File No. 333-259250) for our initial public of offering, or our IPO, dated as of September 23, 2021, and filed with the Securities and Exchange Commission, or the SEC, pursuant to Rule 424(b)(4) under the Securities Act on September 27, 2021. This discussion, particularly information with respect to our future results of operations or financial condition, business strategy and plans and objectives of management for future operations, includes forward-looking statements that involve risks and uncertainties as described under the heading "Forward-Looking Statements" in this Quarterly Report on Form 10-Q for a discussion of important factors that could cause our actual results to differ materially from those anticipated in these forward-looking statements.

Overview

We are a health technology company, and our mission is to enable personalized, proactive and informed healthcare that empowers people to live their healthiest lives. Our proprietary platform, the Cue Integrated Care Platform, which is comprised of our Cue Health Monitoring System, Cue Data and Innovation Layer, Cue Virtual Care Delivery Apps, and Cue Ecosystem Integrations and Apps, enables lab-quality diagnostics-led care at home, at work or at the point of care. Our platform is designed to empower stakeholders across the healthcare ecosystem, including consumers, providers, enterprises and payors with paradigm-shifting access to diagnostic and health data to inform care decisions. We are helping pioneer a new continuous care model that we believe has the potential to significantly improve the user experience, provide measurable and actionable clinical insights, and increase efficiency within the healthcare ecosystem. We believe this model, powered by our platform, will allow users to actively manage their health, which we believe will lead to improved health outcomes and a more resilient, connected, and efficient healthcare ecosystem for all stakeholders.

The Cue Integrated Care Platform consists of the following hardware and software components: (1) our revolutionary Cue Health Monitoring System, made up of a portable, durable and reusable reader, or Cue Reader, a single-use test cartridge, or Cue Cartridge, and a sample collection wand, or Cue Wand, (2) our Cue Data and Innovation Layer, with cloud-based data and analytics capability, (3) our Cue Virtual Care Delivery Apps, including our consumer-friendly App and our Cue Enterprise Dashboard, and (4) our Cue Ecosystem Integrations and Apps, which allow for integrations with third party applications and sensors.

Our Cue Health Monitoring System is designed to deliver a broad menu of tests through one system, enabling two major testing modalities, nucleic acid amplification tests, or NAAT, and immunoassays, in one device. Our system is designed to handle different sample types, including saliva, blood, urine and swabs, and can detect nucleic acids, small molecules, proteins and cells. We believe this will enable us to address many of the diagnostic tests conducted in clinical laboratories, such as tests addressing indications in respiratory health, sexual health, cardiac and metabolic health, women's health, men's health, and chronic disease management.

Initial Public Offering

The Company's registration statement related to its initial public offering ("IPO") was declared effective on September 23, 2021, and the Company's common stock began trading on the Nasdaq Global Stock Market ("Nasdaq") on September 24, 2021. On September 28, 2021, the Company completed its IPO of 14,375,000 shares of the Company common stock at an offering price of $16.00 per share, including 1,875,000 shares purchased by the IPO underwriters. The

Company received aggregate net proceeds of approximately $205.3 million after deducting underwriting discounts and commissions.

Upon completion of the IPO, Convertible Notes outstanding in the principal amount of $235.5 million and accrued interest of $2.7 million were automatically converted into 18,611,914 shares of common stock. All outstanding shares of the Company's redeemable convertible preferred stock were converted into 83,605,947 shares of common stock. Immediately prior to the IPO, all of the Company's outstanding warrants to purchase redeemable convertible preferred stock were converted into the redeemable convertible preferred stock and the related warrant liabilities were reclassified to additional paid-in capital.

COVID-19 Impact

While the ongoing global COVID-19 pandemic has adversely impacted global commercial activity, it served as a catalyst to accelerate our product pipeline and commercialization of our platform. We began selling and recording product revenue for our COVID-19 test in August 2020 after obtaining our first FDA EUA in June 2020. Currently, all of our product revenue is related to sales of our Cue COVID-19 test.

In December 2020, the FDA issued emergency use authorizations ("EUA") for two COVID-19 vaccines and in February 2021, the FDA issued a third EUA for a COVID-19 vaccine. The widely-administered use of an efficacious vaccine or the availability of therapeutic treatments for COVID-19 may reduce the demand for our COVID-19 test and could cause the COVID-19 diagnostic testing market to fail to grow or to decline. However, we believe the need for ongoing detection and monitoring will continue to be high even after effective vaccines have been widely distributed and administered. We also believe COVID-19 will remain endemic for the foreseeable future and people suspected of having COVID-19 will want to obtain a fast and accurate COVID-19 test to confirm a diagnosis in order to receive timely and appropriate treatment. Even while vaccine efforts are underway, public health measures, like testing, will likely need to stay in effect to protect against COVID-19. However, given the unpredictable nature of the COVID-19 pandemic, the development and potential size of the COVID-19 diagnostic testing market is highly uncertain.

Certain Key Factors Affecting Our Performance

U.S. Department of Defense Agreement

Our agreement with the U.S. DoD represents the majority of our current product revenue. Subject to exceptions, the U.S. government is entitled to be the exclusive purchaser of our entire production through the completion of the project, though we have received a waiver from the U.S. DoD allowing us to distribute commercially up to 50% of our COVID-19 Test production, measured monthly in arrears on a calendar month basis, to non-U.S. federal government customers and other recipients. As a result, for at least the duration of the initial U.S. DoD Agreement, we expect that at least 50% of our manufacturing capabilities will be dedicated to meet the demand from the U.S. DoD Agreement. In addition, the U.S. DoD Agreement also provides that we and the U.S. government are expected to negotiate in good faith to enter into a follow-on supply agreement, which would provide the U.S. DoD with the right to purchase up to 45% of our quarterly production for the duration of the contract. Until we can diversify our customer base, the success of our business depends in large part on our ability to fulfill our obligations under the U.S. DoD Agreement.

Expanding Our Manufacturing Capacity

The growth of our business depends on our ability to rapidly expand our current manufacturing capacity to meet the demand for our platform and tests, in particular our COVID-19 test, since at least 50% of our current production capacity is dedicated to fulfilling our current contractual obligations under the U.S. DoD Agreement. We manufacture all of our Cue Cartridges in our vertically integrated facilities in San Diego, California. We also produce all of our biochemistry in-house, including critical enzymes, antibodies and primers for our Cue Cartridges. Production of our Cue Readers is performed for us by third-party contract manufacturers and production of our Cue Wands is performed by both us and by third-party contract manufacturers. We are currently scaling our manufacturing capabilities, including our fully automated production pods. A production pod is a free standing, modular environmentally controlled structure containing an automated cartridge production line. As we expand our manufacturing capacity, we expect to see a reduction in per unit manufacturing costs in 2021 and thereafter.

Investments in Our Growth

We expect to make continued significant investments in our business to drive growth, and therefore we expect our expenses to increase going forward. We expect to invest significant resources in sales and marketing to drive demand for

our products and services as well as research and development to enhance our platform and bring additional tests to market. We also intend to continue investing in our supply chain and logistics operations. As we continue to scale our business, we expect to hire additional personnel and incur additional expenses, including those expenses in connection with our becoming a public company.

Expanding Our Customer Base

The future commercial success of our diagnostic products is dependent on our ability to broaden our customer base beyond the U.S. government to markets including individuals, enterprises and healthcare providers. While our agreement with the U.S. DoD is in place, a substantial portion of our current production capacity is dedicated to fulfilling our contractual obligations under the U.S. DoD Agreement and our ability to acquire new customers will be constrained. Upon conclusion of the U.S. DoD Agreement, we anticipate that our revenue may decline significantly, at least in the short term (if not longer). As a result, our long term growth depends on our ability to acquire new customers. In addition to the U.S. DoD, other current key strategic relationships include the U.S. Biomedical Advanced Research and Development Authority, or BARDA, Google LLC, or Google, the Mayo Clinic, the National Basketball Association, and Henry Schein, Inc. We intend to leverage our success with our COVID-19 Test and the expansion of our manufacturing capabilities to enable broad distribution of our Cue Readers and awareness of our platform across different groups of customers and to enhance pull-through of our future tests. In the three-month period ending September 30, 2021 we sold approximately 56,000 readers and have sold over 120,000 readers since our first FDA EUA in June 2020.

Enhancing and Expanding Our Menu of Tests and Software Capabilities

Currently, our only commercially available test is our molecular COVID-19 test. A key part of our growth strategy is to expand our menu of tests to include other diseases, ailments and general health markers, which we expect will support our growth and continue to contribute to the utility of our platform, including the Cue Health Monitoring System. We are currently developing tests in the fields of respiratory health, sexual health, cardiac and metabolic health, women's health, men's health, and chronic disease management. As we continue to develop and expand our menu of tests, we have made, and will continue to make, significant investments in our business, particularly in research and development, sales and marketing and the hiring of additional personnel. Investing in research and development will allow us to develop new tests as well as enhance our current product offerings and our Cue Integrated Care Platform. To build out our menu of tests and bring additional products to market, we will need to hire additional personnel, such as engineers and researchers, as well as develop robust sales and marketing and customer support teams to be able to sell our products.

Regulatory Clearance of Our Diagnostic Products

Our commercial success will depend upon a number of factors, some of which are beyond our control, including the receipt of regulatory clearances, approvals or authorizations for existing or new product offerings by us, product enhancements, or additions to our proprietary intellectual property portfolio. While we have received two EUAs for our COVID-19 test, a CE mark in the European Union, an Interim Order authorization from Health Canada, and regulatory approval from CDSCO, our COVID-19 test has not been FDA cleared or approved and is only authorized for emergency use during the declaration that circumstances exist justifying the authorization of emergency use, and this declaration could be terminated, or our authorization could be revoked in the future. We will need to seek additional regulatory approval for our COVID-19 test if the EUA declaration or Interim Order is terminated or otherwise revised or revoked, and we will need to seek regulatory authorization, clearance or approval for our other diagnostic products in development. In addition, we will not be able to commercialize any other tests for our platform unless we obtain required regulatory clearances or other necessary approvals or authorizations. As such, our ability to navigate, obtain and maintain the required regulatory clearances, approvals or authorizations, as well as comply with other regulatory requirements, for our products will in part drive our results of operations and impact our business.

Reimbursement and Insurance Coverage

We have been granted two EUAs by the FDA for our COVID-19 test for point-of-care and at-home and over-the-counter indications. The commercial success of our COVID-19 test, and any of our subsequently developed tests, is dependent on a customer’s ability to be able to pay for or otherwise be reimbursed for the purchase of a test, whether out-of-pocket, by insurance or from a governmental or other third-party payor. We believe payment for our products, including our COVID-19 Test Kits, will be billable by a physician, reimbursable by government payors or insurance companies, paid for by a self-insured employer, or eligible under FSA and HSA guidelines. For example, most of our contemplated future tests that are currently offered by others through central labs are reimbursable by health plans and governmental payors if properly ordered by a physician. These third-party payors decide which products will be covered and establish reimbursement levels for those products. Coverage criteria and reimbursement rates for clinical laboratory tests are subject to adjustment by payors, and current reimbursement rates could be reduced, or coverage criteria restricted in the future. If

the Cue Health Monitoring System, including any of our current or future tests, are not reimbursable or covered by insurance, our business may be materially and adversely impacted.

Seasonality

We anticipate that fluctuations in customer and user demand for our COVID-19 test may be similar to those related to influenza, which typically increases during the fall and winter seasons. Although our products will be available throughout the year, we anticipate that we may experience higher sales during the fall and winter seasons, relative to the spring and summer seasons. However, as our portfolio of diagnostic offerings increases beyond our COVID-19 test, we expect the impact of this seasonality on our results to decrease.

Third Quarter 2021 Summary (on a comparative basis)

Key GAAP financial results for the three months ended September 30, 2021 were as follows as compared to the three months ended June 30, 2021:

- Revenues increased by 62.8% to $223.7 million from $137.4 million;
- Product gross margin was 60.2% compared to 59.9%;
- Net income decreased by 2.3% to $19.3 million from $19.8 million and;
- Earnings per diluted share decreased to $0.13 from $0.14

Key non-GAAP financial results for the three months ended September 30, 2021 were as follows as compared to the three months ended June 30, 2021:

- Non-GAAP adjusted net income increased by 33.5% to $67.1 million from $50.2; and
- Non-GAAP adjusted diluted EPS increased by 40.6% to $0.52 from $0.37

Please see a description in the *Non-GAAP Financial Measures* section below.

Results of Operations

The following table sets forth a summary of our results of operations for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
(dollars in thousands)	(unaudited)			
Revenue:				
Product revenue	$ 222,594	$ 2,128	$$ 424,516	$ 2,128
Grant and other revenue	1,085	2,602	1,085	7,562
Total revenue	223,679	4,730	425,601	9,690
Operating costs and expenses:				
Cost of product revenue[1][2]	88,569	2,641	173,746	2,641
Sales and marketing[1]	5,572	19	7,531	64
Research and development[1]	9,079	6,878	21,150	26,558
General and administrative[1]	33,084	3,694	56,336	7,458
Total operating costs and expenses	136,304	13,232	258,763	36,721
Income (loss) from operations	87,375	(8,502)	166,838	(27,031)
Interest expense	(1,786)	514	(9,752)	(274)
Change in fair value of redeemable convertible preferred stock warrants	243	20	53	—
Change in fair value of convertible notes	(36,306)	—	(59,560)	—
Loss on extinguishment of debt	—	(610)	(1,998)	(610)
Other income (expense), net	(80)	40	(19)	99
Net income (loss) before income taxes	49,446	(8,538)	95,562	(27,816)
Income tax expense	30,098	—	43,374	—
Net income (loss)	$ 19,348	$ (8,538)	$ 52,188	$ (27,816)
Net income (loss) per share attributable to common stockholders – diluted	$ 0.13	$ (0.52)	$ 0.35	$ (1.72)

(1) Includes stock-based compensation expense as follows: In total, $0.3 million and $1.5 million of stock-based compensation expense was capitalized to inventory during the manufacturing process during the three and nine months ended September 30, 2021, respectively.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
(dollars in thousands)	(unaudited)			
Cost of product revenue	$ 302	$ —	$ 1,500	$ —
Sales and marketing	11	—	37	—
Research and development	294	41	884	59
General and administrative	19,359	104	23,136	183
Total stock-based compensation expense	$ 19,967	$ 145	$ 25,558	$ 242

(2) Includes $7.9 million and $18.4 million of depreciation and amortization expense for the three and nine months ended September 30, 2021, respectively.

Comparison of the Three Months Ended September 30, 2021 and 2020

The following table sets forth a summary of our results of operations for the three months ended September 30, 2021 and 2020 and the changes between periods:

	Three Months Ended September 30,			
	2021	**2020**	**$ Change**	**% Change**
(dollars in thousands)		**(unaudited)**		
Revenue:				
Product revenue	$ 222,594	$ 2,128	$ 220,466	10,360%
Grant and other revenue	1,085	2,602	(1,517)	(58%)
Total revenue	223,679	4,730	218,949	4,629%
Operating costs and expenses:				
Cost of product revenue	88,569	2,641	85,928	3,254%
Sales and marketing	5,572	19	5,553	29,226%
Research and development	9,079	6,878	2,201	32%
General and administrative	33,084	3,694	29,390	796%
Total operating costs and expenses	136,304	13,232	123,072	930%
Income (loss) from operations	87,375	(8,502)	95,877	(1,128%)
Interest expense	(1,786)	514	(2,300)	(447%)
Change in fair value of redeemable convertible preferred stock warrants	243	20	223	1,115%
Change in fair value of convertible notes	(36,306)	—	(36,306)	n.m
Loss on extinguishment of debt	—	(610)	610	(100%)
Other income (expense), net	(80)	40	120	300%
Net income (loss) before income taxes	49,446	(8,538)	57,984	(679)%
Income tax expense	30,098	—	(30,098)	n.m
Net income (loss)	$ 19,348	$ (8,538)	$ (27,886)	327 %
Net income (loss) per share attributable to common stockholders – diluted	$ 0.13	$ (0.52)	$ —	(120)%

n.m. = not meaningful

Revenue increased to $223.7 million in the three months ended September 30, 2021, from $4.7 million in the three months ended September 30, 2020. This increase was due to the start of product sales in August 2020. Of the $222.6 million of product revenue recorded in the three months ended September 30, 2021, $190.1 million related to sales of our COVID-19 test and $32.5 million was related to the amortization of the U.S. DoD Advance. There were no sales to the U.S. DoD during the three month ended September 30, 2020 because we entered into our agreement with U.S. DoD in October 2020.

Cost of Product Revenue increased to $88.6 million in the three months ended September 30, 2021, from $2.6 million in the three months ended September 30, 2020. This increase was primarily due to the fact that we did not incur cost of product revenue until we began to generate product revenue in August 2020 after receiving our first FDA EUA in June 2020. Our product gross profit margin, or product gross profit as a percentage of product revenue was approximately 60% in the three months ended September 30, 2021 compared to approximately (24)%, in the three months ended September 30, 2020. This increase was primarily due to higher absorption of fixed costs related to higher production volumes and efficiencies.

Sales and Marketing Expense increased to $5.6 million in the three months ended September 30, 2021 from $0 in the three months ended September 30, 2020. This increase was due to the launch of our COVID-19 test in August 2020 and increased sales and marketing personnel costs to support the expected growth and demand for our products, higher expenses related to digital marketing services and increased headcount to support the growth of our business.

Research and Development Expense increased to $9.1 million in the three months ended September 30, 2021, from $6.9 million in the three months ended September 30, 2020. This increase was primarily driven by higher research and

development spend associated new product development and early costs related to upcoming clinical studies for 510(k) approval of our COVID-19 and influenza tests. Subsequent to September 30, 2021, our COVID-19 clinical study enrolled its first participants.

General and Administrative Expense increased to $33.1 million in the three months ended September 30, 2021 from $3.7 million in the three months ended September 30, 2020. This increase was primarily related to an increase in stock-based compensation expenses, legal, banking, headcount growth to build out central team, accounting and other consulting-related costs to support our growing business and prepare us to operate as a public company after our IPO in September 2021.

Interest Expense increased to $1.8 million in the three months ended September 30, 2021 from ($0.5) million in the three months ended September 30, 2020. This increase was primarily driven by $1.7 million of interest expense related to our Convertible Notes.

Change in Fair Value of Convertible Notes was $36.3 million and $0 in the three months ended September 30, 2021 and 2020, respectively, reflecting fair value adjustments associated with the Convertible Notes issued by us in May 2021.

Income Tax Expense increased to $30.1 million in the three months ended September 30, 2021 from $0 in the three months ended September 30, 2020, and our effective tax rate was 61% in the three months ended September 30, 2021, compared to 0% in the three months ended September 30, 2020. The increase in our provision and effective tax rate was primarily due to the current tax liability arising from an increase in income from operations which exceeded available net operating loss carryforwards and the discrete impacts of the non-deductible adjustments associated with the convertible notes that were issued in May 2021 and the forgiveness of the promissory notes. The deduction related to the forgiveness of the promissory notes has limitations applied under Section 162(m) of the Internal Revenue Code. The California Competes Tax Credit will be reflected as a benefit when certified annually which did not occur during the three months ended September 30, 2021. Substantially all of our deferred tax assets continue to maintain a valuation allowance.

Comparison of the Nine Months Ended September 30, 2021 and 2020

The following table sets forth a summary of our results of operations for the nine months ended September 30, 2021 and 2020 and the changes between periods:

	Nine Months Ended September 30,			
	2021	**2020**	**$ Change**	**% Change**
(dollars in thousands)		**(unaudited)**		
Revenue:				
Product revenue	$ 424,516	$ 2,128	$ $ 422,388	19,849 %
Grant and other revenue	1,085	7,562	(6,477)	(86)%
Total revenue	425,601	9,690	415,911	4,292 %
Operating costs and expenses:				
Cost of product revenue	173,746	2,641	171,105	6,479 %
Sales and marketing	7,531	64	7,467	11,667 %
Research and development	21,150	26,558	(5,408)	(20)%
General and administrative	56,336	7,458	48,878	655 %
Total operating costs and expenses	258,763	36,721	222,042	605 %
Income (loss) from operations	166,838	(27,031)	193,869	(717)%
Interest expense	(9,752)	(274)	(9,478)	3,459 %
Change in fair value of redeemable convertible preferred stock warrants	53	—	53	n.m
Change in fair value of convertible notes	(59,560)	—	(59,560)	n.m
Loss on extinguishment of debt	(1,998)	(610)	(1,388)	228 %
Other income (expense), net	(19)	99	(118)	(119)%
Net income (loss) before income taxes	95,562	(27,816)	123,378	(444)%
Income tax expense	43,374	—	43,374	n.m
Net income (loss)	$ 52,188	$ (27,816)	$ 80,004	(288)%
Net income (loss) per share attributable to common stockholders – diluted	$ 0.35	$ (1.72)	—	(120)%

n.m. = not meaningful

Revenue increased to $425.6 million in the three months ended September 30, 2021, from $9.7 million in the nine months ended September 30, 2020. This increase was due to an increase of sales to commercial customers of $126.7 million and an increase in U.S. government revenue of $295.7 million in the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020. The amortization of the U.S. DoD Advance was $74.7 million in the nine months ended September 30, 2021. We did not commence sales to the U.S. government until October 2020.

Cost of Product Revenue increased to $173.7 million in the three months ended September 30, 2021, from $2.6 million in the nine months ended September 30, 2020. This increase was primarily due to the fact that we did not incur cost of product revenue until we began to generate product revenue in August 2020 after receiving our first FDA EUA in June 2020. Our product gross profit margin, or product gross profit as a percentage of product revenue was approximately 59% in the nine months ended September 30, 2021 compared to approximately (24)% in the nine months ended September 30, 2020. This increase was primarily due to higher absorption of fixed costs related to higher production volumes and efficiencies.

Sales and Marketing Expense increased to $7.5 million in the three months ended September 30, 2021, from $0.1 million in the nine months ended September 30, 2020. This increase in both the three and nine months ended September 30, 2021 was due to the launch of our COVID-19 test in August 2020 and increased sales and marketing personnel costs to support the expected growth and demand for our products, higher expenses related to digital marketing services and increased headcount to support the growth of our business
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Research and Development Expense decreased to $21.2 million in the three months ended September 30, 2021, from $26.6 million in the nine months ended September 30, 2020. This decrease was primarily due to the continued shift of our manufacturing-related depreciation and amortization into cost of product revenue upon receipt of the FDA EUA for our COVID-19 test

General and Administrative Expense increased to $56.3 million in the three months ended September 30, 2021, from $7.5 million in the nine months ended September 30, 2020. This increase was primarily related to an increase in legal fee increases, payroll expenses, office expenses, to build out central team, accounting and other consulting-related costs to support our growing business and prepare us to operate as a public company after our IPO in September 2021.

Interest Expense increased to $9.8 million in the three months ended September 30, 2021, from $0.3 million in the nine months ended September 30, 2020. This increase was driven by the termination of our Revolving Credit Agreement, which required us to pay a fee of $1.3 million, equal to 1.00% of the amount of the outstanding revolving commitment. We also wrote-off issuance costs of $0.7 million and incurred issuance costs of $6.0 million related to the issuance of our Convertible Notes in May 2021. Interest expense was $1.7 million related to the Convertible Notes during the nine months ended September 30, 2021.

Change in Fair Value of Convertible Notes was $59.6 million and $0 in nine months ended September 30, 2021 and 2020, respectively reflecting fair value adjustments associated with the Convertible Notes issued by us in May 2021. We did not incur any gains or losses associated with changes in fair value of the Convertible Notes during the nine months ended September 30, 2020 as the Convertible Notes were not outstanding during that period.

Income Tax Expense increased to $43.4 million in the nine months ended September 30, 2021 from $0 in the nine months ended September 30, 2020, and our effective tax rate was 45% in the nine months ended September 30, 2021, compared to 0% in the nine months ended September 30, 2020. The increase in our provision and effective tax rate was primarily due to the current tax liability arising from an increase in income from operations which exceeded available net operating loss carryforwards and the discrete impacts of the non-deductible adjustments associated with the convertible notes that were issued in May 2021 and the forgiveness of the promissory notes. The deduction related to the forgiveness of the promissory notes has limitations applied under Section 162(m) of the Internal Revenue Code. The California Competes Tax Credit will be reflected as a benefit when certified annually which did not occur during the nine months ended September 30, 2021. Substantially all of our deferred tax assets continue to maintain a valuation allowance.

Non-GAAP Financial Measures

We supplement the reporting of our financial information determined under accounting principles generally accepted in the United States, or GAAP, with certain non-GAAP financial measures, adjusted net income and adjusted net income per diluted share, or Adjusted Diluted EPS. We believe these non-GAAP financial measures provide meaningful information to assist investors and shareholders in understanding our financial results and assessing our prospects for future performance. Management believes the adjusted measures described above are important indicators of our operations because they exclude items that may not be indicative of or are unrelated to our core operating results and provide a baseline for analyzing trends in our underlying businesses. Management uses these non-GAAP financial measures for reviewing the operating results and analyzing potential future business trends in connection with our budget process on these non-GAAP financial measures. To measure earnings performance on a consistent and comparable basis, we exclude certain items that affect the comparability of operating results and the trend of earnings. These adjustments are irregular in timing and may not be indicative of our past and future performance.

