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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

OR

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

For the transition period from _____ to_____

Commission File Number: 001-40590

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 ☒ No ☐

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

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

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

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

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

As of November 1, 2022 the registrant had 149,432,436 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 agreements with 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 ("Emergency Use Authorizations") 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;
- inflationary pressures, supply chain disruptions and other macroeconomic factors;
- 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" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 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 CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except share amounts and share data)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 304,654	$ 409,873
Restricted cash	1,334	13,837
Accounts receivable, net	24,779	104,589
Inventories	133,309	88,388
Prepaid expenses	44,355	45,889
Other current assets	13,441	7,446
Total current assets	521,872	670,022
Property and equipment, net	194,259	177,456
Operating lease right-of-use assets	85,284	79,474
Intangible assets, net	16,044	7,673
Other non-current assets	7,577	5,435
Total assets	$ 825,036	$ 940,060
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 32,521	$ 37,208
Accrued liabilities and other current liabilities	47,105	29,498
Income taxes payable	—	8,297
Deferred revenue, current	84,899	82,165
Operating lease liabilities, current	8,356	7,147
Finance lease liabilities, current	2,581	2,621
Total current liabilities	175,462	166,936
Deferred revenue, net of current portion	10,283	10,283
Operating leases liabilities, net of current portion	44,235	46,464
Finance lease liabilities, net of current portion	1,268	3,271
Other non-current liabilities	3,828	6,356
Total liabilities	235,076	233,310
Commitments and contingencies (Note 15)		
Stockholders' Equity (Deficit)		
Common stock, $0.00001 par value; 500,000,000 and 500,000,000 shares authorized, 149,177,691 and 146,402,991 issued and outstanding at September 30, 2022 and December 31, 2021, respectively	1	1
Additional paid-in-capital	776,527	730,767
Accumulated deficit	(186,568)	(24,018)
Total stockholders' equity	589,960	706,750
Total liabilities and stockholders' equity	$ 825,036	$ 940,060

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

Cue Health Inc.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue				
Product revenue	$ 66,660	$ 222,594	$ 328,465	$ 424,516
Grant and other revenue	2,929	1,085	8,234	1,085
Total revenue	69,589	223,679	336,699	425,601
Operating costs and expenses:				
Cost of product revenue	50,595	88,569	239,190	173,746
Sales and marketing	18,129	5,572	69,268	7,531
Research and development	42,516	9,079	115,303	21,150
General and administrative	25,625	33,084	77,946	56,336
Restructuring expense	137	—	2,020	—
Total operating costs and expenses	137,002	136,304	503,727	258,763
(Loss) income from operations	(67,413)	87,375	(167,028)	166,838
Interest expense	(346)	(1,786)	(413)	(9,752)
Change in fair value of redeemable convertible preferred stock warrants	—	243	—	53
Change in fair value of convertible notes	—	(36,306)	—	(59,560)
Loss on extinguishment of debt	—	—	—	(1,998)
Other income (expense), net	409	(80)	458	(19)
Net (loss) income before income taxes	(67,350)	49,446	(166,983)	95,562
Income tax (benefit) expense	(1,047)	30,098	(4,433)	43,374
Net (loss) income	$ (66,303)	$ 19,348	$ (162,550)	$ 52,188
Net (loss) income per share attributable to common stockholders – basic	$ (0.45)	$ 0.14	$ (1.10)	$ 0.37
Weighted-average number of shares used in computation of net (loss) income per share attributable to common stockholders – basic	148,285,721	31,554,720	147,443,196	22,997,311
Net (loss) income per share attributable to common stockholders – diluted	$ (0.45)	$ 0.13	$ (1.10)	$ 0.35
Weighted-average number of shares used in computation of net (loss) income per share attributable to common stockholders – diluted	148,285,721	39,304,978	147,443,196	30,747,569

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

Cue Health Inc.

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at June 30, 2022	147,834,377	$ 1	$ 760,637	$ (120,265)	$ 640,373
Exercise of common stock options	784,024	—	1,468	—	1,468
Issuance of common stock upon vesting of restricted stock units	559,290	—	—	—	—
Tax withholding on exercise of stock options and issuance of shares from restricted stock units	—	—	(1,268)	—	(1,268)
Stock-based compensation	—	—	15,690	—	15,690
Net loss	—	—	—	(66,303)	(66,303)
Balance at September 30, 2022	149,177,691	$ 1	$ 776,527	$ (186,568)	$ 589,960

Cue Health Inc.

CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (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' Equity (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 $24.0 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	—	—	—	—
Issuance of common stock upon 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

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

Cue Health Inc.

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2021	146,402,991	$ 1	$ 730,767	$ (24,018)	$ 706,750
Exercise of common stock options	1,298,215	—	1,980	—	1,980
Issuance of common stock upon vesting of restricted stock units	1,476,485	—	—	—	—
Tax withholding on exercise of stock options and issuance of shares from restricted stock units	—	—	(4,735)	—	(4,735)
Stock-based compensation	—	—	48,515	—	48,515
Net loss	—	—	—	(162,550)	(162,550)
Balance at September 30, 2022	149,177,691	$ 1	$ 776,527	$ (186,568)	$ 589,960

Cue Health Inc.

CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (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' Equity (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 $24.0 million	—	—	—	—	—	—	14,375,000	—	205,293	—	205,293
Exercise of common stock warrant	—	—	—	—	—	—	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	—	—	—	—
Issuance of common stock upon 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

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

Cue Health Inc.