For the Three and Nine Months Ended September 30, 2021

Because non-GAAP financial measures are not standardized, it may not be possible to compare these financial measures with other companies' non-GAAP financial measures having the same or similar names. These adjusted financial measures should not be considered in isolation or as a substitute for reported net income and net income per diluted share, the most directly comparable GAAP financial measures. Our non-GAAP financial measures are an additional way of viewing aspects of our operations when viewed with our GAAP results and the reconciliations to corresponding GAAP financial measures below.

Banking and finance-related items consist of (i) banking and finance fees associated with the issuance of Convertible Notes; (ii) early extinguishment of debt costs; and (iii) fees associated with our termination of our Revolving Credit Agreement. Since such fees and costs can be material, are irregular and often mask underlying operating performance, we excluded such amounts for purposes of calculating adjusted net income and Diluted EPS for the three and

nine months ended September 30, 2021, as they may not be indicative of our past and future performance and we believe excluding such amounts may assist investors in their evaluation of our current operating performance.

The Convertible Notes issued by us in May 2021 were recorded at fair value. We excluded the impact of fair value changes to arrive at adjusted net income (loss) as it is valued based on probability weighted scenarios regarding potential future financing scenarios that may not be indicative of our past and future performance and to assist in the evaluation of our current operating performance.

In September 2021, our board of directors approved the forgiveness of certain promissory notes with our founders.

The reconciliations of net income (loss) (GAAP) and Diluted EPS to adjusted net income (loss) (non-GAAP) and adjusted Diluted EPS were calculated as follows for the three months and nine months ended September 30, 2021:

	Three Months Ended September 30,			
	2021		2020	
	Dollar Amount	Per Diluted Share	Dollar Amount	Per Diluted Share
	(unaudited)			
Net income (loss)/diluted EPS	$ 19,348	$ 0.13	$ (8,538)	$ (0.52)
Fair value adjustment of convertible notes	36,306	0.29	—	—
Forgiveness of promissory notes[1]	12,880	0.11	—	—
Tax effects[2]	(1,458)	—	—	—
Adjusted net income (loss)/adjusted diluted EPS	$ 67,076	$ 0.52	$ (8,538)	$ (0.52)

(1) Represents stock-based compensation expense related to the forgiveness of promissory notes subject to restricted stock purchase agreements with certain executives. The forgiveness of the promissory notes resulted in the modification of the stock option accounting applied to the shares underlying these agreements. See Note 13, *Stock-based Compensation*, to our unaudited interim condensed financial statements included elsewhere in this quarterly report.

(2) Represents the tax impact with respect to the adjustments noted above. We applied an estimated annual effective tax rate of 27% to amounts deductible for tax purposes to estimate the tax effects. The charges related to the convertible notes and the portion of the forgiveness of promissory notes limited by Internal Revenue Code Section 162(m) were not deductible for income tax purposes and were excluded from the tax effects above. Also includes additional tax effects related to banking and financing-related items that became deductible upon the IPO during the 3 months ended September 30, 2021, and conforming the year-to-date tax effects to the estimated annual effective tax rate of 27%.

	Nine Months Ended September 30,			
	2021		2020	
	Dollar Amount	Per Diluted Share	Dollar Amount	Per Diluted Share
	(unaudited)			
Net income (loss)/diluted EPS	$ 52,188	$ 0.35	$ (27,815)	$ (1.72)
Fair value adjustment of convertible notes	59,560	0.49	—	—
Banking and financing-related items	7,998	0.06	—	—
Forgiveness of promissory notes	12,880	0.10	—	—
Tax effects[1]	(2,274)	(0.02)	—	—
Adjusted net income (loss)/adjusted diluted EPS	$ 130,352	$ 0.98	$ (27,815)	$ (1.72)

(1) Represents the tax impact with respect to the adjustments noted above. We applied an estimated annual effective tax rate of 27% to amounts deductible for tax purposes to estimate the tax effects. The charges related to the convertible notes and the portion of the forgiveness of promissory notes limited by Internal Revenue Code Section 162(m) were not deductible for income tax purposes and were excluded from the tax effects above. Also includes additional tax effects related to banking and financing-related items that became deductible upon the IPO during the 3 months ended September 30, 2021, and conforming the year-to-date tax effects to the estimated annual effective tax rate of 27%.

Convertible Notes

In May 2021, we issued and sold convertible promissory notes, or Convertible Notes, for net proceeds of $229.5 million. The Convertible Notes accrue interest at a simple rate of 3.0% per annum during the first 12-month period and will accrue interest at a simple rate of 9.0% per annum thereafter.

The Convertible Notes will be converted into shares of our common stock at the then effective conversion price in the case of a qualified going public transaction: (a) an IPO, (b) a SPAC combination, or (c) a direct listing. If we close an equity financing with gross proceeds of not less than $50.0 million, then the Convertible Notes, unless previously converted into shares of our common stock, will automatically convert into shares of the same class and series of our capital stock issued to investors in such equity financing. The conversion price with respect to a qualified conversion event, which would be a qualified going public transaction or an equity financing, will incorporate the applicable discount: (i) a 20.0% discount if the qualified conversion event is consummated on or prior to September 30, 2021, and (ii) a 25.0% discount if the qualified conversion event is consummated after September 30, 2021. For additional information, see the section titled “Capitalization—2021 Convertible Notes.”

In the event of certain corporate transactions prior to the conversion of the Convertible Notes or the repayment of the Convertible Notes, each purchaser, in its discretion, shall have the right either (a) to convert, effective immediately prior to the closing of the corporate transaction, all, but not less than all, of the outstanding principal amount of a Convertible Note and all accrued and unpaid interest on such Convertible Note immediately prior to the closing of a corporate transaction into shares of common stock at the then effective conversion price, or (b) be paid an amount equal to the sum of 1.75 times the outstanding principal amount of a Convertible Note and all accrued and unpaid interest of such Convertible Note immediately prior to the closing of a corporate transaction.

The Convertible Notes include customary events of default. In the event of any default under the Convertible Notes, the interest rate then in effect shall be increased by 3.0%, and then by an additional 3.0% each year thereafter, so long as such event of default continues.

Upon completion of the IPO, outstanding Convertible Notes in the principal amount of $235.5 million and accrued interest as of September 27, 2021 of $2.7 million were automatically converted into 18,611,914 shares of common stock.

Liquidity and Capital Resources

Overview

As of September 30, 2021, we held $446.6 million of cash and cash equivalents as a result of our IPO proceeds and other financing activities. Our primary cash needs are for the funding of day-to-day operations, financing capital investments and to address our working capital needs. Our largest source of operating cash generation is from sales to our customers. Our primary uses of cash from operating activities are for personnel-related expenses, material and supply costs for manufacturing, direct costs to deliver our products, and sales and marketing expenses and research and development initiatives.

Based on our current business plan, we believe our anticipated operating cash flows, together with our existing cash and cash equivalents, will be sufficient to meet our working capital and capital expenditure requirements for at least the next 12 months.

We expect that our near and longer-term liquidity requirements will consist of working capital and general corporate expenses associated with the growth of our business, including, without limitation, expenses associated with scaling up our operations and continuing to increase our manufacturing capacity, sales and marketing expense associated with rollout of our over-the-counter, at home COVID-19 test to commercial customers, including directly to consumers, increasing market awareness of our platform and brand generally to individual consumers, enterprises and other target customers, additional research and development expenses associated with expanding our care offerings, expenses associated with continuing to build out our corporate infrastructure and expenses associated with being a public company. Our short-term capital expenditure needs relate primarily to the ongoing build out of our manufacturing facilities, and we expect such expenditures to continue throughout 2021. Notwithstanding potential additional capital expenditures related to levels of higher growth or potential global expansion, we expect our capital expenditures to decrease in 2022 and 2023 from 2021 levels.

Revolving Line of Credit

In February 2021, we entered into the Revolving Credit Agreement. In connection with our entering into the Revolving Credit Agreement, we repaid outstanding amounts of $5.4 million and terminated our prior loan and security agreement with Comerica Bank, or the 2015 Credit Agreement, that we initially entered into in May 2015. The 2015 Credit Agreement, as amended, provided for a revolving line with a credit extension of up to $4.0 million and a Growth Capital A Line with a credit extension of up to $6.0 million. The Revolving Credit Agreement provided for a revolving credit facility with an aggregate maximum principal amount of $130.0 million and a letter of credit subfacility of $20.0 million. In June 2021, we terminated the Revolving Credit Agreement and we were required to pay a fee equal to 1.00% of the amount of the outstanding revolving commitment. Upon agreement with East West Bank and the other lenders to the Revolving Credit Agreement, we are keeping in place our outstanding letter of credit in the amount of $6.0 million, which will be cash collateralized. All other obligations under the Revolving Credit Agreement have otherwise been terminated.

Cash Flows

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

	Nine Months Ended September 30,	
	2021	2020
(dollars in thousands)	(unaudited)	
Net cash, cash equivalents and restricted used in by operating activities	$ (18,298)	$ (59,245)
Net cash, cash equivalents and restricted cash used in investing activities	(78,161)	(7,008)
Net cash, cash equivalents and restricted cash provided by financing activities	425,793	102,599
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 329,334	$ 36,346

Cash Flows Provided Used in Operating Activities

Net cash, cash equivalents and restricted cash used in operating activities was $18.3 million in the nine months ended September 30, 2021, primarily reflecting our net income of $52.2 million, net of non-cash cost items and changes in operating working capital. Non-cash cost adjustments were primarily driven by the change in fair value of the Convertible Notes of $59.6 million and depreciation and amortization expenses of $26.1 million. Non-cash deferred revenue of $74.7 million was recognized during the period. The timing of our revenue and collections increased our accounts receivable. The expected increase in demand for our products drove the increase in inventory and prepaid expenses and other assets.

Net cash, cash equivalents and restricted cash used in operating activities was $59.2 million in the nine months ended September 30, 2020, primarily due to increases in inventory and prepaid expenses and other current assets of $11.5 million, and $24.8 million, respectively, related to the commencement of product manufacturing and expansion of production facilities and manufacturing capacity.

Cash Flows Used in Investing Activities

Net cash, cash equivalents and restricted cash used in investing activities was $78.2 million for the nine months ended September 30, 2021, reflecting purchases of property and equipment to expand our production capabilities of our COVID-19 Test Kits in relation to the U.S. DoD Agreement and our commercial customers.

Net cash, cash equivalents and restricted cash used in investing activities was $7.0 million in the nine months ended September 30, 2020, primary reflecting purchases of property and equipment to expand our R&D and production capabilities.

Cash Flows Provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2021 of $425.8 million was primarily driven by $230.0 million in gross proceeds from our IPO and $235.5 million in gross proceeds from the issuance and sale of Convertible Notes.

Net cash, cash equivalents and restricted cash provided by financing activities was $102.6 million for the nine months ended September 30, 2020, primarily reflecting proceeds received from our issuance of Series C redeemable convertible preferred stock in June 2020.

Commitments and Contingencies

See Note 16, *Commitments and Contingencies*, to our unaudited interim condensed financial statements included elsewhere in this quarterly report for a summary of our commitments as of September 30, 2021. Our material cash commitments at September 30, 2021 related to finance leases of manufacturing equipment totaling $6.5 million, real estate leases under non-cancelable operating lease agreements in the amount of $69.9 million, that expire at various dates through 2031 and a legal settlement of a contract dispute totaling $9.0 million, of which $4.5 million has not been paid. We expect to fund these commitments using our existing cash on hand.

As of September 30, 2021, we had an outstanding letter of credit of $12.0 million with East West Bank. This is reflected on the balance sheet as restricted cash.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based upon our financial statements included elsewhere in this report, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities, as well as the reported income generated, and expenses incurred during the reporting periods. We base these estimates and judgments on historical experience, the current economic environment and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ materially from these estimates and judgments.

We believe the following accounting policies and estimates are most critical to an understanding of our financial statements. Policies and estimates are considered to be critical if they meet both of the following criteria: (i) involve a significant level of estimation uncertainty, and (ii) have had or are reasonably likely to have a material impact on our financial condition or results of operations. For a detailed discussion on the application of these and other accounting policies and estimates, please refer to Note 2 to our financial statements.

Deferred Revenue Recognition

We recorded the U.S. DoD Advance as deferred revenue and recognize this liability upon satisfaction of our performance obligations to the U.S. DoD by reference to estimated future performance obligations of a follow-on agreement with the U.S. DoD and the related expected contract consideration. Changes in the assumptions used in our estimate of the future contract with the U.S. DoD, including the future pricing and the projected term of the contract and quantities purchased, may have a material impact on the timing of recognition of deferred revenue.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset or an asset group may not be recoverable. If such triggering event is determined to have occurred, the asset's or asset group's carrying value is compared to the future undiscounted cash flows expected to be generated. If the carrying value exceeds the undiscounted cash flows of the asset, then an impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value.

These analyses require management to make judgments and estimates about future revenue, expenses, market conditions and discount rates related to these assets. Management's assessment of whether or not a triggering event has occurred is an area of significant judgment. Additionally, if actual results are not consistent with management's estimates and assumptions, the carrying value of our long-lived assets may be overstated and a charge would need to be taken against net earnings which would adversely affect our financial statements. There were no impairment indicators during, and no impairments were recorded in the three and nine months ended September 30, 2021 and 2020.

Deferred Tax Assets (and Related Valuation Allowance)

We recognize net deferred tax assets to the extent that we believe these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future

reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If we determine that deferred tax assets may be able to be recognized in the future in excess of their net recorded amount, the deferred tax asset valuation allowance would be adjusted, which would reduce the provision for income taxes. We record uncertain tax positions on the basis of a two-step process whereby (i) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority.

This requires management to make judgments and estimates regarding: (i) the timing and amount of the reversal of taxable temporary differences; (ii) expected future taxable income; and (iii) the impact of tax planning strategies. Future changes to tax rates would also impact the amounts of deferred tax assets and liabilities and could adversely affect our financial statements. All of our deferred tax assets as of December 31, 2020, were fully offset by a valuation allowance.

As of September 30, 2021, we continue to maintain a full valuation allowance on the remaining net deferred tax asset until there is sufficient evidence to support the reversal of all or an additional portion of the allowance. However, given anticipated future earnings and anticipated deferred tax liabilities, we believe that there is a reasonable possibility that by December 31, 2022, sufficient positive evidence may become available to allow us to reach a conclusion that a significant portion of the valuation allowance will no longer be needed. Release of the valuation allowance would result in the recognition of certain deferred tax assets and a decrease to income tax expense for the period the release is recorded. However, the exact timing and amount of the valuation allowance release are subject to change on the basis of the level of profitability that we are able to actually achieve the valuation allowance will no longer be needed. Release of the valuation allowance would result in the recognition of certain deferred tax assets and a decrease to income tax expense for the period the release is recorded. However, the exact timing and amount of the valuation allowance release are subject to change on the basis of the level of profitability that the Company is able to actually achieve.

Stock-Based Compensation

We measure stock-based compensation expense for stock options granted to our employees and directors on the date of grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally three to four years. Our stock-based payments include stock options. Stock-based compensation expense is recognized over the requisite service period, which is generally the vesting period, on a straight-line basis. Forfeitures are recorded as they occur.

We estimate the fair value of stock options granted to our employees and directors on the grant date, and the resulting stock-based compensation expense, using the Black-Scholes-Merton, or BSM, option pricing model. The BSM option-pricing model requires the use of subjective assumptions which determine the fair value of stock option awards. These assumptions include:

- Fair Value of Common Stock. Our board of directors determines the fair market value of our common stock based on its closing price as reported on the date of grant on the Nasdaq.
- Expected Term. The expected term of options represents the period of time that options are expected to be outstanding. Our historical stock option exercise experience does not provide a reasonable basis upon which to estimate an expected term due to lack of sufficient data. We estimate the expected term by using the simplified method, which calculates the expected term as the average of the time-to-vesting and the contractual life of the options.
- Expected Volatility. As there has been no public market for our common stock prior to the IPO, and we have a limited trading history of our common stock, expected volatility incorporates the historical volatility over the expected term of the award of comparable companies whose share prices are publicly available. The comparable companies are chosen based on their similar size, stage in the life cycle or area of specialty.
- Risk-Free Interest Rate. The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the stock option grants.
- Expected Dividend Yield. We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we use an expected dividend yield of zero.

We will continue to use judgment in evaluating the expected terms, expected volatility, risk-free interest rates and expected dividend yields utilized for our stock-based compensation calculations on a prospective basis. Assumptions we used in applying the BSM option pricing model to determine the estimated fair value of our stock options granted involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our equity-based compensation could be materially different.

For stock-based compensation awards with both performance and market-condition vesting, such as restricted stock units, cost is measured at the grant date, based on the fair value of the award considering the market conditions, and recorded over the requisite service period if the performance condition is probable. The Company estimates the fair value of stock-based payment awards considering the market conditions on the date of grant using a Monte Carlo simulation model.

We recorded stock-based compensation expense of $20.0 million and $25.6 million for the three and nine months ended September 30, 2021. As of September 30, 2021, there was $12.6 million of unamortized compensation cost. Stock-based compensation expense was $145.0 million and $242.0 million for the three and nine months ended September 30, 2020. We expect to continue to grant stock options and other equity-based awards in the future, and to the extent that we do, we expect our stock-based compensation expense recognized in future periods will likely significantly increase.

Product Warranty Reserve

We provide our customers with the right to receive a replacement of defective or nonconforming Cue Readers for a period of up to twelve months from the date of shipment. Although no explicit warranty is provided for Cue Cartridges, we may replace Cue Cartridges that result in invalid test results. Provisions for estimated expenses related to product warranty are made at the time products are sold. These estimates are determined using historical information that include testing failure rates, the frequency and probability of replacement units being requested, and the overall cost of replacement units. We evaluate the reserve quarterly and make adjustments when appropriate. Changes to testing failure rates, the overall cost of replacement units and replacement rates could have a material impact on our estimated liability. At September 30, 2021 and December 31, 2020, the product warranty reserve was $6.2 million and $0, respectively.

Recently Adopted and Issued Accounting Pronouncements

Recently issued and adopted accounting pronouncements are described in Note 2 to our financial statements included elsewhere in this document.

Emerging Growth Company Status

We are an “emerging growth company” (as defined in the JOBS Act). Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected to use this extended transition period under the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies who have adopted new or revised accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks 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. To date, we have not been exposed to material risks related to market instruments in the ordinary course of our business, but we may in the future.

Interest Rate Risk

As of September 30, 2021, we had cash, cash equivalents and restricted cash of $458.6 million primarily from net proceeds of our IPO and other financing activities. The goals of our investment policy are liquidity and capital preservation and we do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash and cash equivalents.

Foreign Currency Exchange Risk

All of our employees and our operations are currently located in the United States and our expenses and payment obligations are denominated in and have been satisfied with U.S. dollars. There was no foreign currency risk for the three and nine months ended September 30, 2021. In the future, our sales may be denominated in foreign currencies and to the extent they are, we will be subject to foreign currency transaction gains or losses. To date, we have had no foreign currency transaction gains and losses, and we have not had a formal hedging program with respect to foreign currency. We believe a hypothetical 10% increase or decrease in exchange rates during any of the periods presented would not have a material effect on our financial statements included elsewhere in this prospectus.

Item 4. Controls and Procedures

Evaluation of Disclosure and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. In addition, they are designed to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, as appropriate to allow timely decisions regarding required disclosure. Pursuant to in Rules 13(a)-13(e) and 15(d)-15(e) under the Exchange Act, our management, with the participation of our CEO and CFO, performed an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation and as a result our material weaknesses previously identified and further discussed below, the CEO and CFO concluded that our disclosure controls and procedures were not effective at a reasonable assurance level as of September 30, 2021.

Material Weakness

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. In connection with the audits of our 2019 and 2020 annual financial statements, we identified material weaknesses in internal controls pertaining to information technology general controls, a lack of segregation of duties, documentation and design of formalized processes and procedures, insufficient complement of qualified resources with an appropriate level of knowledge, experience and training important to our financial reporting requirements, timely reconciliation and analysis of certain key accounts and the review of journal entries. These material weaknesses could result in material misstatements of our financial statement account balances or disclosures of our annual or interim financial statements that would not be prevented or detected. We have concluded that these material weaknesses in our internal controls over financial reporting occurred because, prior to the IPO, we were a private company and did not have the internal controls necessary to satisfy the accounting and financial reporting requirements of a public company.

We began to take steps to address our material weaknesses through our remediation plan, which included the hiring of advisors in the fourth quarter of 2020 and a Chief Financial Officer in the first quarter of 2021 and the hiring of a Vice President and Treasurer in the second quarter of 2021, and the continued engagement of additional external advisors to provide financial accounting assistance in the short term. We have substantially grown our team and are in the process of hiring additional personnel to improve the segregation of duties in our financial closing and reporting process and timely review of key accounts and journal entries. In addition, we have engaged external advisors to evaluate and document the design and operating effectiveness of our internal controls and assist with the remediation and implementation of our internal controls as required. We are evaluating the longer-term resource needs of our various financial functions and plan to significantly expand the size of the financial organization to help address these weaknesses.

We and our independent registered public accounting firm were not required to, and did not, perform an evaluation of our internal controls over financial reporting as of December 31, 2020 or any prior period in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses. Material weaknesses may still exist when we report on the effectiveness of our internal controls over financial reporting as required under Section 404 of the Sarbanes-Oxley Act.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we are or may become involved in legal proceedings. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors, and there can be no assurances that favorable outcomes will be obtained.

In February 2018, the staff of the U.S. Securities and Exchange Commission's Division of Enforcement issued a subpoena to us requesting certain documents and information. The SEC's subpoena called for the production of documents and information, including documents and information related to one of our prior private financing rounds. We have been cooperating fully with the SEC's investigation. At this time, however, we cannot predict the outcome of this investigation as to us or our officers, nor can we predict the timing associated with any such conclusion or resolution. Based on information currently known to us, we do not believe the SEC's investigation will have a material adverse effect on our business, financial condition or results of operations. However, we cannot assure you that we will not be required to devote significant time or resources to resolving the SEC investigation, or that the ultimate resolution of the investigation will not have a material adverse effect on our business, financial condition or results of operations.

We are not currently a party to any other legal proceedings that we believe may have a material adverse effect on our business, financial condition or results of operations.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our unaudited financial statements and related notes, before making a decision to invest in our common stock. Our business, results of operations, financial condition or prospects could also be harmed by risks and uncertainties that are not presently known to us or that we currently believe are not material. If any of the risks actually occur, our business, results of operations and financial condition could be adversely affected. In that event, the market price of our common stock could decline, and you could lose all or part of your investment.

Summary Risk Factors

The following summarizes the most material risks that make an investment in our securities risky or speculative. If any of the following risks occur or persist, our business, financial condition, results of operations and prospects could be materially harmed and the market price of our common stock could significantly decline:

- We have a limited operating history, which may make it difficult to evaluate our current business and predict our prospects and likelihood of success.
- We have incurred significant losses since our inception, and only recently started generating revenue from commercial sales. We may incur additional significant losses in the future, and we may never become profitable on a sustainable basis.
- If the FDA or other regulatory bodies revoke or terminate our EUAs or other regulatory authorizations for our COVID-19 test, we will be required to stop commercialization of our Cue Readers and COVID-19 Test Kits unless we can obtain 510(k) or other clearance or approval for our COVID-19 test and its currently authorized uses.
- Our near-term success is dependent on the continued commercialization of our COVID-19 test. If our COVID-19 test is unable to attain or maintain market acceptance or be successfully commercialized, our business could be materially adversely affected.
- Our long-term success will depend on the success of our COVID-19 test and a number of other factors, including widespread market adoption of our Cue Health Monitoring System, Cue Virtual Care Delivery Apps and the overall Cue Integrated Care Platform and our ability to introduce new tests for use with our Cue Health Monitoring System.
- Our revenue for at least the near term will almost exclusively depend on sales of our COVID-19 test until we can develop, obtain regulatory clearance or other appropriate authorization for, and commercialize additional tests.

- We currently rely upon the U.S. DoD and a very small number of other customers for almost all of our current product revenue. As a result, unless and until we can further diversify our customer base and sources of revenue, the loss of any of these customers, or a decline in the amount of our COVID-19 tests purchased by or sold to these customers, could materially adversely affect our business, financial condition and results of operations.

- We may encounter difficulties in managing our growth, which could adversely affect our operations.

- The diagnostic testing market is extremely competitive and rapidly evolving, making it difficult to evaluate our business and future prospects.

- If the Cue Health Monitoring System fails to achieve broad adoption by or support from the medical and professional community, key opinion leaders and other key participants in the healthcare system, our business and prospects may be materially adversely affected.

- We have identified material weaknesses in our internal control over financial reporting and may identify material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, as a result of which, 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.

- The COVID-19 pandemic could materially adversely affect our business, financial condition and results of operations.

- We have limited experience manufacturing our products in commercial quantities; if we are unable to manufacture our products in the required quantities in a timely manner, our business could be materially adversely affected.

- If we, our suppliers or our contract manufacturers experience significant disruptions to our or their manufacturing capabilities or ability to source needed supplies and materials, our business may be materially adversely affected.

- Our patent or other intellectual property protection for the Cue Health Monitoring System, products and Cue Integrated Care Platform may not be sufficient to prevent competitors from developing and commercializing tests and platforms similar to or otherwise comparable to our Cue Test Kits, products and Cue Integrated Care Platform, which could materially adversely affect our business and prospects.

Risks Related to Our Business and Strategy

We have a limited operating history, which may make it difficult to evaluate our current business and predict our prospects and likelihood of success.

We have a limited operating history. We were incorporated in 2010, but prior to commercialization of our COVID-19 Test Kit for use with our Cue Health Monitoring System in the third quarter of 2020, our activities were largely focused on our research and development efforts and we only started realizing revenue from commercial product sales in August 2020. Our COVID-19 test is currently our only commercially available test. Our limited commercial operating history may make it difficult to evaluate our current business and predict our future performance. Any assessment of our future revenue potential, profitability or prospects for our future success is subject to significant uncertainty. We have encountered and will continue to encounter significant risks and difficulties frequently experienced by early commercial-stage companies in rapidly evolving industries. If we do not address these risks successfully, it could have a material adverse effect on our business, financial condition, results of operations and future prospects.

We have incurred significant losses since our inception, and only recently started generating revenue from commercial sales. We may incur additional significant losses in the future, and we may never become profitable on a sustainable basis.

We have incurred significant losses since our inception in 2010, including net losses of $20.6 million and $47.4 million for the years ended December 31, 2019 and 2020, respectively. For the nine months ended September 30, 2021, we had a net income of $52.2 million. As of September 30, 2021, we had an accumulated deficit of $58.2 million. While we were profitable for the first time in the first half of 2021, we cannot assure you that we will be able to continue to be profitable on an ongoing basis, either in the near term or longer term. In connection with our IPO we incurred incremental non-cash charge of $38.0 million as a result of the automatic conversion of our Convertible Notes issued in May 2021. Approximately $62.3 million of discount on these notes that were partially offset by the $59.6 million of noncash expense relating to the change in the fair value of the Convertible Notes that was recognized in our statements of operations for the nine months ended September 30, 2021. We recognized approximately $12.9 million of non-cash stock-based compensation expense related to the forgiveness of certain promissory notes from our executives. We recognized this non-

cash stock-based compensation expense in the period in which our IPO was completed. Of the non-cash items described above, charges related to Convertible Notes were not tax deductible. As a result of these noncash charges, we had a net income of $19.3 for the quarter in which our IPO was completed. We may continue to incur losses both in the near term and longer term as we continue to invest significant additional funds to scale up our business, including continuing to build out our commercial organization and corporate infrastructure, continuing to build out our manufacturing capabilities and engaging in continued research and development as we work to expand our menu of available tests and also as we incur additional costs associated with operating as a public company. Prior to August 2020, we had never generated any revenue from the commercial sale of products, and we had devoted substantially all of our resources to the research and development of our Cue Health Monitoring System. We only first started realizing revenue from commercial product sales in August 2020 following receipt of our first Emergency Use Authorization, or EUA, from the U.S. Food and Drug Administration, or FDA, in June 2020 for our COVID-19 test. Our COVID-19 test includes a Cue Reader and a COVID-19 Test Kit comprised of a Cue COVID-19 Cartridge and a Cue Wand. Since receiving our first FDA EUA, we have incurred significant additional expenses in connection with the commercial scale up of our business, including costs associated with scaling up our manufacturing operations, costs associated with the production of our COVID-19 test, sales and marketing expenses, and costs associated with the hiring of new employees, the growth of our business and building out our corporate infrastructure. In addition, we will incur significant additional expenses as a public company, further grow our business and continue to roll out our COVID-19 tests to the marketplace, pursue new customers and look to develop and commercialize new tests and other products for use with our Cue Integrated Care Platform. Therefore, our losses may continue to increase for at least the near term, if not longer. We are unable to predict whether or when we will become profitable on a sustained basis. Our ability to sustain profitability is based on numerous factors, many of which are beyond our control, including, among other factors, market acceptance of our products, the length of the COVID-19 pandemic, future product development, our market penetration and margins and our ability to expand our menu of tests. We may not be able to sustain or increase profitability in the future. Our inability to achieve and maintain profitability, whether in the near term or longer term, may make it difficult to continue to grow our business and accomplish our strategic objectives, and could materially adversely affect our business, financial condition, results of operations and future prospects.

If the FDA or other regulatory bodies revoke or terminate our EUAs or other regulatory authorizations for our COVID-19 test, we will be required to stop commercialization of our Cue Readers and COVID-19 Test Kits unless we can obtain 510(k) or other clearance or approval for our COVID-19 test and its currently authorized uses.

Our COVID-19 test is currently marketed in the United States pursuant to two EUAs we received from the FDA in June 2020, for point-of-care use, and in March 2021, for at-home and over-the-counter use without a prescription. We cannot predict how long either of these EUAs will remain in effect, and we may not receive advance notice from the FDA regarding revocation of either or both of our EUAs. If our EUAs are terminated or revoked, we will be required to cease commercialization of our COVID-19 Test Kit, unless and until we have obtained marketing authorization from the FDA through another regulatory pathway. In addition, changing policies and regulatory requirements could require us to obtain a 510(k) or other marketing authorization from the FDA for our COVID-19 test, which could limit, delay or prevent further commercialization of our COVID-19 Test Kit and could materially adversely impact our business, financial condition, results of operations and future prospects.

We also received Interim Order authorization from Health Canada for professional use in April 2021. We have begun commercialization activity in Canada, distributing to professional users. In August 2021, we received an amendment to the Interim Order authorization from Canada Health to include self-testing, which is similar to our EUA over-the-counter authorization in the United States. If the Interim Order authorization is revoked or terminated, we would lose our ability to expand into the Canadian market and would need to obtain additional authorization or approvals before we are permitted to sell any of our current or future products.

Our near-term success is dependent on the continued commercialization of our COVID-19 Test Kit. If our COVID-19 Test Kit is unable to attain or maintain market acceptance or be successfully commercialized, our business could be materially adversely affected.

Our near-term success is dependent on the continued commercialization of our COVID-19 Test Kit, which currently is our only commercially available test. The continued commercial success of our COVID-19 Test Kit will depend on many factors, some of which are outside of our control, including the following:

- our ability to continue to scale up our manufacturing and commercial capabilities so we can timely manufacture our Cue Readers, Cue Cartridges and Cue Wands in sufficient capacity to meet customer requirements and market demand;

- acceptance by key opinion leaders, healthcare systems and providers, governments and regulatory authorities, enterprise and health plan customers, consumers and others of the convenience, accuracy and other benefits offered by our COVID-19 test and our Cue Integrated Care Platform;

- the ability of our COVID-19 test to accurately detect different strains of SARS-CoV-2, the virus that causes COVID-19, created by genetic mutation or otherwise, such as the five SARS-CoV-2 variants of concern known as the Alpha, Beta, Gamma and Delta variants or other new variants that have emerged or may emerge;

- the ability of consumers and other customers to pay for or otherwise obtain payment coverage or reimbursement from third-party payors for our Cue Readers and/or our COVID-19 Test Kits;

- the length of the COVID-19 pandemic and the extent to which widespread vaccinations in the U.S. reduces demand for our COVID-19 test;

- our ability to maintain our EUAs received from the FDA or otherwise obtain requisite future regulatory approval, as well as our ability to obtain and maintain regulatory authorizations, clearances and approvals in other jurisdictions; and

- our ability to comply with all regulatory requirements applicable to our COVID-19 test, including applicable FDA marketing, manufacturing and post-market surveillance requirements and other requirements of our EUAs.

If our COVID-19 test does not gain broad market acceptance in the marketplace, it could have a material adverse effect on the broader commercial success of the Cue Health Monitoring System and our future tests.

In addition, the COVID-19 diagnostic testing market is characterized by rapid technological developments. If our COVID-19 test is rendered uncompetitive or obsolete, even if it were to gain widespread market acceptance initially, the demand for our COVID-19 test could be greatly reduced. Further, market adoption of our COVID-19 test may also be materially affected by the availability and efficaciousness of vaccines or the emergence of therapeutic treatments for COVID-19. As current or newly developed vaccines become widely administered and as current or newly developed therapeutic treatments are approved and become widely used, then market interest and the commercial opportunity for our COVID-19 test may significantly lessen or potentially even disappear.

Our long-term success will depend on the success of our COVID-19 test and a number of other factors, including widespread market adoption of our Cue Health Monitoring System, Cue Virtual Care Delivery Apps and the overall Cue Integrated Care Platform and our ability to introduce new tests for use with our Cue Health Monitoring System.

Our long-term commercial success will depend on a number of factors, some of which are beyond our control, including:

- the success of our COVID-19 test;

- the successful completion of validation and clinical studies for our anticipated future tests;

- the timely receipt of marketing authorizations, clearances and approvals from the FDA and other similar regulatory authorities for our anticipated future tests and, if required, additional marketing authorizations, clearances and approvals for our COVID-19 test;

- perceptions by the public and members of the medical community, including healthcare stakeholders, as to the convenience, accuracy and the sufficiency of clinical evidence supporting the performance of the Cue Integrated Care Platform;

- demand from the public and members of the medical community for the Cue Health Monitoring System and adoption of our anticipated menu of tests;

- the availability, perceived advantages, relative cost, relative convenience and relative accuracy of the Cue Health Monitoring System compared to products produced by our competitors;

- positive or negative media coverage of the Cue Health Monitoring System or competing products, as to its convenience, accuracy and the sufficiency of clinical evidence supporting its performance;

- the effectiveness of our marketing and sales efforts;

- unanticipated delays in manufacturing our COVID-19 Test Kits;

- our ability to raise additional capital on acceptable terms, or at all, if needed to support the continued growth of our business and the development and commercialization of additional tests;
- unanticipated delays in manufacturing, developing or launching additional tests for our Cue Health Monitoring System;
- our ability to comply with all regulatory requirements applicable to our Cue Health Monitoring Systems and our current and anticipated future tests;
- our ability to price our Test Kits, including our COVID-19 Test Kit, at an acceptable price;
- our ability to obtain, maintain enforce, protect and defend our intellectual property rights;
- our ability to produce a continued supply of Cue Readers and Cue Test Kits;
- our ability to meet the demands and the requirements of our agreements with our largest customers, including the U.S. DoD;
- limitation on use or warnings required by the FDA in our product labeling; and
- availability of, or changes in, coverage or reimbursement rates for any of our current or future tests from government or other enterprise or healthcare payors.

Our future success also depends upon customers and end users of our products having a positive experience with the Cue Integrated Care Platform in order to increase demand for our COVID-19 test as well as drive interest in our future tests. If our COVID-19 test does not meet the expectations of customers and end users, it could discourage them from purchasing additional COVID-19 tests from us or from referring our COVID-19 test to others or utilizing our future tests. Further, dissatisfied customers and end users may express negative opinions through social media or word of mouth. Any failure to meet customer and end user expectations and any resulting negative publicity could harm our reputation and future sales.

Our revenue for at least the near term will almost exclusively depend on sales of our COVID-19 test until we can develop, obtain regulatory clearance or other appropriate authorization for, and commercialize additional tests.

We expect that sales of our COVID-19 test will account for almost all or the substantial majority of our revenue until at least such time as we can commercialize additional tests or other products. As a result, our ability to execute our growth strategy and become profitable in the near term will depend upon consumer adoption of the Cue Health Monitoring System and positive experiences with our COVID-19 test. We currently have a relatively small number of customers, and our ability to acquire new customers is largely constrained by the terms of our U.S. DoD Agreement through the completion of our performance of that agreement, subject to exceptions. We may not be able to successfully acquire new customers in a timely manner or at all. If we are unable to expand our customer base, we may not be able to increase our revenue. Adoption and use of our COVID-19 test will depend on several factors, including, but not limited to the accuracy, affordability and ease of use of our Cue Health Monitoring System as compared to other products, and coverage and reimbursement policies with respect to our Cue Health Monitoring System, our COVID-19 Test Kit, and products that compete with our COVID-19 test.

Because we expect virtually all of our revenue for at least the near term to be generated from sales of our COVID-19 test, the failure of our COVID-19 test to gain market acceptance or retain regulatory authorization under our EUAs may have a material adverse effect on our business, operating results and financial condition.

In addition, we are currently committing substantial financial resources, manufacturing capacity and personnel to the commercialization and manufacturing of our COVID-19 test. Allocating our available resources in such manner may negatively impact our research and development efforts for our other planned future tests, and result in a delay in our ability to bring new tests to market.

We currently rely upon the U.S. DoD and a very small number of other customers for almost all of our current product revenue. As a result, unless and until we can further diversify our customer base and sources of revenue, the loss of any of these customers, or a decline in the amount of our COVID-19 tests purchased by or sold to these customers, could materially adversely affect our business, financial condition and results of operations.

For the year ended December 31, 2020 and the nine months ended September 30, 2021, the U.S. DoD accounted for approximately 57.7% and 69.7% of our product revenue, respectively, and the U.S. DoD is expected to continue to be a

significant source of our revenue during the term of the U.S. DoD Agreement. In addition, for the year ended December 30, 2020, sales of our Cue Readers and our COVID-19 Test Kits through Henry Schein accounted for approximately 22%. A single non-government enterprise customer accounted for approximately 24% of our product revenue during the nine months ended September 30, 2021. We anticipate our initial U.S. DoD Agreement will be completed by December 31, 2021, which is when we expect to receive our final payment from the U.S. DoD under the agreement. As a result, we anticipate that our revenue may decline significantly upon conclusion of this agreement (at least in the short term, if not longer), and that we will be largely dependent on new and other existing customers for our revenue at such time. Once the U.S. DoD Agreement has been completed, and if we do not enter into a new FAR-based contract, we will be unrestricted in terms of who we can sell our Cue Test Kits to. Should we enter into a FAR-based contract upon termination of the U.S. DoD Agreement, the U.S. DoD will have the right to purchase up to 45% of our quarterly production for the duration of the contract at a specified discount to the lowest price offered by us to a commercial customer for the same products, equivalent quantities and comparable terms of sale, subject to a price floor. Any such additional contract with the U.S. DoD could constrain our ability to grow our business with non-U.S. government customers. Seventy-four other customers were responsible for the remainder of our product revenue during the nine months ended September 30, 2021, excluding certain customers who purchased our COVID-19 Test Kits and Cue Readers through our relationship with Henry Schein, and we expect an equal or greater number of customers to be responsible for the remainder of our 2021 product revenue. We will need to significantly expand our customer base in order for our business to succeed. Unless and until we can further expand and diversify our customer base and sources of revenue, the loss of the U.S. DoD or any of our other major customers, or a significant reduction in the amount of our products purchased by the U.S. DoD or any of our other major customers, would have a material adverse effect on our business, financial condition and results of operations and could have a material adverse effect on our future prospects. Our ability to acquire new customers is largely constrained by the terms of our U.S. DoD Agreement through the completion of our performance of that agreement, subject to exceptions.

If the U.S. DoD terminates or fails to renew our agreement, whether due to our inability to meet our obligations under the agreement or for any other reason, including without cause, our business, results of operations, financial condition and future prospects may be materially adversely affected.

Our agreement with the U.S. DoD may be terminated by the U.S. government for convenience, without cause, or if we materially fail to comply with the provisions of the agreement, including the production requirements under the agreement. We cannot assure you that the agreement will not be terminated by the U.S. DoD prior to its completion.

In order to meet our contractual obligations under the U.S. DoD Agreement, we must deliver 30,000 Cue Readers, 6,000,000 Cue COVID-19 Test Kits and 60,000 COVID-19 Control Swab Packs, which includes six quality control swabs (three positive and three negative) in each pack, to the U.S. government pursuant to an agreed upon delivery schedule, as well as achieve a sustained average of daily manufacturing capacity of approximately 100,000 Cue COVID-19 Test Kits per day over seven consecutive days by December 31, 2021. Under our agreement with the U.S. DoD, we are required to deliver to the U.S. government all of our manufacturing output of Cue COVID-19 Cartridges, subject to certain exceptions for existing contracts and for future contracts we are able to obtain waivers from the U.S. DoD. In April 2021, we received a waiver from the U.S. DoD, or the U.S. DoD Waiver, effective May 1, 2021, allowing us to distribute commercially up to 50% of our COVID-19 Test Kit production, measured monthly in arrears on a calendar month basis, to non-U.S. federal government customers and other recipients. The U.S. DoD Waiver is currently expected to remain in effect for the duration of the U.S. DoD Agreement; however, the U.S. government may modify the waiver upon timely written notice to reasonably accommodate changes in U.S. government requirements.

The date originally specified in the agreement to meet our delivery requirements was April 11, 2021. However, we were unable to meet these requirements in the given timeframe, and therefore, in March 2021, the U.S. DoD agreed to extend this date to October 12, 2021 and in September 2021, the U.S. DoD agreed to further extend this date to December 31, 2021. As of December 31, 2020, our daily manufacturing capacity for Cue COVID-19 Test Kits was approximately 2,000 cartridges per day. As of March 31, 2021, our daily manufacturing capacity for Cue COVID-19 Test Kits increased to approximately 20,000 per day. As of September 30, 2021, our daily manufacturing capacity for Cue COVID-19 Test Kits was on average over 60,000 cartridges per day over a seven-day period with a single day peak of over 67,000 COVID-19 Test Kits. While we have been rapidly expanding our manufacturing capacity since the fall of 2020 and are continuing to do so by adding additional production pods, we will need to create significant additional manufacturing capacity to meet our production target of approximately 100,000 Cue COVID-19 Cartridges per day for a seven-day period by December 31, 2021. We complied with our obligation to deliver all of the Cue Readers as required under the U.S. DoD Agreement. While we currently believe we will also be able to comply with the obligation to deliver 6,000,000 Cue COVID-19 Test Kits and 60,000 COVID-19 Control Swab Packs by December 31, 2021, it is possible that we will be unable to do so due to any number of internal or external factors such as delays in production, delays in the construction of any of our new production pods or issues in obtaining key components from any of our third-party suppliers needed to produce our Cue COVID-19 Test Kits. If we are unable to fulfill any of the requirements of our agreement, the agreement may be terminated or not renewed by the U.S. DoD. However, in the event the U.S. DoD was to terminate our agreement based on our inability to fulfill the delivery or production requirements under the agreement, we believe such termination is

unlikely to be considered a termination for cause. Even if we are able to fulfill the requirements of the agreement, it may still be terminated or not renewed by the U.S. DoD. If the agreement is terminated or not renewed after we satisfy our delivery obligations under the agreement, our business, results of operations, financial condition and future prospects may be materially adversely affected. In addition, if the U.S. DoD Agreement is terminated by the U.S. DoD for cause, the U.S. Government may be entitled to certain remedies, including penalty payments and the grant of a non-exclusive, paid up, perpetual license from us and certain intellectual property rights for the purpose of developing the products with other contractors, potentially competitors. In addition, the U.S. government could have the right to be the exclusive purchaser of our production capacity until we meet this obligation. Upon conclusion of the U.S. DoD Agreement, we anticipate that our revenue may decline significantly (at least in the short term, if not longer), and that we will be largely dependent on new and other existing customers for our revenue at such time.

Our obligations to the U.S. DoD may limit our ability to sell our COVID-19 test to other customers in the near term, including to healthcare systems and healthcare providers, enterprise customers, consumers and strategic partners.

Under our agreement with the U.S. DoD, the U.S. government is entitled to all of our manufacturing output during the term of the agreement, subject to certain exceptions for existing agreements and our ability to obtain waivers from the U.S. DoD. In April 2021, we received the U.S. DoD Waiver, which, effective May 1, 2021, allows us to distribute commercially up to 50% of our COVID-19 Test Kit production, measured monthly in arrears on a calendar month basis, to non-U.S. federal government customers and other recipients. We anticipate that the U.S. DoD Waiver will remain in effect for the duration of the U.S. DoD Agreement; however, the U.S. government may modify the waiver upon timely written notice to reasonably accommodate changes in U.S. government requirements. Because of our obligations to the U.S. DoD under the U.S. DoD Agreement, we have been and may continue to be delayed in our ability to widely roll out our COVID-19 test to other customers, including healthcare systems and healthcare providers, enterprise customers, and consumers, especially if we aren't able to obtain additional waivers from the U.S. DoD for future customer agreements. Any delay by us in making Cue Readers and our COVID-19 Test Kits available to these other customer groups could cause us to lose any advantage we may have otherwise had as a result of our being the first company to receive an EUA from the FDA for at-home and over-the-counter use without a prescription and may allow other companies to gain market share at our expense.

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

From January 1, 2020 to September 30, 2021, the number of our employees increased from 99 to 1,290 as we have been rapidly scaling up our manufacturing and corporate infrastructure during this time. We anticipate continued growth in our business operations. Our recent rapid growth has, and our continued growth is expected to, place significant strain across our organizational, administrative, and operational infrastructure. Our ability to manage our growth properly will require us to implement additional operational, financial, and managerial controls, as well as our reporting systems and procedures, and to continuously improve these controls, systems and procedures.

Our growth requires us to continue to expand our manufacturing capacity, our corporate infrastructure, hire significant additional personnel in a wide range of areas, implement new technology systems and automate equipment processes. In addition, we will need to continue to implement customer service, billing, and general process improvements and expand our internal quality assurance program. Among other areas, customer service could prove to be particularly important to us given that the Cue Health Monitoring System has only very recently been introduced to the commercial market and the lack of experience some of our potential customers will have with our products and its benefits. While we are currently undertaking improvements to our facilities, including development of additional production pods, as part of our rapid growth, such improvements may be delayed for reasons that are outside of our control. As a result of the foregoing, we cannot assure you that we will be successful in implementing any necessary increases in scale, expansion of personnel, equipment, facilities, systems or process enhancements.

In addition, needed components and supplies may not be available when required on terms that are acceptable to us, or at all, and our suppliers, as well as our contract manufacturers of Cue Readers and Cue Wands may not be able to allocate sufficient capacity in order to meet our requirements, which could adversely affect our business, financial condition and results of operations.

Given our very short history of operating a business at commercial scale and our very recent rapid growth, we cannot assure you that we will be able to successfully manage the expansion of our operations or recruit and train additional qualified personnel in an effective manner. Failure to manage our growth could, among other things, result in increased costs, product quality and customer service issues, and hinder our ability to respond to competitive challenges. A failure in any one of these or other areas could make it difficult for us to meet market expectations for our products and could damage our reputation, which in turn could have a material adverse effect on our business, financial condition, results of operations and future prospects.

Our business model is predicated on the idea that the healthcare industry is ripe for innovative disruption and the emergence of a new healthcare paradigm. The healthcare system, particularly in the United States, has historically been very slow to change, and we cannot assure you that we will be successful in our efforts to bring about disruptive change.

The healthcare system, particularly in the United States, has historically been very slow to change. We cannot assure you that we will be successful in our goal to bring about innovative disruption and the emergence of a new healthcare paradigm. There are many different constituencies that make up the healthcare system, many of whom may have a significant interest in trying to maintain the status quo. We cannot assure you that we will not face resistance from certain participants in the healthcare system as we seek to bring about change. To the extent we encounter any such challenges, the market potential for the Cue Integrated Care Platform and our products and other current and future offerings may be more limited than we anticipate. Our success and future growth largely depend on our ability to increase awareness of the Cue Integrated Care Platform and our products and other offerings with consumers, healthcare providers, enterprises, payors and other stakeholders in the healthcare system, and on the willingness of these stakeholders to utilize the Cue Health Monitoring System, including our current and future tests, the Cue Virtual Care Delivery Apps, and the overall Cue Integrated Care Platform. Diagnostic testing in the United States and elsewhere in the world continues to rely significantly on a centralized clinical testing model. We cannot assure you that we will be successful in changing historical practices in the way diagnostic testing is done, or in our efforts to bring about connectivity within the healthcare system. Consumers and other stakeholders in the healthcare system may be slow in changing their habits and may be hesitant to use the Cue Integrated Care Platform for a variety of reasons, including:

- lack of experience with our company, Cue Integrated Care Platform and products, and concerns about the newness of our technology or that we are relatively new to the industry;
- perceived health, safety or quality risks associated with the use of a new platform and the process of an individual conducting a diagnostic test at home;
- perception that diagnostic testing can only be administered by a healthcare provider;
- traditional or existing relationships between and among healthcare stakeholders that administer, process and sell diagnostic testing;
- concerns about the privacy and security of patient information and data that is available on and that can be shared with or through our Cue Integrated Care Platform;
- competition and negative selling efforts from competitors, including competing tests and platforms and other providers of healthcare technology platforms and services; and
- perception regarding the complexity of using the Cue Health Monitoring System or Cue Virtual Care Delivery Apps.

If we are unsuccessful in bringing about the disruptive change we are seeking to achieve, the opportunity for our company may be more limited than we currently anticipate.

The diagnostic testing market is extremely competitive and rapidly evolving, making it difficult to evaluate our business and future prospects.

The market for diagnostic testing is extremely competitive. Further, the diagnostic testing industry, as well as the manner in which healthcare services are delivered more broadly, is currently experiencing rapid change, technological and scientific breakthroughs, new product introductions and enhancements and evolving industry standards, as well as the emergence of telehealth and other changes in the way healthcare services are delivered. All of these factors could affect the degree to which our products gain market acceptance or approval or result in our products being less marketable or becoming obsolete. Our future success will depend on our ability to successfully compete with established and new market participants and to keep pace with scientific and technological changes and the evolving needs of customers and the healthcare marketplace.

We will be required to continuously enhance the Cue Health Monitoring System and develop new tests to keep pace with evolving standards of care. If we do not update our products to keep pace with technological and scientific advances, our products could become obsolete and sales of our products could decline or fail to grow as expected.

Central labs continue to represent the most significant portion of the diagnostic testing market, and as a result we will be competing against very large and well-established lab companies such as Quest Diagnostics, Inc. and Laboratory Corporation of America. These companies have also expanded beyond centralized laboratory testing into home sample

collection. In addition, we also face intense competition from other companies that develop or already have molecular tests, whether at point-of-care or at-home, as well as companies that have or are developing antigen and antibody tests. Competitors with diagnostic testing platforms include private and public companies, such as Abbott Laboratories, Becton, Dickinson and Company, BioMerieux SA, Bio-Rad Laboratories, Inc., Danaher Corp., Ellume Limited, Everly Health, Inc., F. Hoffman-La Roche Ltd., Fluidigm Corporation, GenMark Diagnostics Inc., Ginkgo Bioworks, Inc., Mammoth Biosciences, Inc., LetsGetChecked, Lucira Health, Inc., Mesa Biotech, Inc., Qiagen N.V., Quidel Corporation, Sherlock Biosciences, Inc., Siemens AG, Talis Biomedical Corporation, Thermo Fisher Scientific, Inc. and Visby Medical, Inc. as well as several retailers, such as The Kroger Company, Walmart Inc. and Alberstons Companies, Inc.

In addition, we may also experience competition from technology-enabled health companies such as 1Life Healthcare, Inc. (d/b/a as OneMedical), American Well Corporation, Hims and Hers Health, Inc., and Teledoc Health, Inc. We may also face competition from other companies, including other technology companies. For example, it has been publicly reported that Amazon.com, Inc. may be considering launching an at-home diagnostic testing business.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise than we do in research and development, manufacturing, obtaining regulatory clearances and approvals and regulatory compliance, and sales and distribution. Mergers and acquisitions involving diagnostic testing or other healthcare companies may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies or customer networks. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize diagnostic products or services that are more accurate, more convenient to use or more cost-effective than our products. Our competitors also may obtain FDA or other regulatory clearance or approval for their products more rapidly than we may obtain clearance or approval for our products, which could result in our competitors establishing a strong market position before we are able to enter a particular market.

Further, some of our competitors' products may be sold at prices that may be lower than our pricing, which could adversely affect our sales or force us to reduce our prices, which could harm our revenue, operating income or market share. If we are unable to compete successfully, we may be unable to increase or sustain our revenue or achieve profitability and our future growth prospects may be materially harmed.

To remain competitive, we will need to expand our test menu and continually develop improvements to our products and other offerings. We cannot assure you that we will be able to successfully compete in the marketplace or develop and commercialize new tests or improvements to our products and other offerings on a timely basis. Our competitors may develop and commercialize competing or alternative products or services and improvements faster than we are able to do so, which would negatively affect our ability to increase or sustain our revenue or achieve profitability and could materially adversely affect our future growth prospects.

If the Cue Health Monitoring System fails to achieve broad adoption by or support from the medical and professional community, key opinion leaders and other key participants in the healthcare system, our business and prospects may be materially adversely affected.

The success of the Cue Integrated Care Platform and our business model will depend on our ability to gain wide acceptance of the Cue Health Monitoring System in the marketplace. This will require us to obtain support from members of the professional and medical community, key opinion leaders and other key participants in the healthcare system.

Our ability to obtain the support of these constituencies will depend on a number of factors, including:

- our ability to demonstrate the accuracy, ease of use, and affordability of Test Kits using the Cue Health Monitoring System;
- our ability to demonstrate the comparability of test results using the Cue Health Monitoring System to other testing methodologies, including those utilized by centralized labs, such as polymerase chain reaction, or PCR, tests, reverse transcription PCR, or RT-PCR, tests, and loop-mediated isothermal amplification, or LAMP;
- any lack or perceived lack of sufficient clinical evidence supporting the accuracy and performance of our tests;
- a willingness of constituents in the healthcare system to adopt the Cue Integrated Care Platform and our current and future tests over other diagnostic products and tests;
- overcoming any biases these constituencies may have toward the Cue Integrated Care Platform and our current and future tests relative to other diagnostic products and tests;

- the cost and reimbursement from third-party payors or other payment coverage for Cue Readers and Cue Test Kits in relation to other diagnostic products and tests;
- satisfaction with the accuracy and ease of use of the Cue Health Monitoring System and overall customer experience;
- changes in pricing and promotional efforts by competitors;
- demand for point-of-care and over-the-counter diagnostic testing;
- the effectiveness of our sales, marketing and distribution efforts; and
- adverse publicity about the Cue Health Monitoring System, including any current or future developed test kits, competitive products, or the industry as a whole, or favorable publicity about competitive products.

If our tests fail to achieve broad support from members of the professional and medical community, key opinion leaders and other key participants in the healthcare system, our business and future prospects may be materially adversely affected.

Our sales cycle with institutional customers may be lengthy and variable, which may make it difficult for us to forecast revenue and other operating results.

We expect that our sales process with healthcare systems and providers, enterprise customers, strategic partners, governments and other institutional customers will require numerous interactions with multiple individuals within any given organization and involve in-depth analysis by potential customers of our products, preparation of extensive documentation and a lengthy review process. As a result of these factors and the budget cycles of these types of customers, coupled with the fact that our product involves new technology and a new model for diagnostic testing and care paradigm, the time from initial contact with a potential enterprise or other institutional customer to our receipt of a purchase order or subscription agreement may vary significantly and may be many months or longer. Given the length and uncertainty of this expected sales cycle, we may experience fluctuations in our product revenue on a period-to-period basis.

If the Cue Health Monitoring System does not perform as expected, including with respect to accuracy, errors, defects or reliability, our reputation and market acceptance of our products could be materially harmed, and our business and reputation could suffer.

Our success depends on customer confidence that we can provide reliable and highly accurate diagnostic tests and enable better patient care. We believe that healthcare stakeholders are likely to be particularly sensitive to defects, errors or reliability issues in our products, including if our products fail to accurately diagnose infections with high accuracy from patient samples, and there can be no guarantee that our products will meet their expectations. There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue as our product deliveries increase, our menu of tests expands and our other offerings through the Cue Integrated Care Platform continue to develop.

Our products use a number of complex and sophisticated biochemical and bioinformatics processes. Our diagnostic tests may contain errors or defects or be subject to reliability issues, and while we have made efforts to test them extensively, we cannot assure that our COVID-19 test, or any diagnostic test we develop in the future, will not have performance problems. An operational, technological or other failure in one of these complex processes or fluctuations in external variables may result in sensitivity or specificity rates that are lower than we anticipate or result in longer than expected turnaround times or they may cause our products to malfunction. In addition, our Cue Virtual Care Delivery Apps or other technology interfaces may contain undetected bugs, errors or defects. Due to the complexity of the Cue Health Monitoring System, it may be difficult or impossible to identify the reason for any performance errors or malfunctions or reliability issues. Performance issues could increase our costs and adversely affect our business, financial condition and results of operations. In addition, 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 and our ability to sell our Cue Health Monitoring System. We may also be subject to warranty claims or breach of contract for damages related to errors, defects or reliability issues in our products.

Further, our products are designed to be used at the customer’s location by untrained individuals. We cannot provide assurance that our customers will always use our products in the manner in which we intend.

If our products do not perform, or are perceived to not have performed, as expected or favorably in comparison to competitive products, our operating results, reputation, and business may suffer, our future prospects may be materially adversely affected, and we may also be subject to legal claims arising from product limitations, errors, or inaccuracies.

Additionally, COVID-19 and many of the other pathogens for which we are developing tests are known to mutate over time. Such mutations may negatively affect the accuracy of our tests or even make our tests obsolete. The failure of our products to perform as expected could significantly impair our operating results and our reputation, including if we become subject to legal claims arising from any defects or errors in our products or test results.

Operational, technical and other difficulties adversely affecting test performance may harm our reputation, impact the commercial attractiveness of our products, increase our costs or divert our resources, including management's time and attention, from other projects and priorities. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations and adversely affect our prospects.

Our products may be subject to recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA has the authority to require the recall of commercialized products that are subject to FDA regulation. Manufacturers may also, under their own initiative, recall a product or service if any deficiency is found. For reportable corrections and removals, companies are required to make additional periodic submissions to the FDA after initiating the recall, and often engage with the FDA on their recall strategy prior to initiating the recall. A government-mandated or voluntary recall by us or a distributor could occur as a result of an unacceptable health risk, component failures, malfunctions, manufacturing errors, design or labeling defects, or other deficiencies and issues. Recalls of any of our commercialized products would divert managerial and financial resources and adversely affect our business, results of operations, financial condition and reputation. A recall of any component of the Cue Health Monitoring System could be required for any number of problems. Given the number of components, determining the cause of the malfunction may be particularly challenging and costly. In addition, any recall of any component of the Cue Health Monitoring System would decrease the market for our authorized tests given the decreased availability of such instruments. We may also be subject to liability claims, be required to bear other costs or take other actions that may negatively impact our future sales and our ability to generate profits. Companies are also required to maintain certain records of corrections and removals, even if these do not require reporting to the FDA. We may initiate voluntary recalls involving our commercialized products. The FDA or other agency could take enforcement action for failing to report the recalls when they were conducted. In addition, if we are required to make changes to our products to redress the deficiencies leading to the recall, we may be required to seek marketing authorization for the modified device prior to commercializing it. Any recall announcement by us or the FDA or any other governmental authority, or any changes that we make to our products as a result of such recall, could harm our reputation with customers and negatively affect our business, financial condition, and results of operations.

If we initiate a recall, including a correction or removal, for one of our commercialized products, issue a safety alert, or undertake a field action or recall to reduce a health risk, could lead to increased scrutiny by the FDA, other governmental and regulatory enforcement bodies, and our customers regarding the quality and safety of our products, and to negative publicity, including FDA alerts, press releases, or administrative or judicial actions. Furthermore, the submission of these reports could be used against us by competitors and cause customers to delay purchase decisions or cancel orders, which would harm our reputation.

The use of the Cue Health Monitoring System and Cue Virtual Care Delivery Apps requires users to follow instructions, and not adhering to such instructions may lead to negative outcomes, which could harm our business. In addition, if product users view our products as difficult to use or invasive, it could affect the degree of utilization and market adoption of our products.

The successful use of the Cue Health Monitoring System and Cue Virtual Care Delivery Apps depends on each user following the instructions provided. Any user, whether it be a healthcare stakeholder or customer at home, could experience difficulty performing a test using our Cue Health Monitoring System and Cue Virtual Care Delivery Apps if they fail to follow the instructions, or otherwise misuse the test. If healthcare stakeholders or other users utilize our tests incorrectly, or without adhering to our instructions, their test result outcomes may not be consistent with the outcomes achieved in our clinical trials. For example, if a user removes the Cue Wand from the Cue Cartridge while conducting a test on the Cue Health Monitoring System, which our instructions explicitly state not to do, they could be exposed to genetic material and the result of the user's test could return a false positive. Additionally, healthcare stakeholders and customers could find the Cue Health Monitoring System difficult to use, invasive or ultimately prefer a different diagnostic testing system. This could harm our ability to achieve the broad degree of adoption necessary for commercial success or cause negative publicity and word-of-mouth as a result of our tests not meeting user expectations and accordingly, our operating

results and financial condition could be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business.

The Cue Health Monitoring System and the Cue Virtual Care Delivery Apps rely on access to the Internet, mobile networks and Bluetooth for connectivity.

The ability to conduct testing using the Cue Health Monitoring System and the availability of the Cue Virtual Care Delivery Apps depends on access to the Internet, mobile networks and Bluetooth connectivity and storage of data in the "cloud." Our services are designed to operate without interruption. If performance of our products is adversely affected due to lack of availability of Internet access, mobile networks or Bluetooth connectivity for any reason, or security concerns arise relating to our products reliance on these means of connectivity and data storage, our relationship with customers and users of our products and our reputation could be materially adversely affected.

The total addressable market opportunity for our current and future products may be much smaller than we estimate.

Our estimates of the total addressable market for the Cue Integrated Cate Platform are based on internal and third-party estimates as well as a number of significant assumptions. Market opportunity estimates and growth forecasts included in this report are subject to significant uncertainty and are based on assumptions and estimates. These estimates, which have been derived from a variety of sources, including market research and our own internal estimates, may prove to be incorrect. Further, the continued development of, and approval or authorizations for, vaccines and therapeutic treatments may affect these market opportunity estimates. Our market opportunity may also be limited by new diagnostic tests or other products that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for platform and products could be significantly less than we estimate. If this turns out to be the case, our potential for growth may be limited and our business and future prospects may be materially adversely affected.

If we are unable to obtain and maintain adequate levels of coverage and reimbursement from third-party payors for our Cue Readers and Cue Test Kits, the market opportunity for our tests may be less than we expect.

Our market success is dependent upon government and commercial third-party payors providing coverage and adequate reimbursement for our Cue Readers and Cue Test Kits. While the reimbursement status for COVID-19 tests generally is still evolving, our COVID-19 tests are not currently being reimbursed by federal or state health care programs or third-party payors for at-home and over-the-counter use in the United States. However, we expect that in the future healthcare providers that purchase our COVID-19 test will look to various third-party payors, such as Medicare, Medicaid, private commercial insurance companies, health maintenance organizations, accountable care organization, or ACOs, and other healthcare-related organizations, to cover and pay for our COVID-19 test. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-payor basis. Sales volumes and prices of our COVID-19 test will depend in large part on the availability of coverage and reimbursement from such third-party payors. These third-party payors decide which products will be covered and establish reimbursement levels for those products. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a clinical laboratory test is safe, effective and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental, nor investigational. Even if a third-party payor covers a particular test or procedure, the resulting reimbursement payment rates may not be adequate. Coverage criteria and reimbursement rates for diagnostic tests are subject to adjustment by payors, and current reimbursement rates could be reduced, or coverage criteria restricted in the future, which could adversely affect the market for our COVID-19 test or any test we may receive governmental or other regulatory approval for in the future. In addition, the reimbursement rate for our at-home test is uncertain. Third-party payors may require additional clinical or other data in order to cover any of our COVID-19 tests or any future test we may develop in certain settings.

Our operating results may fluctuate significantly, including without limitation, due to the prevalence of COVID-19 or other conditions addressed by our tests as well as due to seasonality, which may make our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide or may be provided by investment banking research analysts or other third parties.

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

- the level of demand for any of our authorized or approved tests, which may vary significantly;
- authorization, approval and commercialization activities relating to our Cue Test Kits, which may change from time to time;

- the timing and cost of, and level of investment in, research, development, manufacturing, regulatory and commercialization activities related to our tests, which may change from time to time;
- the size, seasonality and customer mix of the COVID-19 diagnostic testing market;
- the effect of the COVID-19 pandemic and the end of the COVID-19 pandemic on our business;
- the effect of current and new therapeutic treatments for COVID-19 and vaccines;
- sales and marketing efforts and expenses;
- the rate at which we grow our sales force and the speed at which newly hired salespeople become effective;
- changes in the productivity of our sales force;
- positive or negative coverage in the media of, or clinical publications about, the Cue Health Monitoring System or any of our current or future tests or competitive products;
- the cost of manufacturing any of the components of the Cue Health Monitoring System;
- the introduction of new tests or enhancements or technologies by us or others in the diagnostic testing industry;
- pricing pressures;
- coverage and reimbursement policies with respect to our tests and products that compete with our tests;
- expenditures that we may incur to acquire, develop or commercialize tests for additional indications, if any;
- the degree of competition in our industry and any change in the competitive landscape of our industry;
- changes in governmental regulations or in the status of our regulatory approvals or applications;
- future accounting pronouncements or changes in our accounting policies; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

The cumulative effect of the factors discussed above could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our 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, which in turn could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to accurately forecast inventory needs and manufacture sufficient quantities of any component of the Cue Health Monitoring System, we may experience shortages or excesses of inventory, which could result in us having insufficient capacity to meet customer demand or lead to write-downs or write-offs of inventory.

To ensure adequate supply, we must forecast inventory needs and manufacture the components of the Cue Health Monitoring System based on our estimates of future demand. Our ability to accurately forecast demand for the Cue Health Monitoring System, including the demand for any one or more of our current or future tests, 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 and user demand for our tests or for products of our competitors, our failure to accurately forecast market acceptance of new products, unanticipated changes in general market conditions, including the production and distribution of additional efficacious vaccines or other treatments for COVID-19, seasonal demands, or regulatory matters and weakening of economic conditions or user confidence in future economic conditions. In addition, we anticipate that we will experience fluctuations in customer and user demand based on seasonality, which for COVID-19 remains unknown. However, for example, to the extent we are able to commercialize a test for influenza, we would expect our forecasts of inventory for the fall and winter seasons to reflect a significant increase in inventory for that product relative to our forecasts for the spring and summer seasons. If this expectation does not materialize, our inventory forecasts may be inaccurate, resulting in shortages or excesses of inventory. Inventory levels in excess of customer and user 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.

In addition, if we experience a significant increase in demand, 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 negatively affect our business, financial condition and results of operations. Furthermore, our inability to meet manufacturing and production requirements could cause us to lose our existing customers or lose our ability to acquire new customers which would also negatively impact our business, financial condition and results of operations.

We will seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions. As a result, we are subject to the risk that a portion of our inventory will become obsolete or expire. As an example, our Cue COVID-19 Cartridges sold in the United States and Canada currently have a nine-month shelf life within which they must be used before they expire, and in India they currently have a four-month shelf life. Any such expiration or obsoleteness of any of our products could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

We may not be able to achieve or maintain satisfactory pricing and margins for our Cue Test Kits, which could harm our business and results of operations.

Manufacturers of diagnostic tests have a history of price competition, and we may not be able to achieve or maintain satisfactory prices for our Cue Readers or any of our current or future Cue Test Kits. The pricing of our Cue Readers or any of our Cue Test Kits could be impacted by several factors, including pressure to improve margins as a result of competitive or customer pricing pressure or a limit or decline in the amount that third-party payors reimburse our customers, which could make it difficult for customers to adopt the Cue Health Monitoring System.

Furthermore, at this time, in most cases we expect to receive payment for our over-the-counter at-home tests directly from point-of-care customers and not to bill third-party payors directly. Because our COVID-19 test is the first over-the-counter and at-home use FDA-authorized molecular diagnostic test that does not require physician supervision or a prescription, there is not a well-established market for this type of product and therefore the price that we are able to charge or the price that our customers are willing to pay may be less than what we have been able to charge to date.

If we are forced to lower the price we charge for any components of our Cue Health Monitoring System, our gross margins will decrease. In addition, if our costs increase and we are unable to offset such increase with an increase in our prices, our margins would also be adversely affected. We may be subject to significant pricing pressure, which could harm our business, financial condition and results of operations and our future prospects.

If we are not successful in developing and obtaining regulatory clearance or other authorization or approval for, and commercializing additional tests, our ability to expand our business and achieve our strategic objectives will be adversely affected.

We believe our flexible platform enables us to launch different tests for other infectious diseases in addition to COVID-19 as well as for additional clinical uses, including in the areas of respiratory health, sexual health, cardiac and metabolic health, women's health, men's health, and chronic disease management. Capitalizing on the flexibility of our Cue Integrated Care Platform is a key pillar to our strategy. We will be required to conduct significant additional research and development activities and obtain necessary regulatory clearances or other required authorizations or approvals before we are able to commercialize additional tests, and we do not expect to be able to introduce any additional tests into the commercial market before the end of 2022, at the earliest. Developing new tests requires substantial technical, financial and human resources, whether or not any tests are ultimately developed or commercialized, which may divert management’s attention away from other aspects of our business. We may pursue what we believe are promising opportunities only to discover that certain of our risk or resource allocation decisions were incorrect or insufficient, or that certain tests or the Cue Integrated Care Platform in general has risks that were previously unknown or underappreciated. In addition, even if we successfully develop new tests, we will not be able to commercialize them unless we obtain the necessary regulatory clearance or other required authorization or approval. If we are unable to successfully develop or commercialize new tests for whatever reason, we may not be able to realize what we anticipated to be the full potential of the Cue Integrated Care Platform and our business, financial condition, results of operations and future prospects may be materially adversely affected.

If the Cue Health Monitoring System does not perform as expected, our business, operating results, reputation and future prospects may suffer.

Our success depends on our ability to provide reliable tests that enable high-quality diagnostic testing with high accuracy, ease of use, and short turnaround times. The accuracy and reproducibility we have demonstrated to date with respect to our COVID-19 test may not continue or be indicative of actual future performance as the product attains more widespread usage.

The Cue Health Monitoring System uses a number of complex and sophisticated biochemical and bioinformatics processes, many of which are highly sensitive to external factors, including human error. An operational, technological, user or other failure in one of these complex processes or fluctuations in external variables may result in sensitivity or specificity rates that are lower than we anticipate or result in longer than expected turnaround times. Operational, technical, user and other difficulties may also adversely affect test performance. If our tests do not perform, or are perceived to not have performed, as expected or favorably in comparison to competitive products, our business, operating results, reputation, and future prospects may suffer, and we may also be subject to legal claims arising from product limitations, errors, or inaccuracies. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

We have identified material weaknesses in our internal control over financial reporting and may identify material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, as a result of which, 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.

We were a private company from our inception until the closing of our IPO on September 28, 2021, and, as such, we previously had not had the internal control and financial reporting requirements that are required of a publicly-traded company. We are required to comply with the requirements of The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, following the date we are deemed to be an "accelerated filer" or a "large accelerated filer," each as defined in the Exchange Act, which could be as early as our next fiscal year. 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, 2022. This assessment will need to include disclosure of any material weaknesses identified 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.

In connection with the audits of our 2019 and 2020 annual financial statements, we identified material weaknesses in internal controls pertaining to information technology general controls, a lack of segregation of duties, documentation and design of formalized processes and procedures, insufficient complement of qualified resources with an appropriate level of knowledge, experience and training important to our financial reporting requirements, timely reconciliation and analysis of certain key accounts and the review of journal entries. These material weaknesses could result in material misstatements of our financial statement account balances or disclosures of our annual or interim financial statements that would not be prevented or detected. We have concluded that these material weaknesses in our internal controls over financial reporting occurred because, prior to our IPO, we were a private company and did not have the internal controls necessary to satisfy the accounting and financial reporting requirements of a public company.

Beginning in the fourth quarter of 2020, we began to take steps to address our material weaknesses through our remediation plan, which included the hiring of advisors in the fourth quarter of 2020 and a Chief Financial Officer in the first quarter of 2021 and the hiring of a Vice President and Treasurer in the second quarter of 2021, and the continued engagement of additional external advisors to provide financial accounting assistance in the short term. We have substantially grown our team and are in the process of hiring additional personnel to improve the segregation of duties in our financial closing and reporting process and timely review of key accounts and journal entries. In addition, we have engaged external advisors to evaluate and document the design and operating effectiveness of our internal controls and assist with the remediation and implementation of our internal controls as required. We are evaluating the longer-term resource needs of our various financial functions and plan to significantly expand the size of the financial organization to help address these weaknesses. We cannot assure you that our efforts to remediate the material weakness will be successful.

If we fail to remediate the identified material weaknesses or identify new material weaknesses by the time we have to issue our first Section 404(a) assessment on the effectiveness of our internal control over financial reporting, we will not be able to conclude that our internal control over financial reporting is effective, which may cause investors to lose confidence in our financial statements, and the trading price of our common stock may decline. If we fail to remedy any material weakness, our financial statements may be inaccurate, our access to the capital markets may be restricted and the trading price of our common stock may suffer.

Our management and independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting during any period in accordance with the provisions of Sarbanes-Oxley Act. Had we performed an evaluation and had our independent registered public accounting firm performed an audit of our internal control over financial reporting in accordance with the provisions of Sarbanes-Oxley Act, additional material weaknesses may have been identified.

We are highly dependent on our senior management team and key personnel, and we will need to hire additional personnel in connection with the current scale up and growth of our business. Our business may be materially harmed if we are unable to attract and retain personnel necessary for our growth and success.

We are highly dependent on our senior management team and 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, commercial and manufacturing personnel, research and development personnel, finance and accounting personnel and other highly skilled personnel and to integrate current and additional personnel in all areas of our business. The loss of members of our senior management and other important employees could have a material adverse effect on our business. In particular, the loss of the services of our co-founders, Ayub Khattak, our President and Chief Executive Officer, and Clint Sever, our Chief Product Officer, could significantly delay or prevent the achievement of our strategic objectives and otherwise have a material adverse impact on our business. If we are not successful in attracting and retaining highly qualified personnel, it would have a negative impact on our business, financial condition and results of operations.

Competition for skilled personnel across virtually all areas where we need to attract additional personnel is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued, and expect in the future to issue, stock options, restricted stock units or other equity awards. The value to employees of stock options, restricted stock units or other equity awards may be significantly affected by movements in our stock price, including due to events unrelated to our performance, 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 and other employees may terminate their employment with us on short notice, even where we have employment agreements in place. We also do not maintain “key man” insurance policies on the lives of these people or the lives of any of our other employees.

Furthermore, in the last twelve months we have experienced significant growth and anticipate further significant growth as we continue to ramp up our business operations. We expect to continue to increase our headcount and to hire more specialized personnel as we grow our business. Rapid expansion in personnel could mean that less experienced people are performing important functions within our company, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. 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, we may not be able to maintain the quality of our products or satisfy customer demand and our business may otherwise be materially harmed.

If we are unable to build-out our sales and marketing and customer support capabilities or enter into agreements with third parties for these services, we may not be successful in commercializing our COVID-19 test or our future products.

We currently have only a limited sales and marketing infrastructure, and have very limited experience in the sales, marketing, customer support or distribution of diagnostic or other commercial stage products. To achieve commercial success for our COVID-19 test or any of our future tests, we must build our sales, marketing, customer support, managerial and other capabilities or make arrangements with third parties to perform these services. We currently have limited internal sales and marketing and customer support teams in place and are in the process of hiring more employees in the near-term and plan to hire additional individuals in the future as we continue to grow our business.

Our future sales will depend in large part on our ability to develop, and substantially expand, our sales force and to increase the scope of our marketing efforts. We plan to take a measured approach to expand and optimize our sales infrastructure to grow our customer base and our business. Identifying and recruiting qualified personnel and training them in the use of the Cue Health Monitoring System, applicable federal and state laws and regulations and our internal policies and procedures, requires significant time, expense and attention. In addition, our EUA authorizations with respect to our COVID-19 test specify the scope and conditions of authorization, including limitations on distribution and conditions related to product advertising and promotion. It can take significant time before our sales representatives are fully trained and productive. Our business may be harmed if our efforts to expand do not generate a corresponding increase in revenue or result in a decrease in our operating margin. In particular, if we are unable to hire, develop and retain talented sales personnel or if new sales personnel are unable to achieve desired productivity levels in a reasonable period of time, we may not be able to realize the expected benefits of this investment or increase our revenue.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If any future authorized test for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

In addition, the introduction of our tests into our customers' existing workflows, and in the over-the-counter and at-home contexts requires us to maintain technical, customer and user support teams. Accordingly, we need trained technical and customer and user support personnel, the market for hiring these types of personnel is very competitive. If we are unable to attract, train or retain the number of qualified technical and customer and user support personnel that our business needs, our business and prospects will suffer.

If we enter into arrangements with third parties to perform sales and marketing and customer support services, our revenue or the profitability of the revenue to us may be lower than if we were to market and sell any current or future products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our current or future products or may be unable to do so on terms that are favorable to us. We likely would have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our current or future products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our current or future products. Further, our business, results of operations, financial condition and future prospects may be materially adversely affected.

We rely on third-party vendors and consultants to assist with software and technology development and other aspects of our business. If any of these vendors or consultants do not perform as expected or if our relationship with any of them is terminated or otherwise changes, our business operations could be adversely affected.

We rely on third-party vendors and consultants to assist us with software and technology development and with other aspects of our business. We anticipate that we will continue to depend on these and other third-party relationships in order to grow our business for the foreseeable future. If our third-party vendors and consultants are unable or unwilling to provide the services necessary to support our business, or if our agreements with such vendors or consultants are terminated or we are otherwise unable to maintain these relationships, our business and operations could be adversely affected. If any of our relationships with existing third-party vendors or consultants are terminated, we may not be able to enter into similar relationships in the future on reasonable terms or at all. We may also incur substantial costs, delays and disruptions to our business in transitioning such services to ourselves or other third-party vendors or consultants. In addition, third-party vendors and consultants may not be able to provide the services required in order to meet the changing needs of our business or scale as quickly as we require. Any of the foregoing could harm our business, financial condition, results of operations and competitive position.

If we are subject to orders from federal or state governments under the Defense Production Act of 1950, as amended, or the DPA, or similar federal or state legislation or other authorizations permitting the government to require companies to distribute goods, products or services or make manufacturing capacity available to or as directed by the government, our opportunity to grow our business may be adversely affected.

The DPA is a federal statute that confers upon the President of the United States a broad set of authorities to influence domestic industry in the interest of national defense. "National defense" can include emergency and disaster response and, since the start of the current COVID-19 crisis, this authority has been used on several occasions to address the public health crisis. Through the DPA, the executive branch has struck agreements with multiple companies to accelerate COVID-19 countermeasures, like N95 protective masks, testing swabs, and vaccine development, and, in September 2020, used the DPA to acquire point-of-care diagnostic testing instruments from two diagnostics industry competitors for placement in nursing homes. The government may apply the DPA, or another law or program, to our other existing contracts or a new contract to acquire our testing instruments or to direct us to distribute our products in a particular manner, and we may be likewise required to prioritize distribution to certain government agencies or other recipients, or to allocate inventory, supplies or facilities for government or government-directed use. The DPA provides that orders pursuant to the statute must "meet regularly established terms of sale or payment" and further provides that no person "shall be held liable for damages or penalties for any act or failure to act resulting directly or indirectly from compliance with a rule, regulation, or order" under the DPA. However, compliance with the DPA could potentially cause business disruption, interfere with our commercial sales and marketing efforts, and depending on the demand, could even prevent or delay our ability to sell our products commercially, or may have other implications that significantly affect our commercialization and development efforts and general ability to conduct our business operations as planned. For example, government directed use of our products under such a program may result in our Cue Readers not being placed in settings where they will be used often for additional tests following the COVID-19 pandemic, which would adversely affect our long-term commercial plan that is

based on increasing our installed base to roll out additional tests for use on the Cue Health Monitoring System. In addition, such government requirements may adversely affect our regular operations and financial results, result in differential treatment of customers and/or adversely affect our reputation and customer relationships. It is also possible that any change in the current administration could impact the manner in which the government uses the DPA and its other authorities, and result in additional or different risk to us.

The COVID-19 pandemic could materially adversely affect our business, financial condition and results of operations.

Like other companies, our business has been and will continue to be affected by the COVID-19 pandemic. For example, the spread of COVID-19 has caused us to modify our business practices (including on-site employee and visitor testing, employee travel, employee work locations, and the cancellation of physical participation in meetings, events and conferences) and delay our clinical study for our influenza test. We started our external influenza clinical study in January 2020. The study utilized a number of sites throughout the country. Many of these sites were research facilities that focused on clinical studies and do not provide clinical care. When the COVID-19 pandemic began spreading in the United States in early February and March 2020, many of these facilities began preventing potential enrollees from entering the sites if they exhibited any respiratory disease symptoms. This significantly impacted the enrollment of participants in our influenza test studies. We subsequently chose to pause, and ultimately stop, the study due to very low enrollment. Future planned clinical studies may also be postponed due to low infection prevalence and/or the shuttering of research facilities where clinical studies are conducted. Postponement of such studies may delay us from completing development and seeking regulatory clearances or approvals for our tests currently in development and future products. We may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, consumers and partners. The degree to which COVID-19 will impact our business and operations going forward is unknown and will depend on future developments, which are highly uncertain and cannot be predicted, including, but not limited to, the continued duration and spread of the outbreak, the emergence of novel variants, the degree of severity of the outbreak and existing and new variants, the development and administration of existing and new therapeutic treatments and vaccines, the actions taken by national, regional, and local governments and health officials to contain the virus or treat its impact, how quickly and to what extent normal economic and operating conditions can resume, whether the supply of components and raw materials will remain sufficient to satisfy demand and any impact on its pricing, and whether any of our third-party manufacturers experience any business interruptions which result in the delay of delivery of our products or components. Even after the outbreak of COVID-19 has subsided, we may experience material impacts to our business as a result of its global economic impact, including any recession or other negative widespread economic impacts that may occur as a result of the pandemic.

If we were to be sued for product liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of the Cue Health Monitoring System and any of our current and future tests and products could lead to the filing of product liability claims where someone may allege that the Cue Health Monitoring System identified inaccurate or incomplete information or otherwise failed to perform as designed. We may also be subject to liability for errors in, a misunderstanding of or inappropriate reliance upon, the information we provide in the ordinary course of our business activities. In addition, we may be subject to product liability claims resulting from misuse or off-label use of the Cue Health Monitoring System. See the risk factor titled "—The misuse or off-label use of our tests may harm our reputation or the image of our tests in the marketplace, or result in injuries that lead to product liability suits, which could be costly to our business. Moreover, we could be subject to FDA sanctions if we are deemed to have engaged in off-label promotion." A product liability claim could result in substantial damages and be costly and time-consuming for us to defend. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- costs of litigation;
- distraction of management's attention from our primary business;
- the inability to continue commercializing the Cue Health Monitoring System or other new products;
- decreased demand for our Cue Readers or Cue Test Kits;
- damage to our business reputation;
- product recalls or withdrawals from the market;
- withdrawal of clinical trial participants;
- substantial monetary awards to patients or other claimants;

- loss of sales; or
- termination of existing agreements by our partners and potential partners failing to partner with us.

We maintain product liability insurance, but this insurance may not fully protect us from the financial impact of defending against product liability claims. Any product liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future.

While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of any component of the Cue Health Monitoring System may delay the supply of those components to our customers and may impact our reputation. We may not be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future and these efforts may not have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our tests, either of which could negatively affect our business, financial condition and results of operations.

Current or future litigation, government investigations and other legal proceedings may harm our business.

We have been, currently are and may in the future become, involved in legal proceedings that could have a negative impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. The types of legal proceedings we may be or become subject to include patent and other intellectual property claims, product liability claims, employee claims, tort or contract claims, federal or state regulatory investigations, securities class actions, and other legal proceedings, investigations or claims. For example, in February 2018, the staff of the SEC's Division of Enforcement issued a subpoena to us requesting certain documents and information and we have been cooperating fully with the SEC's investigation. Litigation and other legal proceedings are 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 harm 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 any of our products or other offerings under our Cue Integrated Care Platform, even if the regulatory or legal action is unfounded or not material to our operations. For additional information, see "Item 1. Legal Proceedings."

We depend on our information systems and those of third parties for the effective and efficient functioning of our business.

We depend on our information systems for the effective and efficient functioning of our business, including the manufacture, distribution and maintenance of the components of the Cue Health Monitoring System, as well as for accounting, data storage, compliance, purchasing and inventory management. Our information systems and those of third parties upon whom we rely 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 and other cyber-attacks. 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 the release of our confidential information. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. Third parties upon whom we rely or with whom we have business relationships, including our customers, collaborators, suppliers, and others, are subject to similar risks that could potentially have an adverse effect on our business.

Technological interruptions could disrupt our operations, including our manufacturing operations, our ability to timely ship and track product orders, our ability to manage project inventory requirements, our ability to manage our supply chain and our ability to otherwise adequately service our customers or disrupt our customers' ability use the Cue Health Monitoring System or the Cue Integrated Care Platform.

In the event we experience significant disruptions in our information systems, we may be unable to address such disruptions in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and harm our business, financial condition and results of operations. Any business interruption insurance carried

by us may not be sufficient to protect us against any such business disruptions. 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 harm our business, financial condition and results of operations.

Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business, or information of our customers, users of our products, healthcare stakeholders or others, or prevent us or our customers, users of our products, healthcare providers, healthcare payors or others from accessing critical information, all of which could result in a material adverse effect, including without limitation, a material operational or service interruption, harm to our reputation, significant fines, penalties and liability, breach or triggering of Data Protection Laws, Privacy Policies and Data Protection Obligations, loss of customers or sales, or customers curtailing or ceasing their use of our services.

In the ordinary course of our business, we and our third-party service providers will collect, use, generate, transfer, and disclose, or Process, sensitive data, including legally protected health information, or PHI, and medical information, personally identifiable information, intellectual property and proprietary business information owned or controlled by us or our customers. In addition, we offer online customer-facing portals accessible through private and web portals. It is critical that we Process sensitive data in a secure manner to maintain the confidentiality and integrity of such confidential information. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems, and cloud-based data center systems. These applications and related data encompass a wide variety of business-critical information including research and development information, commercial and financial information.

Although we take measures designed to protect such information from unauthorized access, use or disclosure, our information technology and infrastructure, and that of our third-party service providers may be vulnerable to natural disasters, war, terrorism, telecommunications and electrical failures, ransomware, nation-state attacks, social engineering, denial-of-service attacks, phishing attacks, cyber-criminals, cyber-attacks by hackers or viruses, or breaches due to employee error, malfeasance or other disruptions. We also face the ongoing challenge of managing access controls to our information technology systems. If we do not successfully manage these access controls it further exposes us to risk of security breaches or disruptions. Any such security breaches or disruptions could compromise the security or integrity of our networks or result in the loss, misappropriation, and/or unauthorized access, use, modification or disclosure of, or the prevention of access to, sensitive data or confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information). For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. If our or our vendors' information systems are breached, sensitive data are compromised, surreptitiously modified, rendered inaccessible for any period of time or maliciously made public, or if we fail to make adequate or timely disclosures to affected individuals, appropriate state and federal regulatory authorities or law enforcement agencies, if appropriate, following any such event, whether due to delayed discovery or a failure to follow existing protocols, it could result in significant fines, penalties, orders, sanctions and proceedings or actions against us by governmental bodies or other regulatory authorities, customers or third parties. Any of the foregoing could result in significant legal and financial exposure and reputational damages that could potentially have a material adverse effect on our business, financial condition, results of operations and prospects.

Cyber-attacks are increasing in frequency and evolving in nature, and this activity has increased even further during the COVID-19 pandemic. We are at risk of attack by a variety of adversaries, including state-sponsored organizations, organized crime, hackers or "hactivists" (activist hackers), through the use of increasingly sophisticated methods of attack, including long-term, persistent attacks referred to as advanced persistent threats. The techniques used to obtain unauthorized access or sabotage systems include, among other things, computer viruses, malicious or destructive code, ransomware, social engineering attacks (including phishing and impersonation), hacking and denial-of-service attacks. Our systems are also subject to compromise from internal threats, such as theft, misuse, unauthorized access or other improper actions by employees, vendors and other third parties with otherwise legitimate access to our systems. Third parties may also attempt to fraudulently induce our employees and contractors into disclosing sensitive information such as user names, passwords, or other information or otherwise compromise the security of our electronic systems, networks, and/or physical facilities in order to gain access to our data. Additionally, due to the COVID-19 pandemic, our employees are temporarily working remotely, which may pose additional data security risks. Given the unpredictability of the timing, nature and scope of information technology disruptions, there can be no assurance that any security procedures and controls that we or our third-party service providers have implemented will be sufficient to prevent cyber-attacks from occurring. The latency of a compromise is often measured in months, but could be years, and we may not be able to detect a compromise in a timely manner. New techniques may not be identified until they are launched against a target, and we may be unable to anticipate these techniques or detect an incident, assess its severity or impact, react or appropriately respond in a timely manner or

implement adequate preventative measures, resulting in potential data loss or other damage to our information technology systems.

As the breadth and complexity of the technologies we use and the software and platforms we develop continue to grow, the potential risk of security breaches and cyber-attacks also increases. Our policies, employee training (including phishing prevention training), procedures and technical safeguards may be insufficient to prevent or detect improper access to confidential, proprietary or sensitive data, including personal data. In addition, the competition for talent in the data privacy and cybersecurity space is intense, and we may be unable to hire, develop or retain suitable talent capable of adequately detecting, mitigating or remediating these risks. As cybersecurity threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. The inability to implement, maintain and upgrade adequate safeguards could have a material adverse effect on our business. Additionally, federal, state, local, and international laws, rules, regulations, guidance and opinions regarding privacy and information security, or collectively, Data Protection Laws, external and internal privacy and security policies, representations, certifications, standards, publications and frameworks, or collectively, Privacy Policies, and contractual obligations to third parties related to privacy and information security, or collectively, Data Protection Obligations, may require us to implement specific security measures or use industry-standard or reasonable measures to protect against security breaches, which may be costly or difficult to implement without adversely affecting our operations.

We expect that we may have numerous vendors and other third parties who receive personal data from us in connection with the products we offer our customers. In addition, we have migrated certain data, and may increasingly migrate data, to a cloud hosted by third-party vendors. Some of these vendors and third parties also have direct access to our systems. Due to applicable Data Protection Laws and Data Protection Obligations, we may be held responsible for any information security failure or cyber-attack attributed to our vendors as they relate to the information we share with them. In addition, because we do not control our vendors and our ability to monitor their data security is limited, we cannot ensure the security measures they take will be sufficient to protect confidential, proprietary, or sensitive data, including personal data, or prevent cyber-attackers from gaining access to our infrastructure or data through our vendors or other third parties.

Regardless of whether an actual or perceived cyber-attack is attributable to us or our third-party service providers, such an incident could, among other things, result in improper disclosure of information, harm our reputation and brand, reduce the demand for our products, lead to loss of customer confidence in the effectiveness of our security measures, disrupt normal business operations or result in our systems or products being unavailable. In addition, it may require us to spend material resources to investigate or correct the breach and to prevent future security breaches and incidents. The costs related to significant security breaches or disruptions could be material and exceed the limits of any cybersecurity insurance we maintain, increase our risk of regulatory scrutiny, expose us to legal liabilities, including litigation, regulatory enforcement, indemnity obligations or damages for contract breach, divert the attention of management from the operation of our business and cause us to incur significant costs, any of which could affect our financial condition, operating results and our reputation. Moreover, there could be public announcements regarding any such incidents and any steps we take to respond to or remediate such incidents, and if securities analysts or investors perceive these announcements to be negative, it could, among other things, have a substantial adverse effect on the price of our common stock. In addition, our remediation efforts may not be successful. Any of the foregoing events could have a material adverse effect on our business, financial condition and results of operations.

We may not have adequate insurance coverage to protect us against the various types of business risks we face.

We may not have adequate insurance coverage to protect us against the various types of business risks we face. This includes risks such as product liability risk, business interruption risk and other risks we may face. The successful assertion of one or more large claims against us that exceeds our available insurance coverage or for which we are self-insured, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside the United States.

An element of our business strategy is to market our products outside the United States, if cleared, authorized or approved. Currently, we have a CE mark in the European Union, as well as Interim Order authorization from Health Canada, which is the department of the Government of Canada responsible for national health policy, for our COVID-19 test. In June 2021, our COVID-19 test also received regulatory approval from the CDSCO for professional point-of-care use in India. We expect to seek further authorizations, clearances and approvals outside of the United States. As a result,

we expect that our business will be subject to risks associated with doing business outside the United States, including an increase in our expenses and diversion of our management's attention from other aspects of our business. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- failure by us or our distributors to obtain regulatory clearance, authorization or approval for the use of our products in various countries and other jurisdictions;
- multiple, conflicting and changing laws and regulations such as privacy security and data use regulations, tax laws, export and import restrictions, economic sanctions and embargoes, employment laws, anti-corruption laws, regulatory requirements, reimbursement or payor regimes and other governmental approvals, permits and licenses;
- additional potentially relevant third-party patent rights;
- pricing pressures and differing reimbursement regimes;
- complexities and difficulties in obtaining intellectual property protection and maintaining, defending and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- employment risks related to hiring employees outside the United States;
- logistics and regulations associated with shipping samples, including infrastructure conditions and transportation delays;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- regulatory authorities revoking or terminating our authorizations and approvals in Canada, the European Union and India, or other jurisdictions;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- regulatory and compliance risks related to adherence with foreign privacy and data security laws, including the General Data Protection Regulation 2016/679 and other similar bodies of law;
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions, or its anti-bribery provisions, or laws similar to the FCPA in other jurisdictions in which we may now or in the future operate, such as the United Kingdom's Bribery Act of 2010, or U.K. Bribery Act; and
- onerous anti-bribery requirements of several member states in the EU, the United Kingdom, and other countries that are constantly changing and require disclosure of information to which U.S. legal privilege may not extend.

Any of these factors or other risks associated with international operations could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other

collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

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

We may in the future make acquisitions or investments in complementary companies, technologies or products that we believe fit within our business model and can address the needs of our customers and potential customers. We may not be able to integrate any acquired companies, technologies or products in a successful manner. In addition, 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. 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.

We may not realize the intended benefits of any acquisition we may make. To the extent we pursue any strategic alliances or joint ventures, we may similarly fail to realize the intended benefits of any such transaction.

Risks Related to Our Financial Condition and Capital Requirements

We may in the future consider raising additional capital for any number of reasons, including to fund our operations, further develop our Cue Integrated Care Platform, develop and commercialize new tests and products, and expand our operations.

We may in the future consider raising additional capital for any number of reasons and to do so, we may seek to sell common or preferred equity or convertible debt securities, enter into one or more credit facilities or another form of third-party funding, or seek other debt financing. We may also need to raise capital sooner or in larger amounts than we anticipate for numerous reasons, including because of lower demand for our COVID-19 test, the cancellation of any of our contracts with our largest customers, through no fault of our own, or as a result of failure to obtain regulatory approvals for our other tests, or other risks described in this report.

We may also consider raising 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 facilitate market adoption of our products and address competitive developments;
- fund development and marketing efforts of any future products;
- further expand our operations outside the United States;
- acquire, license or invest in technologies, including information technologies;

- satisfy any outstanding or future debt obligations;
- 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 successfully commercialize the Cue Health Monitoring System, including our COVID-19 test;
- the costs of the sales and marketing activities associated with commercializing the Cue Health Monitoring System, including our COVID-19 test;
- the length of the COVID-19 pandemic;
- our ability to secure and maintain domestic and international regulatory authorization, clearance or approval for our products;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our products;
- our rate of progress in, and cost of research and development activities associated with, products in research and early development;
- our ability to control our manufacturing and operating costs;
- our ability to satisfy any outstanding or future debt obligations;
- the effect of competing technological and market developments;
- litigation expenses we incur to defend against claims that we infringe the intellectual property of others or judgments we must pay to satisfy such claims;
- the potential cost of and delays in research and development as a result of any regulatory oversight applicable to our products; and
- the costs of responding to the other risks and uncertainties described in this report.

The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, our stockholders' ownership interests will be diluted. Any equity securities we issue could also 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.

Additional equity or debt financing might not be available on reasonable terms, if at all. If we cannot secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more research and development programs or sales and marketing initiatives. In addition, we may have to work with a partner on one or more of our development programs, which could lower the economic value of those programs to us.

Lastly, if we are unable to obtain the requisite amount of financing needed to fund our planned operations, it could have a material adverse effect on our business and ability to continue operating as a going concern.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act, or the TCJA, which significantly reformed the Code. The TCJA, among other things, contained significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), the limitation of the deduction for net operating losses, or NOLs, arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of NOL carrybacks for losses arising in taxable years ending after December 31, 2017

(though any such NOLs may be carried forward indefinitely), the imposition of a one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, the elimination of U.S. tax on foreign earnings (subject to certain important exceptions), the allowance of immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repeal of many business deductions and credits.

As part of Congress's response to the COVID-19 pandemic, the Families First Coronavirus Response Act, or the FFCR Act, was enacted on March 18, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted on March 27, 2020, and COVID relief provisions were included in the Consolidated Appropriations Act, 2021, or CAA, which was enacted on December 27, 2020. All contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80% of-income limitation on the use of NOLs, which was enacted as part of the TCJA. It also provides that NOLs arising in any taxable year beginning after December 31, 2017 and before January 1, 2021 are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation of the tax deductibility for net interest expense by increasing the limitation from 30% to 50% of adjusted taxable income.

Regulatory guidance under the TCJA, the FFCR Act, the CARES Act, and the CAA is and continues to be forthcoming, and such guidance could ultimately increase or lessen impact of these laws on our business and financial condition. Congress may enact additional legislation in connection with the COVID-19 pandemic, and, as a result of the changes in the U.S. presidential administration and control of the U.S. Senate, additional tax legislation may also be enacted, some of which could have an impact on our company. In addition, it is uncertain if and to what extent various states will conform to the TCJA, the FFCR Act, the CARES Act, or the CAA.

Our ability to use our net operating losses, or NOLs, and certain other tax attributes to offset future taxable income is subject to certain limitations.

As of December 31, 2020, we had federal and state NOL carryforwards of approximately $108.7 million and $90.8 million, respectively. The federal NOLs include $26.2 million that may be used to offset up to one hundred percent (100%) of future taxable income. The federal and state NOLs, if unused, will begin to expire in calendar year 2031. The NOL carryforwards subject to expiration could expire unused and be unavailable to offset future income tax liabilities.

In general, under Sections 382 and 383 of the Code and corresponding provisions of state law, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We have conducted a study and determined that, through December 31, 2020, such ownership changes occurred in 2014 and 2018. Accordingly, our ability to use certain of our NOLs and other tax attributes to offset our taxable income is limited by Sections 382 and 383. We may also experience such ownership changes in the future as a result of our IPO and/or subsequent changes in our stock ownership (which may be outside our control). As a result, our ability to use our pre-change NOLs and other tax attributes to offset taxable income may be subject to limitations.

There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise become unavailable to offset future income tax liabilities. The TCJA, as amended by the CARES Act, includes changes to U.S. federal tax rates and the rules governing NOL carryforwards that may significantly impact our ability to utilize our NOLs to offset taxable income in the future. In addition, for state income tax purposes, there may be period during which the use of NOLs is suspended or otherwise limited, such as recent California legislation limiting the usability of NOLs for tax years beginning after 2019 and before 2023. Additionally, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, we may be unable to use a material portion of our NOLs and other tax attributes.

Our business may be subject to additional obligations to collect and remit sales tax and other taxes, and we may be subject to tax liability for past sales.

Any successful action by state, foreign (if we start selling internationally) or other authorities to collect additional or past sales tax could harm our business. States and various local taxing jurisdictions have differing rules and regulations governing sales and use taxes, and these rules and regulations are subject to varying interpretations that may change over time. It is possible that we could face sales tax audits and that our liability for these taxes could exceed our estimates as state tax authorities could assert that we are obligated to collect additional amounts as taxes from our customers and remit those taxes to those authorities. We could also be subject to audits in states and foreign jurisdictions (if we start selling internationally) for which we have not accrued tax liabilities. A successful assertion that we should be collecting additional sales or other taxes on our products in jurisdictions where we have not historically done so and do not accrue for sales taxes could result in substantial tax liabilities for past sales, discourage customers from purchasing our products or otherwise harm our business, financial condition and results of operations.

We file sales tax returns in certain states within the United States as required by law.

We file sales tax returns in certain states where we have been advised or have determined we have an obligation to do so, however, we do not collect sales or other similar taxes in all states, and one or more states (or foreign authorities if we start selling internationally) could seek to impose additional sales, use or other tax collection and record-keeping obligations on us or may determine that such taxes should have, but have not been, paid by us. Liability for past taxes may also include substantial interest and penalty charges. Any successful action by state, foreign or other authorities to compel us to collect and remit sales, use or other taxes, either retroactively, prospectively or both, could harm our business, financial condition and results of operations.

We hope to be a multinational organization, in which case we would be faced with increasingly complex tax issues in many jurisdictions, and we could be obligated to pay additional taxes in various jurisdictions.

If we become a multinational organization, we may be subject to taxation in several jurisdictions around the world with increasingly complex tax laws, the application of which can be uncertain. The amount of taxes we pay in these jurisdictions could increase substantially as a result of changes in the applicable tax principles, including increased tax rates, new tax laws or revised interpretations of existing tax laws and precedents, which could have a material adverse effect on our liquidity and results of operations. Furthermore, one or more jurisdictions in which we do not believe we are subject to tax payment, withholding or filing requirements could assert that we are subject to such requirements. Any of these claims or assertions could have a material impact on us and the results of our operations.

Risks Related to Manufacturing Our Products

We have limited experience manufacturing our products in commercial quantities; if we are unable to manufacture our products in the required quantities in a timely manner, our business could be materially adversely affected.

We have only limited experience in manufacturing our products in commercial quantities, and only first began commercializing the Cue Health Monitoring System in June 2020. We currently lease and operate three manufacturing facilities for the production of our Cue Cartridges: our Nancy Ridge facility, Vista facility and Waples facility. Given our limited commercial manufacturing experience and rapid ramp up of our manufacturing capabilities, we may be more susceptible to encountering production delays, interruptions or shortfalls than other companies with a longer track record of manufacturing products at commercial scale. Such production delays, interruptions or shortfalls may be caused by many factors, including the following:

- production issues that may arise out of the rapid expansion of our manufacturing capacity, including the opening of two new manufacturing facilities within the last 12 months;
- a setback in our anticipated timeline for finalizing the construction of our new production pods, which would result in manufacturing delays;
- key components of our products are provided by a single supplier or limited number of suppliers, and we do not maintain large inventory levels of these components such that, if we experience a shortage or quality issues in any of these components, we would need to identify and qualify new supply sources, which could increase our expenses and result in manufacturing delays;
- a delay in completing assembly of new controlled environment rooms at our manufacturing facility;
- state and federal regulations, including the FDA's Quality System Regulations, or QSR, for the manufacture of our products, noncompliance with which could cause an interruption in our manufacturing; and
- attraction and retention of qualified employees for our operations in order to significantly increase our manufacturing output.

We currently expect that customer demand for our COVID-19 test will exceed our manufacturing capacity in 2021. If we are unable to continue to keep up with demand for our products, our growth could be impaired, and market acceptance for our products and our reputation could be harmed and customers and other users of our products may instead elect to use our competitors' products. Our inability to successfully manufacture our products in sufficient quantities would materially harm our business.

In addition, our manufacturing facility and processes and those of our third-party suppliers are subject to unannounced FDA and state regulatory inspections for compliance with the QSR. Developing and maintaining a compliant quality

system is time consuming and expensive. Failure to maintain compliance with, or not fully complying with the requirements of the FDA and state regulators, could result in enforcement actions against us or our third-party suppliers, which could include the issuance of warning letters, seizures, prohibitions on product sales, recalls and civil and criminal penalties, any one of which could significantly impact our manufacturing supply and impair our financial results.

If we, our suppliers or our contract manufacturers experience significant disruptions to our or their manufacturing capabilities or ability to source needed supplies and materials, our business may be materially adversely affected.

Our operations, or those of our suppliers or third-party contract manufacturers, could become subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and pandemics, including the COVID-19 pandemic, and other natural or man-made disasters or business interruptions. Our corporate headquarters and manufacturing facilities are located in San Diego, California, near major earthquake faults and fire zones, and our suppliers and contract manufacturers may be subject to similar risks, whether due to earthquakes, fires or other natural disasters or business interruption risks. Our ability to obtain components for our Cue Cartridges would be disrupted if the operations of our suppliers were affected by a man-made or natural disaster or other business interruption. In addition, we rely on third party contract manufacturers for the manufacture of our Cue Readers and for some of the production of our Cue Wands. The occurrence of any type of business disruption at any of our own facilities or those of our suppliers or contract manufacturers could materially harm our operations, financial condition and results of operations, as well as otherwise have a material adverse effect on our business. While we maintain business interruption insurance to protect us from some of these risks, such insurance may not cover us for all business interruption risks we face and, even where we do have coverage, such coverage may not be sufficient in amount.

Over time, we may add new manufacturing facilities or relocate manufacturing to one more additional facilities, which may include additional facilities located elsewhere within or outside of the United States. The use of a new facility or new manufacturing, quality control, or environmental control equipment or systems generally requires FDA review and approval. Because of the time required to authorize manufacturing in a new facility under FDA and non-U.S. regulatory requirements, we may not be able to commence production at such a facility on a timely basis. The inability to perform our manufacturing activities, combined with our limited inventory of materials and components and manufactured products, may cause us to be unable to meet customer demand, cause customers and other users of our products to discontinue using the Cue Health Monitoring System, or harm our reputation, and we may be unable to reestablish relationships with such customers and users in the future.

We contract with third parties for the manufacture of our Cue Readers, Cue Wands and certain other components of the Cue Health Monitoring System. This reliance on third parties increases the risk that we will not have sufficient quantities of our Cue Health Monitoring System or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

While we manufacture all of our Cue Cartridges in our own manufacturing facilities, we rely, and expect to continue to rely, on third parties for the manufacture of our Cue Readers, Cue Wands and Cue Control Swab Packs. This reliance on third parties increases the risk that we will not have sufficient quantities of our Cue Readers, Cue Wands or quality control swabs that are included in our Cue Control Swab Packs or, ultimately, of our Cue Health Monitoring System or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

During the duration of our EUAs for our COVID-19 test, the FDA has waived certain current good manufacturing practices, or cGMP, requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of our COVID-19 test but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 280.90), and Subpart O (Statistical Techniques, 21 CFR 820.250). This means that our third-party manufacturing facilities will not need to, and may not, be compliant with all of the FDA's cGMPs. To the extent that we no longer have an EUA and need to seek FDA authorization for our COVID-19 test, we need to comply with cGMPs which may cause delays in production at our and our third-party manufacturing facilities.

In addition, while we audit and monitor our contract manufacturers to ensure they meet our contracted specifications, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies with the manufacture of our products or if it finds deficiencies or withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to produce or market our COVID-19 tests and any future contemplated tests, if authorized for commercialization by the relevant regulatory agency.

If any contract manufacturing organization, or CMO, with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In

such scenario, our Cue Health Monitoring System supply could be delayed significantly as we establish alternative supply sources for components of our Cue Health Monitoring System, such as Cue Readers or Cue Wands. In some cases, the technical skills required to manufacture our product components may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product components according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop products or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our products that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our products. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior contract manufacturing organization used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating comparability which could require the conduct of additional clinical trials.

Further, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals or authorizations, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our products.

We may be unable to establish any additional agreements with third-party manufacturers or do so on acceptable terms. Reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible delay or stoppage in production of certain components of the Cue Health Monitoring System that delays shipments of Cue Readers or Cue Test Kits to our customers;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Any products that we may develop may compete with our other products for access to manufacturing facilities.

Any performance failure on the part of our existing or future manufacturers could delay production and cause us to miss certain production targets. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our products may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

Our suppliers may fail to deliver components according to schedules, prices, quality and volumes that are acceptable to us, or we may be unable to manage these components effectively.

Our products contain components and raw materials that we purchase globally from mostly single-source direct suppliers, generally without long-term supply agreements. This exposes us to multiple potential sources of component shortages. Unexpected changes in business conditions, materials pricing, labor issues, wars, governmental changes, tariffs, natural disasters, health epidemics such as the global COVID-19 pandemic, trade and shipping disruptions and other factors beyond our or our suppliers' control could also affect these suppliers' ability to deliver components to us or to remain solvent and operational. For example, a global shortage of microchips has been reported since early 2021. The semiconductor supply chain is complex and has historically been characterized by wide fluctuations in the demand for, and supply of, its products. These fluctuations have resulted in circumstances where supply of and demand for semiconductors has been widely out of balance. Wafer foundries that support chipmakers have not invested enough in recent years to increase capacities to the levels needed to support demand from all of their customers. Wafers have a long lead time for production which further exacerbates the shortage. The full extent to which this global shortage might impact us is not yet known. The unavailability of any component or supplier could result in production delays, idle manufacturing facilities,

product design changes and loss of access to important technology and tools for producing and supporting our products. Moreover, our ramp up in production of our Cue Cartridges, or product design changes by us have required and may in the future require us to procure additional components in a short amount of time. Our suppliers may not be willing or able to sustainably meet our timelines or our cost, quality and volume needs, or to do so may cost us more, which may require us to replace them with other sources. Finally, we have limited manufacturing experience outside of our Nancy Ridge manufacturing facility and we may experience supply chain and procurement issues at the Nancy Ridge Facility as well as at our new Vista and Waples facilities. While we believe that we will be able to secure additional or alternate sources or develop our own replacements for most of our components, there is no assurance that we will be able to do so quickly or at all. Additionally, we may be unsuccessful in our continuous efforts to negotiate with existing suppliers to obtain cost reductions and avoid unfavorable changes to terms, source less expensive suppliers for certain components and redesign certain parts to make them less expensive to produce. Any of these occurrences may harm our business, prospects, financial condition and operating results.

As the scale of our Cue Health Monitoring System production increases, we will also need to accurately forecast, purchase, warehouse and transport components and raw materials at high volumes to our own and our third-party manufacturing facilities and servicing locations, which includes locations in the U.S. and China. If we are unable to accurately match the timing and quantities of component purchases to our actual needs or successfully implement automation, inventory management and other systems to accommodate the increased complexity in our supply chain and parts management, we may incur unexpected production disruption, storage, transportation and write-off costs, which may harm our business and operating results.

Risks Related to Our Intellectual Property

Our patent or other intellectual property protection for the Cue Health Monitoring System, products and Cue Integrated Care Platform may not be sufficient to prevent competitors from developing and commercializing tests and platforms similar to or otherwise comparable to our Cue Test Kits, products and Cue Integrated Care Platform, which could materially adversely affect our business and prospects.

As with other diagnostic testing companies, our success depends in large part on our ability to obtain, maintain and solidify a proprietary position for our Cue Integrated Care Platform and our current and any future tests, which will depend upon our success in obtaining effective patent protection and other intellectual property, in the United States and other countries, with respect to, such tests, their manufacturing processes and their intended methods of use, as well as enforcing those patent claims once granted and other intellectual property rights. In some cases, we may not be able to obtain issued patent claims or other registered intellectual property covering various aspects of our technologies which are sufficient to prevent third parties, such as our competitors, from utilizing our Cue Integrated Care Platform. Any failure to obtain or maintain patent and other intellectual property protection with respect to our Cue Integrated Care Platform or our current and any future tests or other aspects of our business could harm our business, financial condition and results of operations.

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 or narrow the scope of our patents. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

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. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. 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, corporate collaborators, outside scientific collaborators, suppliers, 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 and obtain patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends in part on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, the publication of discoveries in scientific literature often lags behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to file for patent protection of such inventions.

Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties, and are therefore reliant on our licensors or licensees, and may be reliant on future licensors or licensees, to protect certain of our intellectual property used in our business. If such licensors or licensees fail to adequately protect this intellectual property

or if we do not have exclusivity for the marketing of our tests, whether because our licensors do not grant us exclusivity or they do not enforce the intellectual property against our competitors, our ability to commercialize products could suffer.

Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship and the like, although we are unaware of any such defects that we believe are of importance. If we or any current or future licensors or licensees fail to establish, maintain, protect or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. If any current or future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and/or unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may materially harm our business.

The strength of patent rights generally, and particularly the patent position of medical device companies, involves complex legal and scientific questions and can be uncertain, and has been the subject of much litigation in recent years. This uncertainty includes changes to the patent laws through either legislative action to changes to statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents or the chances that patent applications will result in issued claims and the scope of any such claims. Our current or future patent applications may fail to result in issued patents in the United States or foreign countries with claims that cover our current and any future tests. Even if patents do successfully issue from our patent applications, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of the Cue Health Monitoring System or our current and any future tests, which may harm our business. Furthermore, even if they are unchallenged, our patents may not adequately protect the Cue Health Monitoring System or our current and any future tests, provide exclusivity for our Cue Integrated Care Platform or such current or future tests or prevent others from designing around our claims. If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and tests would be adversely affected. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our current and any future tests is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, the Cue Health Monitoring System and our current and any future tests.

Patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after its effective filing date and the natural expiration of a design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for the components of our Cue Health Monitoring System, we may be open to competition, which may harm our business prospects. Further, if we encounter delays in our development efforts, the period of time during which we could market the Cue Health Monitoring System under patent protection would be reduced and, given the amount of time required for the development, testing and regulatory review of planned or future tests, patents protecting our current and any future tests might expire before or shortly after such tests are commercialized. As our patents expire, the scope of our patent protection will be reduced, which may reduce or eliminate any competitive advantage afforded by our patent portfolio. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing platforms or tests similar or identical to ours.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted 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 any competitive advantage. Any patents that we own now or in the future may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether our current and any future tests or other technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or tests in a non-infringing manner which could harm our business, financial condition and results of operations.

Some of our patents and patent applications may in the future be jointly-owned with third parties. If we are unable to obtain an exclusive license to any such third-party joint-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 platforms or tests and technology. In addition, we may need the cooperation of any such joint-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 harm our business, financial condition and results of operations.

We have obtained license or service agreements from certain third-party intellectual property holders. If we breach our agreements, it could have a material adverse effect on our commercialization efforts for the Cue Health Monitoring System or our current and any future tests and services. Further, we may find it necessary or prudent to acquire or obtain licenses from third-party intellectual property holders. However, we may be unable to acquire or secure such licenses to any intellectual property rights from third parties that we identify as necessary for our current and any future tests. The acquisition or licensing of third-party intellectual property rights is a competitive area, and our competitors may pursue strategies to acquire or license third-party intellectual property rights that we may consider attractive or necessary. Our competitors may have a competitive advantage over us due to their size, capital resources and greater development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to acquire or license third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant tests, which could harm our business, financial condition and results of operations.

Patents covering our current, and any future tests, the Cue Health Monitoring System, or our technologies could be challenged by third parties. If our patents are found to be invalid or unenforceable, our business could be materially adversely affected.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad and may not provide us with adequate proprietary protection or competitive advantage against competitors with similar products. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or IPR, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, such patent rights, allowing third parties to commercialize the Cue Health Monitoring System or our current and any future tests and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize the Cue Health Monitoring System or any current or future tests without infringing third-party patent rights. Moreover, we may have to participate in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and tests, or limit the duration of the patent protection of the Cue Health Monitoring System or our current and any future tests or technologies. Such proceedings also may result in substantial cost and require significant time from our management, even if the eventual outcome is favorable to us.

In addition, if we initiate legal proceedings against a third-party to enforce a patent covering the Cue Health Monitoring System or our current and any future tests, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant 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 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. Defenses of these types of claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Third parties may also raise claims challenging the validity or enforceability of our patents before administrative bodies in the United States or abroad, even outside the context of litigation, including through re-examination, post-grant review, IPR, derivation proceedings and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover the Cue Health Monitoring System, our current and any future tests or technologies. The outcome for any particular patent 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 defendant or other 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 the Cue Health Monitoring System, our current and any future tests and technology. Such a loss of patent protection would harm our business, financial condition and results of operations.

We rely substantially on our trademarks and trade names. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be harmed.

We rely substantially upon trademarks to build and maintain the integrity of our brand. Our registered and unregistered trademarks or trade names may be challenged, infringed, circumvented, declared unenforceable or determined to be violating or infringing on other intellectual property rights. We may not be able to protect or enforce our rights to these trademarks and trade names, which we rely upon 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. Asserting claims against such third parties may be prohibitively expensive. In addition, there could be potential trade name or trademark infringement or dilution claims brought by owners of other trademarks against us. 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. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names or other intellectual property may be ineffective, could result in substantial costs and diversion of resources and could harm our business, financial condition and results of operations.

The diagnostic testing industry is characterized by intellectual property litigation and in the future we could become subject to litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages or prevent us from marketing the Cue Health Monitoring System or our existing or future tests.

Litigation regarding patents, trademarks, trade secrets, and other intellectual property rights is prevalent in the medical device and diagnostic sectors and companies in these sectors have used intellectual property litigation to gain a competitive advantage. Our commercial success depends in part upon our ability and that of our contract manufacturers and suppliers to manufacture, market, and sell our planned tests, and to use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. Because we have not conducted a comprehensive freedom to operate analysis for patents related to the Cue Health Monitoring System or our tests, we may not be aware of issued patents that a third-party, including a competitor, might assert are infringed by the Cue Health Monitoring System or our current or any future tests, which could materially impair our ability to commercialize the Cue Health Monitoring System or our current or any future tests. Even if we diligently search third-party patents for potential infringement by the Cue Health Monitoring System or our current or any future tests, we may not successfully identify patents that the Cue Health Monitoring System or our current or any future tests may infringe. If we are unable to secure and maintain freedom to operate, others could preclude us from commercializing the Cue Health Monitoring System or our current or future tests. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future tests and technology, whether or not we are actually infringing, misappropriating or otherwise violating the rights of third parties. Like other companies operating in the diagnostic testing space, we have, from time to time, received demand letters from third parties claiming that our business allegedly infringes their patents; however, in each case we have investigated the alleged claims and, in our responses to the claimants, have disputed their allegations as lacking any merit, and to date, no legal proceeding has ever been initiated by such third parties. In addition, while we have not conducted a comprehensive freedom to operate analysis, we are aware of patent claims that could be alleged to cover the methodology and compositions used by the Cue Health Monitoring System. While we believe that the patent claims may not be valid and that they may be reasonably challenged for validity, there can be no assurance that any such challenge would be successful. In the future, other third parties may assert infringement claims against us based on existing or future intellectual property rights, regardless of merit. If we are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing and marketing the Cue Health Monitoring System, our current and any future tests and technology. We may also elect to enter into such a license to settle pending or threatened litigation. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and could require us to pay significant royalties and other fees. We could be forced, including by court order, to cease commercializing the infringing technology or tests. In addition, we could be found liable for monetary damages, which may be significant. If we are found to have willfully infringed a third-party patent, we could be required to pay treble damages and attorneys' fees. A finding of infringement could prevent us from commercializing our planned tests in commercially important territories, or force us to cease some of our business operations, which could harm our business. A number of our employees were or may have been previously employed at, and a number of our current advisors and consultants are employed or may be employed by, universities or other biotechnology, medical device or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, advisors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we, or these employees, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above.

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses, and could distract our technical and management 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 negative impact on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could harm our business, financial condition and results of operations.

Many countries 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 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 harmed.

Obtaining and maintaining our intellectual property, including patent, protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government agencies, and our intellectual property, including patent, protection could be reduced or eliminated for non-compliance with these requirements.

Obtaining and maintaining our intellectual property, including patent, protection depends on compliance with various procedural measures, document submissions, fee payments and other requirements imposed by government agencies, and our intellectual property, including patent, protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on intellectual property registrations and applications will be due to be paid to the applicable government agencies, including with respect to patents and patent applications the USPTO and similar agencies outside of the United States, over the lifetime of our intellectual property registrations and applications, including our patents and patent applications. The various applicable government agencies, including with respect to patents and patent applications the USPTO and similar agencies outside of the United States, require compliance with several procedural, documentary, fee payment and other similar provisions during the application process. 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. There are situations, however, in which non-compliance can result in the abandonment or lapse of the intellectual property registration or application, resulting in a partial or complete loss of intellectual property rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of an intellectual property registration or application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical platforms, tests or technology, which could harm our business, financial condition and results of operations.

We have foreign intellectual property rights and may not be able to protect our intellectual property and proprietary rights throughout the world, which could harm our business, financial condition and results of operations.

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents or trademarks on the Cue Health Monitoring System, Cue Virtual Care Delivery Apps, Cue Data and Innovation Layer and our current and any future tests 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 or utilizing our trademarks in all countries outside the United States, or from selling or importing the Cue Health Monitoring System or tests made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own platforms or tests and, further, may export otherwise infringing platforms or tests to territories where we have patent protection but enforcement is not as strong as that in the United States. These platforms and tests may compete with the Cue Health Monitoring System or our current and any future tests, 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 tests in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary 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 and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect the Cue Health Monitoring System or our current and any future tests.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third-party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third-party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to file any patent application related to the Cue Health Monitoring System or our current and any future tests.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, IPR and derivation proceedings.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. Therefore, the America Invents 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. In addition, future actions by the U.S. Congress, the federal courts and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. Any of the foregoing could harm our business, financial condition and results of operations.

In addition, recent U.S. Supreme Court rulings have made and will likely continue to make changes in how the patent laws of the United States are interpreted. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict how this and future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse changes in the patent laws of other jurisdictions could also harm our business, financial condition, results of operations and prospects.

We may be subject to claims challenging the ownership or inventorship of our patents and other intellectual property and, if unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, or to cease the development, manufacture and commercialization of one or more of our current and any future tests.

We may be subject to claims that current or former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our current and any future tests. Litigation may be necessary to defend against these and other claims challenging inventorship of our patents, trade secrets or other intellectual property. If we 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 that is important to our current and any future tests. If we were to lose exclusive ownership of such intellectual property, other owners may be able to license their rights to other third parties, including our competitors. We also may be required to obtain and maintain licenses from third parties, including parties involved in any such 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 current and any future tests. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and tests. 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 harm our business, financial condition and results of operations.

Third-party claims of intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the sale and marketing of Cue Health Monitoring Systems.

The diagnostic testing industry is highly competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, we could become subject to significant intellectual property-related litigation and proceedings relating to our or third-party intellectual property and proprietary rights.

Our commercial success depends in part on our and any potential future collaborators' ability to develop, manufacture, market and sell the Cue Health Monitoring System, including any tests that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents and other intellectual property or proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us or any potential collaborators to alter our development or commercial strategies, obtain licenses or cease certain activities. The medical device industry is characterized by extensive litigation regarding patents and other intellectual property rights, as well as administrative proceedings for challenging patents, including interference, inter partes or post-grant review, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions.

Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the point-of-care and at-home over-the-counter molecular diagnostic testing field, and such third parties, including our competitors, may currently have patents or obtain patents in the future and claim that the manufacture, use or sale of the Cue Health Monitoring System or our current and any future tests infringes upon these patents. Although no third party has initiated any legal proceedings asserting a claim of patent infringement against us as of the date of this registration statement, third parties may hold proprietary rights that could prevent the manufacture, use or sale of the Cue Health Monitoring System. For example, while we have not conducted a comprehensive freedom to operate analysis, we are aware of patent claims that could be alleged to cover the methodology and compositions used by the Cue Health Monitoring System. While we believe that the patent claims may not be valid and that they may be reasonably challenged for validity, there can be no assurance that any such challenge would be successful. Beyond the foregoing potential conflicts, we have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and can give no assurance that other patents containing claims covering the Cue Health Monitoring System or our current and any future tests, parts of the Cue Health Monitoring System or our current and any future tests, technology or methods do not exist, have not been filed or could not be filed or issued. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which the Cue Health Monitoring System or our current or future tests infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us escalates.

In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, 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 by the Cue Health Monitoring System or our current and any future tests, which could harm our ability to commercialize the Cue Health Monitoring System or any test we may develop and any other technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. 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 U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe third-party intellectual property rights, including patents, and we are unsuccessful in demonstrating that such patents or other intellectual property rights are invalid or unenforceable, such third parties may be able to block our ability to commercialize the Cue Health Monitoring System, the applicable tests or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to

be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay significant license fees and/or royalties, and the rights granted to us might be non-exclusive, which could result in our competitors gaining access to the same technology. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, we may be unable to commercialize the Cue Health Monitoring System or our current and any future tests, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Defense of infringement claims, regardless of their merit or outcome, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the Cue Health Monitoring System, the infringing tests and/or have to pay substantial damages for use of the asserted intellectual property, including treble damages and attorneys' fees were we found to willfully infringe such intellectual property. Claims that we have misappropriated the confidential information or trade secrets of third parties could harm our business, financial condition and results of operations. We also might have to redesign the Cue Health Monitoring System, our infringing tests or technologies, which may be impossible or require substantial time and monetary expenditure.

Engaging in litigation to defend against third-party infringement claims is very expensive, particularly for a company of our size, and time-consuming. 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 negative impact 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 litigation or administrative proceedings more effectively than we can because of greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could harm our business, financial condition and results of operations.

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

Competitors may infringe our patents, or the patents of any future licensing partners, or we may be required to defend against claims of infringement. In addition, our patents or the patents of any such licensing partners also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time-consuming. In an infringement proceeding, a court may decide that our patent 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. An adverse result in any litigation 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.

Even if resolved in our favor, litigation or other legal 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 negative impact 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 harm our ability to compete in the marketplace. Any of the foregoing could harm our business, financial condition and results of operations.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Such claims could harm our business, financial condition and results of operations.

As is common in the diagnostic testing industry, our employees, consultants and advisors may be currently or previously employed or engaged at universities or other medical device, healthcare and technology companies, including our competitors and potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may in the future become subject to claims that we or these people have, inadvertently or otherwise, used or disclosed intellectual property, including trade secrets or

other proprietary information, of their current or former employer. Also, we may in the future be subject to claims that these people are violating non-compete agreements with their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could harm our business, financial condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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 to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property 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. Such claims could harm our business, financial condition and results of operations.

Intellectual property rights do not necessarily address all potential threats, and limitations in intellectual property rights could harm our business, financial condition and results of operations.

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 systems or tests that are similar to the Cue Health Monitoring System or our current and any future tests or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in the Cue Health Monitoring System or our current and any future tests that is in the public domain;
- we, or our current and future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we, or our current and future licensors or collaborators, may fail to meet our obligations to the U.S. government regarding any future patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- 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;
- it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our current and any future test or technology similar to ours;
- it is possible that our patents or patent applications omit people that should be listed as inventors or include people that should not be listed as inventors, which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- 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;
- the claims of our patents or patent applications, if and when issued, may not cover our current and any future tests or technologies;
- the laws of foreign countries may not protect our proprietary rights or the rights of future licensors or collaborators to the same extent as the laws of the United States;
- the inventors of our patents or patent applications may become involved with competitors, develop test or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;

- 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 platforms or tests for sale in our major commercial markets;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing platforms or tests that are outside the scope of our patents;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; or
- 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.

Any of the foregoing could harm our business, financial condition and results of operations.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for the Cue Health Monitoring System and our current and any future tests, we also rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain a competitive position, especially where we do not believe patent protection is appropriate or obtainable. Trade secrets and know-how can be difficult to protect. We seek to protect such proprietary information, in part, through non-disclosure and 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 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.

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 people, 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 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 harm our business, financial condition and results of operations.

Risks Related to Government Regulation and Our Industry

We received two EUAs and intend to seek additional and/or amended EUAs for our COVID-19 test. The FDA may not timely grant any additional or amended EUAs, if at all. For our existing EUAs and any new EUA, the FDA may revoke any EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, which would adversely impact our ability to market our COVID-19 test in the United States.

The FDA has the authority to grant an EUA to allow unapproved 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. On January 31, 2020, the Secretary of the U.S. Department of Health and Human Services, or U.S. HHS, issued a declaration of a public health emergency related to COVID-19. On February 4, 2020, U.S. HHS determined

that COVID-19 represents a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and, subsequently, declared on March 24, 2020, that circumstances exist to justify the authorization of emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 pandemic, subject to the terms of any authorization as issued by the FDA. On February 29, 2020, the FDA issued an immediately in effect guidance with policy specific to development of in vitro diagnostic tests during the COVID-19 public health emergency. This guidance was updated on March 16, 2020, May 4, 2020 and May 11, 2020. It is uncertain whether the widespread availability of approved and effective vaccinations could expedite or influence any such decision making with respect to the underlying health emergency.

The speed at which companies and institutions are acting to create and test medical products for COVID-19 is unusually rapid, and evolving or changing plans or priorities within the FDA, including changes based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory timelines for our COVID-19 test. Results from our continued development and planned clinical trials may raise new questions and require us to redesign proposed clinical trials with minimal lead time.

On June 10, 2020, we received an EUA from the FDA for our COVID-19 test for use at the point-of-care with specimens collected using the Cue Wand from individuals who are suspected of having COVID-19 by their healthcare provider. On August 20, 2020, the FDA granted an amendment to our EUA to add testing of previously collected nasal specimens in viral transport media from individuals who are suspected of having COVID-19 by their healthcare provider. On March 5, 2021, we received an EUA for our COVID-19 test for home and over-the-counter use by individuals aged two years or older with or without symptoms or other epidemiological reasons to suspect COVID-19 and without a prescription. We cannot predict how long the EUAs for our COVID-19 test will remain in place.

There can be no assurances that the FDA will authorize any request for additional and/or amended EUAs and if we do not receive the authorization, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Because the FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, we cannot predict how long our EUAs will remain in place. The FDA may also revoke an EUA when the circumstances justifying its issuance no longer exist, such as when an alternative is authorized for marketing through the standard procedures, such as through a 510(k) clearance. The FDA has stated that, given the magnitude of the COVID-19 health crisis and the testing capacity challenges in the United States, it has no intention of terminating EUAs for COVID-19 diagnostic tests based solely on a test receiving 510(k) clearance. However, the FDA may change this position at any time and without notice.

FDA policies regarding diagnostic tests, therapies and other products used to diagnose, treat or mitigate COVID-19 remain in flux as the FDA responds to new and evolving public health information and clinical evidence. Changes to FDA regulations or requirements could require changes to our authorized test, necessitate additional measures, or make it impractical or impossible for us to market our test. The revocation of an EUA, if granted, could necessitate that we pursue the lengthy and expensive 510(k) clearance process, if available, or another similarly burdensome marketing authorization process, such as a de novo classification. Indeed, FDA has recommended that manufacturers of tests subject to an EUA pursue pre-market submissions such as a 510(k), de novo classification, or pre-market approval, or PMA, as applicable, during the declared public health emergency so that their devices can remain on the market after the emergency terminates. As a result, any such revocation could adversely impact our business, financial condition and results of operations.

If the FDA revokes either of our existing EUAs prior to us having received regulatory approval to commercialize our COVID-19 test through a traditional approval pathway, we would be required to cease our commercialization efforts, which would substantially and negatively impact our business.

The Cue Health Monitoring System and our current and future tests require marketing authorizations, clearances or approvals from regulatory agencies before they can be marketed. Any such regulatory process would be expensive, time-consuming and uncertain both in timing and in outcome. If we fail to obtain or maintain necessary marketing authorizations, clearance, or approval, or if such authorizations, clearances or approvals for future products are delayed or not issued, it will negatively affect our business, financial condition and results of operations.

While we received two EUAs for our COVID-19 test, our strategy is to expand our product line to encompass products that are intended to be used at the point-of-care and at-home. Such products will be subject to regulation by the FDA as medical devices, including requirements for regulatory authorization, clearance or approval of such products before they can be marketed. Accordingly, we will be required to obtain marketing authorization, clearance, or approval, in order to sell our future products in a manner consistent with FDA laws and regulations. Such processes are expensive, time-consuming and uncertain; our efforts may never result in any marketing authorization, clearance, or approval; and failure by us to obtain or comply with such marketing authorizations, clearances or approvals could have an adverse effect

on our business, financial condition or operating results. The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

In the United States, before we can market a new medical device, or a new use of, or claim for, an existing product, we must first receive either 510(k) clearance, PMA approval or approval of a de novo application from the FDA, unless an exemption applies. The FDA also has authority to issue EUAs in times of crises such as pandemics (declaration of emergencies), which the FDA granted us for our COVID-19 test.

In the United States, outside of the context of the EUA application process, our tests will likely need to obtain clearance through the 510(k) premarket notification process. If the FDA requires us to go through a lengthier, more rigorous process for future products or modifications to existing products than expected, our product introductions or modifications could be delayed or cancelled, which could cause our sales to decline. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain PMA process. Although we do not currently market any devices under a PMA, the FDA may demand that we obtain a PMA prior to marketing certain of our future products. Further, even with respect to those future products where a PMA is not required, we may not be able to obtain the 510(k) clearances with respect to those products. The FDA can delay, limit or deny 510(k) clearance or PMA approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our tests are safe and effective for their intended uses;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- the manufacturing process or facilities we use or contract to use may not meet applicable requirements; and
- disruptions at the FDA caused by funding shortages or global health concerns, including the COVID-19 pandemic.

The FDA may refuse our requests for 510(k) clearance, de novo or PMA of new products, new intended uses or modifications to existing products.

From time to time, legislation is drafted and introduced in the United States that could significantly change the statutory provisions governing any regulatory approval or clearance that we receive in the United States. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our tests under development or impact our ability to modify our currently approved or cleared tests on a timely basis.

Modifications to our Cue Health Monitoring System and any current or future tests may require new regulatory authorizations, clearances or approvals or may require us to recall or cease marketing our Cue Health Monitoring System or any current or future tests until authorizations, clearances or approvals are obtained.

Once our Cue Health Monitoring System or any current or future tests are initially authorized, cleared or approved, modifications to such products may require new regulatory authorizations, approvals or clearances, including additional EUAs, 510(k) clearances or PMA approvals, or require us to recall or cease marketing the modified devices until these authorizations, 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 authorization, 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 may make modifications to our tests in the future. For example, we are developing additional software component to our tests, which may require new clearances or approvals from the FDA. If the FDA requires new authorizations, clearances or approvals for the modifications, we may be required to recall and to stop marketing our tests, as approved and as modified, which could require us to redesign our 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 510(k)-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 PMA application. Where we determine that modifications to our products require a new 510(k) clearance or PMA, 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 authorizations, 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 tests in a timely manner, which in turn would harm our future growth.

We require a waived designation under the Clinical Laboratory Improvement Amendments of 1988 from the FDA for our products to be used at the point-of-care, and outside of the clinical laboratory setting.

A Clinical Laboratory Improvement Amendments of 1988, or CLIA,-waived designation by the FDA is required for our products to be used at the point-of-care, and outside of the clinical laboratory setting but is not required for our at-home and over-the-counter COVID-19 test. We are subject to CLIA and its implementing regulations in the United States which establish quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test is performed. Laboratory tests regulated under CLIA are categorized by the FDA as waived, moderate complexity or high complexity based on set criteria. Tests that are waived by regulation, or cleared, approved, or otherwise authorized by the FDA for home use or a point-of-care test, are deemed waived following marketing authorization. Our COVID-19 test is currently marketed pursuant to EUAs we received from the FDA in June 2020, for point-of-care use, and in March 2021, for at-home and over-the-counter use without a prescription. If a test is not deemed waived, a manufacturer of a test categorized as moderate complexity may request categorization of the test as waived through a CLIA Waiver by Application submission to the FDA. The manufacturer must provide evidence to the FDA that a test meets the CLIA statutory criteria for waiver, including, among other things, that the test employs methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible. When a test is categorized as waived, it may be performed by laboratories with a Certificate of Waiver, which is issued by the Centers for Medicare & Medicaid Services, or CMS, the federal agency responsible for the oversight of clinical laboratories, which includes issuing waiver certificates. We are also required to maintain a license to conduct testing in California. California laws establish standards for day-to-day operation of our clinical laboratory, including the training and skills required of personnel and quality control. If, for future tests, we fail to obtain, or experience significant delays in obtaining, a waiver approval by the FDA for our tests, our tests will only be able to be performed by CLIA certified or accredited and state licensed laboratories, which may limit our commercial success and have an adverse effect on our business, financial condition or operations. Further, if we fail to meet the requirements for our CLIA Waiver or California state laboratory license, we could be subject to significant fines, penalties, administrative sanctions, any of which could have an adverse effect on our business, financial condition or operations.

If we fail to comply with the FDA's QSR our manufacturing operations could be interrupted and our Cue Health Monitoring System sales and operating results could suffer.

Although full compliance may not be required under an EUA, we will be required to comply with some requirements of the FDA's QSR, which covers the methods used in, and the facilities and controls used for, the design, testing, manufacture, quality assurance, labeling, packaging, sterilization, storage and shipping of our tests. The FDA enforces the QSR through periodic announced and unannounced inspections of our manufacturing facilities. The failure by us or one of our current or future manufacturers or suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory authorities, or the failure to timely and adequately respond to any adverse inspectional observations, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, injunctions, civil penalties and criminal fines;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our tests;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for approval of a PMA or 510(k) clearance of new products, modified products or new indications of cleared products;
- withdrawing PMA approvals or reclassifying devices that have 510(k) clearances;
- refusal to grant export certificates for our tests; or
- criminal prosecution.

Any of these actions could impair our ability to produce our tests in a cost-effective and timely manner to meet our customers' demands once approved for marketing. Furthermore, our key 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 components of our Cue Health Monitoring System on a timely basis and in the required quantities, if at all.

Our Cue Health Monitoring System is and will continue to be, subject to extensive regulation and compliance obligations, which are costly and time-consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required authorizations, clearances or approvals to commercialize our Cue Health Monitoring System and any current or future test.

The manufacture, labeling, advertising, promotion, record-keeping, post-market surveillance and marketing of medical devices are subject to extensive regulation and review by the FDA and numerous other governmental authorities in the United States as well as foreign countries where we may sell our tests. Even after we have obtained EUA approval, 510(k) clearance or PMA approval to market a product, we have ongoing responsibilities under FDA and other regulations. The FDA and other national governmental authorities have broad enforcement powers. The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs or lower than anticipated sales. Our failure to comply with applicable regulatory requirements could result in enforcement actions such as:

- civil penalties;
- delays on or denials of pending requests for 510(k) clearance or PMA approval;
- recalls or seizures;
- withdrawals or suspensions of current PMA approvals or reclassification of 510(k) cleared devices, resulting in prohibitions on sales of our tests, if approved;
- warning letters or untitled letters;
- operating restrictions, including a partial or total shutdown of production on our tests for any indication;
- refusal to issue export approvals or certifications;
- obtaining injunctions preventing us from manufacturing or distributing our products;
- commencing criminal prosecutions; and
- total prohibitions on our sales.

For example, in the past, we have received inquiries from the FDA into the marketing of our tests, reporting of any potential inaccurate test results, and canceled tests. The incurrence or commencement of any such action would harm our reputation and cause sales of our tests to suffer and may prevent us from generating revenue.

In order to facilitate the rapid and thorough public health response to the COVID-19 pandemic, the CARES Act requires every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 to report the results from each such test to the Secretary of U.S. HHS. The CARES Act also authorized the HHS Secretary to identify the form and manner, as well as the timing and frequency, of such reporting. Based on subsequent guidance issued by the U.S. HHS on June 4, 2020, all laboratories, including testing locations operating as temporary overflow or remote locations for a laboratory, and other facilities or locations performing testing at point-of-care or with at-home specimen collection related to SARS-CoV-2, will report data for all testing completed, for each individual tested, within 24 hours of results being known or determined, on a daily basis to the appropriate state or local public health department based on the individual's residence. If governmental authorities conclude that our reporting processes do not comply with applicable law, we may be subject to penalties and other damages.

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a

reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

The misuse or off-label use of our tests may harm our reputation or the image of our tests in the marketplace, or result in injuries that lead to product liability suits, which could be costly to our business. Moreover, we could be subject to FDA sanctions if we are deemed to have engaged in off-label promotion.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition on the promotion of a medical device for an indication that has not been approved or cleared by the FDA, referred to as an off-label use. The FDA does not restrict or regulate a physician's use of a medical device within the practice of medicine, and we cannot prevent a physician from using our tests for an off-label use. If the FDA determines that our promotional materials constitute the unlawful promotion of an off-label use, it could subject us to regulatory or enforcement actions, including revocation of our existing EUA, additional civil money penalties, criminal fines and penalties, and exclusion from participation in federal health programs, among others. For example, in connection with our existing EUA, our COVID-19 test must comply with certain labeling requirements, including the label that our COVID-19 test has not been FDA cleared or approved but has been authorized by the FDA under an EUA and that our COVID-19 test has been authorized only for the detection of nucleic acid from SARS-CoV-2, and not for any other viruses or pathogens. Other federal, state or foreign governmental authorities might also take action if they consider our promotion or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities. In that event, our reputation could be damaged and the use of our tests in the marketplace could be impaired.

Furthermore, the use of our tests for indications other than those that have been approved or cleared by the FDA may lead to performance issues or produce erroneous results, which could harm our reputation in the marketplace among physicians and consumers and increase the risk of product liability. Product liability claims are expensive to defend and could divert our management's attention from our primary business and result in substantial damage awards against us. Any of these events could harm our business, results of operations and financial condition.

Clinical trials necessary to support a future test submission will be expensive and may require the enrollment of large numbers of subjects, and suitable subjects may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new tests and will adversely affect our business, operating results and prospects.

Initiating and completing clinical trials necessary to support a future EUA, 510(k), PMA, or de novo submission, 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 test we advance into clinical trials may not have favorable results in later clinical trials.

We expect all of our tests in our expected future test menu to require clinical studies or trials.

Conducting successful clinical trials will require the enrollment of large numbers of subjects, and suitable subjects may be difficult to identify and recruit. Subject enrollment in clinical trials and completion of subject participation depends on many factors, including the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the indication of the underlying test, the availability of appropriate clinical trial investigators, support staff, and proximity of subjects to clinical sites and able to comply with the eligibility and exclusion criteria for participation in the clinical trial and subject compliance. In addition, subjects may not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products.

In addition, our clinical trials may in the future be affected by the COVID-19 pandemic. For example, the COVID-19 pandemic may impact subject enrollment. In particular, some sites may pause enrollment to focus on, and direct resources to, COVID-19, while at other sites, subjects may choose not to enroll or continue participating in the clinical trial as a result of the pandemic. As a result, potential subjects in our clinical trials may choose to not enroll, not participate in follow-up clinical visits, or drop out of the trial as a precaution against contracting COVID-19. Further, some subjects may not be able or willing to comply with clinical trial protocols if quarantines impede subject movement or interrupt healthcare services. We are unable to predict with confidence the duration of any such potential subject enrollment delays and difficulties, whether related to COVID-19 or otherwise. Delays in subject enrollment or failure of subjects to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our tests or result in the failure of the clinical trial.

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 subjects 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. In addition, despite considerable time and expense invested in our clinical trials, the FDA may not consider our data adequate for approval. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

Changes in funding or disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner, or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product applications to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including for 35 days beginning on December 22, 2018, the U.S. government shut down several times and certain regulatory agencies, including the FDA, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities. On March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We expect to rely on third parties in conducting future clinical studies of diagnostic products that may be required by the FDA or other regulatory authorities, and those third parties may not perform such clinical studies satisfactorily.

We do not have the ability to independently conduct clinical studies that may be required to obtain FDA and other regulatory clearance or approval for future diagnostic products. Accordingly, we expect that we would rely on third parties, such as, laboratories, clinical investigators, CROs, consultants, and collaborators to conduct such studies if needed. Our reliance on these third parties for clinical and other development activities would reduce our control over these activities but will not relieve us of our responsibilities. We will remain responsible for ensuring that each of our clinical studies is conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us to comply with standards, commonly referred to as GCPs, for conducting, recording and reporting the results of clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of patients in clinical studies are protected. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to current GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, including on account of the outbreak of infectious disease, such as the COVID-19 pandemic, or otherwise, we may be affected by increased costs, program delays or both, any resulting data may be unreliable or unusable for regulatory purposes, and we may be subject to enforcement action.

If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised, our preclinical 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 products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected.

We are subject to stringent and changing Data Protection Laws, Privacy Policies and Data Protection Obligations. The actual or perceived failure by us or our third-party service providers or vendors, to comply with such obligations could harm our reputation, subject us to significant fines and liability, or otherwise adversely affect our business.

We are subject to numerous Data Protection Laws that govern the Processing of individually identifiable information and health information and Data Protection Obligations. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these Data Protection Laws could result in enforcement actions against us, including 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.

As we seek to expand our business, we are, and will increasingly become, subject to various Data Protection Laws as well as Data Protection Obligations, relating to the Processing of sensitive and personal information in the jurisdictions in which we operate. In many cases, these laws, regulations and standards apply not only to disclosures to third parties, but also to transfers of information between or among us and other parties with which we have commercial relationships. These Data Protection Laws may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that will materially and adversely affect our business, financial condition and results of operations. The regulatory framework for data privacy, data security and data transfers worldwide is rapidly evolving and, as a result, interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. These laws and regulations include the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, or collectively referred to as the HIPAA Rules, which establish a set of national privacy and security standards to safeguard Protected Health Information, or PHI, by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates and their subcontractors with whom such covered entities contract for services that involve the creation, receipt, maintenance or transmission of PHI for or on behalf of a covered entity or another business associate. HIPAA requires covered entities and business associates to, among other things, develop and maintain policies and procedures with respect to PHI that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information and ensure the confidentiality, integrity and availability of electronic PHI. As this applies to our business, we are required to maintain security standards for any PHI that we create, receive, maintain or transmit. For example, we plan to offer cloud-based portal software to help our customers more efficiently use our products. The software will maintain security safeguards that are designed to be consistent with the HIPAA Rules, but we cannot guarantee that these safeguards will not fail or that they will not be deemed inadequate in the future. In addition, we could be subject to periodic audits for compliance with the HIPAA Privacy and Security Standards by the U.S. HHS, and our customers. The U.S. HHS Office for Civil Rights may impose significant penalties on entities subject to HIPAA for a failure to comply with a requirement of the HIPAA Rules. Penalties will vary significantly depending on factors such as the date of the violation, whether the

entity knew or should have known of the failure to comply, or whether the entity's failure to comply was due to willful neglect. A single breach incident may violate multiple standards. In addition, a person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face significant criminal penalties and imprisonment. 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. Additionally, if we are unable to properly protect the privacy and security of the PHI of our customers, we could be found to have breached our contracts. Determining whether PHI has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and we cannot be sure how these regulations will be interpreted, enforced or applied to our operations.

In addition, many states in which we operate have laws that protect the privacy and security of sensitive and personal information, including health-related information. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. For example, the California Confidentiality of Medical Information Act, or CMIA, which is a state version of the HIPAA Rules, that protects "medical information" held by providers of health care, health plans, and subcontractors, specifically regulates mobile applications used for, among other things, the diagnosis of medical conditions as "health care providers pursuant to Section 56.06 of the Civil Code. This means that we are subject to additional privacy requirements that are not otherwise applicable to business associates under the HIPAA Rules. If, for example, we were to disclose information to a third party where such disclosure is not permitted by CMIA, we could be subject to administrative fines and/or civil penalties per violation that vary based on whether the disclosure was due to negligence, was done knowingly and willfully, or was knowingly and willfully and "for purposes of financial gain," The CMIA also imposes criminal penalties. Section 56.36 provides that any violation of the CMIA's nondisclosure provisions that results in an economic loss or personal injury to a patient is punishable as a misdemeanor. Moreover, unlike HIPAA, CMIA authorizes a private right of action for any violation of its provisions, including inappropriate access to, use, or disclosure of "medical information." Actual injuries are not required to bring an action under CMIA. The courts may award nominal damages of $1,000 per person, plus costs and attorney's fees for a negligent disclosure and may award compensatory and punitive damages, plus attorneys costs and attorneys fees for economic losses or personal injury resulting from the disclosure. This private right of action may increase the likelihood of, and risks associated with, litigation in association with any data breach.

Another recent California law, the California Consumer Privacy Act of 2018, or CCPA, increases privacy rights for California residents and imposes stringent data privacy and security obligations on companies that process their personal information, came into effect on January 1, 2020. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information but does not apply to health care providers subject to CMIA or business associates subject to HIPAA. In addition, laws governing online privacy, such as the California Online Privacy Protection Act, or CalOPPA, applies to our mobile application and online services. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. The CCPA has been amended from time to time, and it is possible that further amendments will be enacted, but even in its current form it remains unclear how various provisions of the CCPA will be interpreted and enforced. Further, California voters recently approved the California Privacy Rights Act of 2020, or CPRA, that goes into effect on January 1, 2023. It is expected that the CPRA would, among other things, give California residents the ability to limit the use of their sensitive information, provide for penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the law. As the number and breadth of California privacy law increases, it is possible that we may be subject to additional standards or enforcement authorities under laws such as CCPA or CPRA in the future with respect to some of the information that we collect or maintain.

Although California often leads the nation in privacy laws, state laws are also changing rapidly. Additional states are enacting more stringent consumer privacy laws, and there is continuing discussion in Congress of a new federal data protection and privacy law to which we would become subject if it is enacted. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data processing practices and policies, divert resources from other initiatives and projects, and could restrict the way products involving data are offered, all of which may have a material and adverse impact on our business, financial condition and results of operations.

Laws, regulations and standards in many other jurisdictions also apply broadly to the Processing of personal information, which impose significant compliance obligations. For example, in the European Economic Area, or EEA, and the United Kingdom, the collection and use of personal data, including clinical trial data, is governed by the provisions of the General Data Protection Regulation, or GDPR, which came into effect in May 2018. The GDPR imposes stringent data privacy and security requirements on companies in relation to the processing of personal data of data subjects within the EEA and the United Kingdom. The GDPR, together with national legislation, regulations and guidelines of the EEA

member states and the United Kingdom governing the Processing of personal data, impose strict obligations and restrictions on the ability to Process personal data, including health data from clinical trials and adverse event reporting. The law is also developing rapidly and, in July 2020, in its Schrems II ruling, the Court of Justice of the EU invalidated the EU-U.S. Privacy Shield data transfer mechanism, limiting how organizations could lawfully transfer personal data from the EEA to the U.S. Other data transfer mechanisms such as the Standard Contractual Clauses approved by the European Commission have faced challenges in European courts (including being called into question in Schrems II), may require additional risk analysis and supplemental measures to be used, and may be challenged, suspended or invalidated. In addition, the European Commission recently proposed updates to the Standard Contractual Clauses. Such developments may cause us to have to make further expenditures on local infrastructure, limit our ability to Process personal data, change internal business processes or otherwise affect or restrict sales and operations. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any Data Protection Laws or any security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive or confidential information, whether by us, one of our service providers or another third party, could negatively affect our business, financial condition and results of operations, including but not limited to: investigation costs, material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; and injunctive relief.

Further, while the United Kingdom enacted the Data Protection Act 2018 in May 2018 that supplements the GDPR and has publicly announced that it will continue to regulate the protection of personal data in the same way post-Brexit for a period of time, Brexit has created uncertainty with regard to the future regulation of data and data protection in the United Kingdom. Other countries also are considering or have passed legislation requiring local storage, processing or security of data, or similar requirements, which could increase the cost and complexity of delivering our products.

We will make public statements about our use and disclosure of personal information through our Cue Virtual Care Delivery Apps and external Privacy Policies. Although we endeavor to comply with our external Privacy Policies, we may at times fail to do so or be alleged to have failed to do so. The publication of our external Privacy Policies that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any failure, real or perceived, by us to comply with our external Privacy Policies, Data Protection Laws, or consumer protection-related laws and regulations applicable to us could cause our customers to reduce their use of our products and could materially and adversely affect our business, financial condition and results of operations. In many jurisdictions, enforcement actions and consequences for non-compliance can be significant and are rising. In addition, from time to time, concerns may be expressed about whether our products or processes compromise the privacy of customers and others. Concerns about our practices with regard to the collection, use, retention, security, disclosure, transfer and other processing of personal information or other privacy-related matters, even if unfounded, could damage our reputation and materially and adversely affect our business, financial condition and results of operations.

Many statutory requirements, both in the United States and abroad, include obligations for companies to notify individuals of security breaches involving certain personal information, which could result from breaches experienced by us or our third-party service providers. For example, laws in all 50 U.S. states and the District of Columbia require businesses to provide notice to consumers whose unencrypted personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify affected customers, regulators, credit reporting agencies or other affected individuals of a security breach. Such notifications are costly, and the disclosures or the failure to comply with such requirements, could lead to material adverse effects, including without limitation, negative publicity, a loss of customer confidence in our services or security measures or breach of contract claims. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable Data Protection Laws, Data Protection Obligations or other legal obligations. In addition, although we may have contractual protections with our third-party service providers, contractors and consultants, any actual or perceived security breach by our subcontractors could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach. Any contractual protections we may have from our third-party service providers, contractors or consultants may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. New laws, amendments to or re-interpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations. Because the interpretation and application of health-related and Data Protection Laws and other obligations are still uncertain, and often contradictory and in flux, it is possible that the scope

and requirements of these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business.

We cannot assure you that our third-party partners and service providers with access to our or our customers', suppliers' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us or violate Data Protection Laws, or that they will not experience security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under the Data Protection Laws, which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy- and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information.

We may receive inquiries or be subject to investigations, proceedings or actions, by various government entities regarding our privacy and information security practices and Processing ("Regulatory Proceedings"). These Regulatory Proceedings could result in a material adverse effect, including without limitation, interruptions of, or required changes to, our business practices, the diversion resources and the attention of management from our business, regulatory oversights and audits, discontinuance of necessary Processing, or other remedies that adversely affect our business.

In addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded to require changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with customers and have a material and adverse impact on our business.

While we maintain general liability insurance coverage, cyber insurance coverage and other insurance, we cannot assure that such coverage will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or material adverse effects arising out of our privacy and security practices, Processing or security breaches we may experience, or that such coverage will continue to be available on acceptable terms or at all. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Laws and regulations affecting government contracts and grants, including our grants, make it more costly and difficult for us to successfully conduct our business. Failure to comply with these laws and regulations could result in significant civil and criminal penalties and adversely affect our business.

We must comply with numerous laws, regulations, and agency-specific policies and procedures relating to the administration and performance of our grant and sub-award agreements. Among the most significant are:

- the Federal Acquisition Regulation, or FAR, and agency-specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts;
- the business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the AKS, the Procurement Integrity Act, the FCA and the FCPA; and
- laws, regulations and executive orders restricting the exportation of certain products and technical data.

In addition, as a U.S. government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices, including unique accounting requirements regarding allowable and unallowable costs, and are subject to periodic audits and reviews. As part of any such audit or review, the U.S. government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Based on the results of its audits, the U.S. government may adjust our agreement-related costs and fees, including allocated indirect costs. This adjustment could impact the amount of revenue reported on a historic basis and could impact our cash flows under the

contract prospectively. In addition, in the event the U.S. government determines that certain costs and fees were unallowable or determines that the allocated indirect cost rate was higher than the actual indirect cost rate, it would be entitled to recoup any overpayment from us as a result. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our agreements, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us, which could cause our stock price to decline. Further, as a U.S. government contractor, we are subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities as compared to private sector commercial companies. In addition, the qui tam provisions of the civil FCA authorize a private person to file civil actions on behalf of the federal and state governments and retain a share of any recovery, which can include treble damages and civil penalties.

If we or our suppliers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and our suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations, and the manufacturer of our products, involve the production and use of hazardous and flammable materials and waste, including chemicals and biological materials. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

We are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

If we fail to comply with U.S. federal and state fraud and abuse and other healthcare laws and regulations, including those relating to kickbacks and false claims, we could face substantial penalties and our business operations and financial condition could be harmed.

Healthcare providers and third-party payors play a primary role in the distribution, recommendation, ordering and purchasing of any medical device for which we have or obtain marketing clearance or approval. Through our arrangements with healthcare professionals and customers, we are exposed to broadly applicable anti-fraud and abuse, anti-kickback, false claims and other healthcare laws and regulations that may constrain our business, our arrangements and relationships with customers, and how we market, sell and distribute our marketed medical devices. We intend to have a compliance program, code of conduct and associated policies and procedures, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent noncompliance may not be effective in protecting us from governmental investigations for failure to comply with applicable fraud and abuse or other healthcare laws and regulations.

In the United States, we are subject to various state and federal anti-fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal civil False Claims Act, or the FCA. There are similar laws in other countries. Our relationships with physicians, other health care professionals and hospitals are subject to scrutiny under these laws.

The laws that may affect our ability to operate include, among others:

- the Anti-Kickback Statute, which prohibits, among other things, knowingly and willingly soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward

either the referral of a person, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under a federal healthcare program such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value, and the government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate. In addition, the government may assert that a claim, including items or services resulting from a violation of the Anti-Kickback Statute, constitutes a false or fraudulent claim for purposes of the FCA. There are a number of statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution under the Anti-Kickback Statute; however, those exceptions and safe harbors are drawn narrowly, and there may be limited or no exception or safe harbor for many common business activities. Certain common business activities including, certain reimbursement support programs, educational and research grants or charitable donations, and practices that involve remuneration to those who prescribe, purchase or recommend medical devices, including discounts, providing items or services for free or engaging such people as consultants, advisors or speakers, may be subject to scrutiny if they do not fit squarely within any available exception or safe harbor and would be subject to a facts and circumstances analysis to determine compliance with the Anti-Kickback Statute. Our business may not in all cases meet all of the criteria for statutory exception or regulatory safe harbor protection from anti-kickback liability;

- the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA's reach extends beyond federal health care programs to include private insurance (i.e., it is an "all payor" statute);

- the federal false claims and civil monetary penalties laws, including the Civil Monetary Penalties Law and the FCA, which prohibit, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Actions under the FCA may be brought by the government or as a qui tam action by a private person in the name of the government. These people, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any monetary recovery. Many medical device manufacturers have been investigated and have reached substantial financial settlements with the federal government under the FCA for a variety of alleged improper activities, including causing false claims to be submitted as a result of the marketing of their products for unapproved and thus non-reimbursable uses and interactions with prescribers and other customers, including those that may have affected their billing or coding practices and submission of claims to the federal government. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory monetary penalties for each false or fraudulent claim or statement. Because of the potential for large monetary exposure, healthcare and medical device companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings. Settlements may require companies to enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance. Medical device manufacturers and other healthcare companies also are subject to other federal false claims laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs;

- HIPAA, which imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making a materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, and their implementing regulations, also impose obligations, including mandatory contractual terms, on covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates and their subcontractors that perform certain services for them or on their behalf involving the use or disclosure of individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- various state laws govern the privacy and security of personal information, including the CMIA, which provides for a private right of action for data breaches;

- the federal Physician Payments Sunshine Act, implemented as Open Payments, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually, with certain exceptions to CMS, information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse-midwives; and

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require medical device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state beneficiary inducement laws, which are state laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. Most recently, the Bipartisan Budget Act of 2018, or the BBA, increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti-Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies have increased regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient support programs, including bringing criminal charges or civil enforcement actions under the Anti-Kickback Statute, FCA and HIPAA's healthcare fraud and privacy provisions.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including certain sales and marketing practices of our Cue Health Monitoring System, and financial arrangements with physicians, other healthcare providers, and other customers, could be subject to challenge under one or more such laws. If an arrangement were deemed to violate the Anti-Kickback Statute, it may also subject us to violations under other fraud and abuse laws such as the federal civil FCA and civil monetary penalties laws. Moreover, such arrangements could be found to violate comparable state fraud and abuse laws.

Achieving and sustaining compliance with applicable federal and state anti-fraud and abuse laws may prove costly. If we or our employees are found to have violated any of the above laws we may be subjected to substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action or investigation against us for the violation of these healthcare fraud and abuse laws, even if successfully defended, could result in significant legal expenses and could divert our management's attention from the operation of our business. Companies settling FCA, Anti-Kickback Statute or civil monetary penalties law cases also may enter into a Corporate Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General, or the OIG, in order to avoid exclusion from participation (such as loss of coverage for their products) in federal healthcare programs such as Medicare and Medicaid. Corporate Integrity Agreements typically impose substantial costs on companies to ensure compliance. Defending against any such actions can be costly, time-consuming and may require significant personnel resources, and may harm our business, financial condition and results of operations.

In addition, the medical device industry's relationship with physicians is under increasing scrutiny by the OIG, the U.S. Department of Justice, or the DOJ, the state attorney generals and other foreign and domestic government agencies. Our failure to comply with requirements governing the industry's relationships with physicians or an investigation into our compliance by the OIG, the DOJ, state attorney generals and other government agencies, could harm our business, financial condition and results of operations.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business, financial condition and results of operations.

We are exposed to the risk that our employees, independent contractors, consultants, commercial partners, distributors and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (1) the laws of the FDA and other similar regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators, (2) manufacturing standards, (3) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or (4) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed 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, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We adopted a code of business conduct and ethics that applies to our directors, officers and employees, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities 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 result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, additional integrity reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees and reputational harm, and divert the attention of management in defending ourselves against any of these claims or investigations, which could harm our business, financial condition and results of operations.

Healthcare policy changes may have a material adverse effect on our business, financial condition and results of operations.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, enacted in March 2010, made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which the ACA may significantly impact our business, the ACA includes: provisions regarding coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures; initiatives to revise Medicare payment methodologies; and initiatives to promote quality indicators in payment methodologies.

Since enactment of the ACA, there have been, and continue to be, numerous executive and legal challenges and Congressional actions to repeal and replace provisions of the law. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017, repealed the “individual mandate.” The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and the medical device tax and, effective January 1, 2021, also eliminated the health insurer tax.

During his term, President Trump signed several Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. On January 28, 2021, however, President Biden issued a new Executive Order which directed federal agencies to reconsider rules and other policies that limit Americans’ access to health care and consider actions to protect and strengthen that access. Under this Executive Order, federal agencies were directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents.

On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of legislation enacted in 2017, informally titled the Tax

Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On June 17, 2021, the Supreme Court held that the states and individuals that brought the lawsuit challenging the ACA's individual mandate do not have standing to challenge the law. The Supreme Court did not reach the merits of the challenge, but the decision ends the case. It is unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden Administration will impact the ACA.

In addition, there have been numerous governmental reform activities in response to the COVID-19 pandemic. For example, the FFCRA authorized state Medicaid programs to provide access to coverage for certain medically necessary testing, testing-related services and treatment related to COVID-19 at no cost to the individual during the emergency period. Such programs are evolving and vary among state Medicaid programs. In addition, the California Department of Health Care Services implemented a COVID-19 Uninsured Group program on August 28, 2020. Under the program, California covers COVID-19 diagnostic testing, testing-related services, and treatment services, including hospitalization and all medically necessary care, at no cost to the individual, for up to 12 months or the end of the public health emergency, whichever comes first. It is possible that additional governmental action will be taken to address the COVID-19 pandemic, which may impact our business.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. The expansion of government's role in the U.S. healthcare industry as a result of the ACA's implementation, and changes to the reimbursement amounts paid by Medicare and other payors for our tests and our planned future tests, may reduce our profits, if any, and have a materially adverse effect on our business, financial condition, results of operations and cash flows.

We cannot predict the impact changes to these laws or the implementation of, or changes to, any other laws applicable to us in the future may have on our business, financial condition and results of operations.

Risks Related to Our Common Stock

An active trading market for our common stock may not be sustained.

An active public trading market for our common stock it may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

Our stock price may be volatile, and the value of our common stock may decline.

The market price of our common stock may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control, including, but not limited to:

- actual or anticipated fluctuations in our financial condition or results of operations;
- variance in our financial performance from expectations of securities analysts;
- changes in the pricing of our products;
- changes in our projected operating and financial results;
- changes in laws or regulations applicable to our products;
- changes in the number of enterprise customers we are able to partner with;
- the level of market adoption of the Cue Health Monitoring System, including in the over-the-counter and at-home context;
- announcements by us or our competitors of significant business developments, acquisitions, or new offerings;
- changes in the structure of healthcare payment systems;
- significant data breaches of our company, providers, vendors or pharmacies;

- our involvement in litigation;
- future sales of our common stock by us or our stockholders, as well as the anticipation of lock-up releases;
- changes in senior management or key personnel;
- negative publicity, such as whistleblower complaints or unsupported allegations made by short sellers, about us or our products;
- the trading volume of our common stock;
- changes in investor perceptions of us or our industry;
- changes in the anticipated future size and growth rate of our market;
- the effect of the COVID-19 pandemic and the end of the COVID-19 pandemic on our business;
- general economic, political, regulatory, industry, and market conditions; and
- natural disasters or major catastrophic events.

These and other factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In recent years, stock markets in general, and the market for life science technology companies in particular (including companies in the genomics, biotechnology, diagnostics and related sectors), have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

Future sales of our common stock in the public market could cause the market price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities.

All of our directors and officers and the holders of substantially all of our capital stock and securities convertible into our capital stock are subject to lock-up agreements that restrict their ability to transfer shares of our capital stock for 180 days from September 23, 2021. These lock-up agreements limit the number of shares of capital stock that may be sold, subject to certain exceptions. Subject to certain limitations, substantially all of these shares will become eligible for sale upon expiration of the 180-day lock-up period. Goldman Sachs & Co. LLC and Morgan Stanley & Co. LLC may, in their sole discretion, permit our stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

Beginning 180 days from September 23, 2021, holders of approximately 111,434,865 shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

The issuance of shares in connection with any subsequent issuance could depress the market price of our common stock. We are unable to predict the effect that such issuances and/or sales may have on the prevailing market price of our common stock.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, as amended, or JOBS Act. For so long as we remain an emerging growth company, we are permitted by the U.S. Securities and Exchange Commission, or SEC, rules and plan to rely on exemptions from certain disclosure requirements that are applicable to other SEC-registered public companies that are not emerging growth companies.

These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different from the information that is available with respect to other public companies. In this report, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions.

In addition, as an emerging growth company the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies, unless we later irrevocably elect not to avail ourselves of this exemption. We have elected to use this extended transition period under the JOBS Act; however, we may choose to early adopt new or revised accounting pronouncements, if permitted under such pronouncements.

If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We do not expect to pay any dividends for the foreseeable future.

You should not rely on an investment in our common stock to provide dividend income. We have never declared or paid cash dividends on our capital stock, and we do not anticipate that we will pay any dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain all available funds and future earnings to fund the development and expansion of our business. In addition, any credit facility or other financing we obtain may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

Concentration of ownership of our common stock among our executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Based on the number of shares of common stock outstanding as of September 30, 2021, our executive officers, directors and current beneficial owners of 5% or more of our common stock will, in the aggregate, beneficially own approximately 37% of our common stock. These stockholders, acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, respectively, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66 2/3% of the voting power of all of our then outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;

- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;

- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and

- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66 2/3% of our then-outstanding common stock.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

General Risk Factors

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company, which we expect to further increase after we are no longer an emerging growth company. The Sarbanes–Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Stock Market LLC and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel will devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We cannot predict or estimate the amount of additional costs we will incur as a public company or the specific timing of such costs.

As a result of being a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting, and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We are required, pursuant to 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 for the fiscal year ending December 31, 2022, which is the year covered by the second annual report following our IPO. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company if we are not a non-accelerated filer at such time. We are commencing the costly and challenging process of compiling the information systems, processes and internal controls documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes–Oxley Act, but we may not be able to complete our evaluation, testing and any required remediation in a timely fashion once initiated. Our compliance with Section 404 of the Sarbanes–Oxley Act will require that we incur substantial accounting expenses and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff

with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes–Oxley Act.

If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

For a discussion of material weaknesses that were identified in connection with the audit of our 2019 and 2020 financial statements see "—We have identified material weaknesses in our internal control over financial reporting and may identify material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, as a result of which, 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" above.

Our amended and restated certificate of incorporation designates the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for the following types of proceedings: (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, other employees or stockholders to our company or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware or (4) any action asserting a claim arising pursuant to any provision of our amended and restated certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. This exclusive forum provision will not apply to actions arising under the Securities Act, the Exchange Act or any other claim for which federal courts have exclusive jurisdiction.

Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Accordingly, the exclusive forum provision does not designate the Court of Chancery as the exclusive forum for any derivative action arising under the Exchange Act, as there is exclusive federal jurisdiction in that instance, and instead designates the federal district court for the District of Delaware for such an action.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, the enforceability of our exclusive forum provision is uncertain, and a court may determine that such provision will not apply to suits brought to enforce any duty or liability created by the Securities Act or any other claim for which the federal and state courts have concurrent jurisdiction. Further, compliance with the federal securities laws and the rules and regulations thereunder cannot be waived by investors in our common stock.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. We also note that stockholders cannot waive compliance (or consent to noncompliance) with the federal securities laws and the rules and regulations thereunder. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could significantly harm our business.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition. Additionally, the dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements, and damages awarded to plaintiffs.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operation could fall below our publicly announced guidance or 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 U.S. 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 estimates 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. For example, in connection with the implementation of the new revenue accounting standard if and when we have product sales, management makes judgments and assumptions based on our interpretation of the new standard. The new revenue standard is principle-based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice and guidance may evolve as we apply the new standard. If our assumptions underlying our estimates and judgements relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates or judgements, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our common stock, the price of our common stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or securities analysts. If no or few analysts commence coverage of us, the trading price of our common stock could decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our common stock, the price of our common stock could decline. If one or more of these analysts cease to cover our common stock, we could lose visibility in the market for our common stock, which in turn could cause the price of our common stock to decline.

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

Unregistered Sale of Equity Securities

From July 1, 2021 through September 24, 2021 (the date of the filing of our registration statement on Form S-8), we granted to our directors, officers, employees, consultants and other service providers restricted stock units for an aggregate of 128,000 shares of our common stock under our 2014 Plan, and no restricted stock awards under our 2014 Plan.

From July 1, 2021 through September 24, 2021 (the date of the filing of our registration statement on Form S-8), we issued and sold to our directors, officers, employees, consultants and other service providers an aggregate of 367,559 shares of common stock upon the exercise of options issued under our 2014 Plan at a weighted-average exercise price of $0.43 per share, for an aggregate exercise price of $0.2 million.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. We believe the offers, sales, and issuances of the above securities were exempt from registration under the Securities Act (or Regulation D or Regulation S promulgated thereunder) by virtue of Section 4(a)(2) of the Securities Act because the issuance of securities to the recipients did not involve a public offering, or in reliance on Rule 701 because the transactions were pursuant to compensatory benefit plans or contracts relating to compensation as provided under such rule. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. All recipients had adequate access, through their

relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Use of Proceeds

On September 28, 2021, we completed our IPO, in which we sold 14,375,000 shares of our common stock at an offering price of $16.00 per share, including 1,875,000 shares pursuant to the exercise in full of the underwriters' option to purchase additional shares. We received net proceeds of $205.3 million after deducting underwriting commissions and legal, accounting, and consulting fees related to the IPO. All of the shares of common stock issued and sold in our IPO were registered under the Securities Act of 1933, as amended pursuant to a registration statement on Form S-1 (File No. 333-259250), which was declared effective by the SEC on September 23, 2021. The representatives of the underwriters of our IPO were Goldman Sachs & Co. LLC, Morgan Stanley & Co. LLC and Cowen and Company, LLC.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates. As of September 30, 2021, approximately $22.1 million of expenses incurred in connection with our IPO had been paid.

There has been no material change in the planned use of proceeds from our IPO from those disclosed in the Final Prospectus.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant	8-K	001-40824	3.1	September 28, 2021
3.2	Amended and Restated Bylaws of the Registrant	8-K	001-40824	3.2	September 28, 2021
4.1	Specimen Stock Certificate evidencing the shares of common stock	S-1	333-259250	4.1	September 1, 2021
10.1+	2021 Stock Incentive Plan	S-1/A	333-259250	10.5	September 15, 2021
10.2+	Form of Stock Option Agreement under the 2021 Stock Incentive Plan	S-1/A	333-259250	10.6	September 15, 2021
10.3+	Form of Restricted Stock Unit Agreement for Non-Employee Directors under the 2021 Stock Incentive Plan	S-1/A	333-259250	10.7	September 15, 2021
10.4+	Form of Restricted Stock Unit Agreement for Participants (other than Non-Employee Directors) under the 2021 Stock Incentive Plan	S-1/A	333-259250	10.8	September 15, 2021
10.5+	2021 Employee Stock Purchase Plan	S-1/A	333-259250	10.9	September 15, 2021
10.6+	Form of Indemnification Agreement between the Registrant and each of its Executive Officers and Directors	S-1	333-259250	10.20	September 1, 2021
10.7+	Employment Agreement, dated July 8, 2021, by and between the Registrant and Ayub Khattak	S-1	333-259250	10.21	September 1, 2021

10.8+	Employment Agreement, dated July 8, 2021, by and between the Registrant and Clint Sever	S-1	333-259250	10.22	September 1, 2021
10.9+	Employment Agreement, dated July 8, 2021, by and between the Registrant and Chris Achar	S-1	333-259250	10.23	September 1, 2021
10.10+	Form of Restricted Stock Unit Agreement, by and between the Registrant and Ayub Khattak	S-1/A	333-259250	10.24	September 15, 2021
10.11+	Form of Restricted Stock Unit Agreement, by and between the Registrant and Clint Sever	S-1/A	333-259250	10.25	September 15, 2021
10.12+	Form of the Restricted Stock Agreement under 2014 Equity Incentive Plan between the Registrant and each of Rohan Oza and Robin Farias-Eisner	S-1/A	333-259250	10.26	September 15, 2021
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 Chief Executive Officer and Chief 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 its 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 (formatted as inline XBRL and contained in Exhibit 101				

+ Indicates management contract or compensatory plan

* Exhibit is furnished and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

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.

Cue Health Inc.

Date: November 10, 2021

By: /s/ Ayub Khattak
Ayub Khattak
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ John Gallagher
John Gallagher
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

I, Ayub Khattak, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cue Health Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 10, 2021 By: /s/ Ayub Khattak

Ayub Kahattak
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, John Gallagher, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cue Health Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 10, 2021 By: /s/ John Gallagher

John Gallagher
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021 of Cue Health Inc. (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned hereby certifies in his capacity as the specified officer of the Company, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

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

a. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 10, 2021 By: /s/ Ayub Khattak

Ayub Khattak
President and Chief Executive Officer

(Principal Executive Officer)

Date: November 10, 2021 By: /s/ John Gallagher

John Gallagher
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Quarterly Report on Form 10-Q to which it relates and shall not be deemed filed with the Securities and Exchange Commission or incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.