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

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities		
Net (loss) income	$ (162,550)	$ 52,188
Adjustments to reconcile net (loss) income to net cash, cash equivalents and restricted cash used in operations		
Depreciation and amortization	32,989	26,079
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	48,515	25,558
Loss on extinguishment of debt	—	1,998
Non-cash lease expense	6,215	3,462
Convertible notes issuance costs	—	6,000
Deferred income taxes	(3,478)	883
Interest on finance leases	137	154
Stock-based compensation expense from issuance of fully vested warrant to vendor	—	1,239
Non-cash interest expense	319	1,857
Inventory reserve (see Note 4, *Inventories*)	33,191	—
Product warranty reserve (see Note 4, *Inventories*)	12,263	—
Changes in operating assets and liabilities:		
Accounts receivable	79,810	(86,022)
Inventories	(78,112)	(33,897)
Prepaid expenses and other current assets	(7,151)	(25,487)
Other non-current assets	(1,912)	(3,871)
Operating lease right-of-use assets	(9,364)	—
Accounts payable, accrued liabilities and other current liabilities	1,138	5,270
Income taxes payable	(11,331)	37,365
Deferred revenue	2,734	(75,529)
Operating lease liabilities	(3,632)	(15,052)
Net cash, cash equivalents and restricted cash used in operating activities	(60,219)	(18,298)
Cash flows from investing activities		
Purchase of property and equipment	(43,179)	(74,637)
Expenditures for software development	(9,767)	(3,524)
Net cash, cash equivalents and restricted cash used in investing activities	(52,946)	(78,161)
Cash flows from financing activities		
Proceeds from convertible notes	—	235,480
Payments for issuance costs of Series C-1 redeemable convertible preferred stock	—	89
Payments of issuance costs of convertible notes	—	(6,000)
Proceeds from exercise of common stock options	1,980	418
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
Tax withholding on exercise of stock options	(4,735)	(4,586)

Proceeds from employee stock purchase plan activity	977	—
Debt issuance and prepayment costs	(599)	(781)
Repayment of debt	—	(87,684)
Payments for finance leases	(2,180)	(1,408)
Net cash, cash equivalents and restricted cash (used in) provided by financing activities	(4,557)	425,793
Net change in cash, cash equivalents and restricted cash	(117,722)	329,334
Cash, cash equivalents and restricted cash, beginning balance	423,710	129,255
Cash, cash equivalents and restricted cash, ending balance	$ 305,988	$ 458,589
Reconciliation of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	$ 304,654	$ 446,589
Restricted cash, current	1,334	12,000
Total cash, cash equivalents and restricted cash	$ 305,988	$ 458,589
Supplemental disclosure for cash flow information		
Cash paid for taxes	$ —	$ 5,100
Cash paid for interest	$ —	$ 760
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	$ 2,611	$ 47,611
Prepaid rent reclassified to right-of-use assets	$ 50	$ 15,966
Purchase of property and equipment included in accounts payable	$ 4,313	$ 18,708
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
Software development costs included in accounts payable	$ 995	$ —

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

Cue Health Inc.

NOTES TO CONDENSED CONSOLIDATED 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.

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements should be read in conjunction with the audited annual financial statements and notes thereto for the year ended December 31, 2021. The unaudited interim condensed consolidated balance sheet as of December 31, 2021 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, 2022 are not necessarily indicative of the results for the fiscal year ending December 31, 2022 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 statement 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 consolidated 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.

Initial Public Offering

On September 28, 2021, the Company completed its initial public offering ("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 pursuant to the exercise in full of the underwriters' option to purchase additional shares. The Company received aggregate net proceeds of approximately $206.0 million after deducting underwriting commissions and legal, accounting, and consulting fees related to the IPO.

Upon completion of the IPO, Convertible Notes outstanding, see Note 10, *Debt*, in the principal amount of $235.5 million and accrued interest of $2.8 million were automatically converted into 18,611,914 shares of common stock. All outstanding shares of the Company's redeemable convertible preferred stock, see Note 11, *Capital 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.

Use of Estimates

The preparation of the accompanying unaudited interim condensed consolidated 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 usage and recoverability of its inventories and long-lived assets and net deferred tax assets (and related valuation allowance). 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. The majority of revenue to date is from customers located in the United States and the majority of long-lived assets are located in the United States. The Company had an immaterial amount of revenue from customers located in Canada and Singapore and an immaterial amount of long-lived assets are located in Mexico.

COVID-19 Impact

COVID-19 was declared a global pandemic by the World Health Organization in March 2020 and 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 various emergency use authorizations for COVID-19 vaccines. 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

There have been no material changes to the Company's significant accounting policies from its Annual Report on Form 10-K for the fiscal year ended December 31, 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 adopted this standard effective January 1, 2022, using the modified retrospective approach. The standard did not have a material impact on the financial statements for the nine months ended September 30, 2022.

In May 2021, the FASB issued ASU No. 2021-04, Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. ASU 2021-04 aims to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange based on the economic substance of the modification or exchange. Early adoption is permitted and the guidance must be applied prospectively to all modifications or exchanges that occur on or after the date of adoption. The guidance is effective for annual periods beginning after December 15, 2021. The Company adopted ASU 2021-04 on January 1, 2022 under the prospective method of adoption and there was no impact to our results of operations as we did not modify or exchange any freestanding equity-classified written call options.

In November 2021, the FASB issued ASU No. 2021-10, Government Assistance (Topic 832). This ASU requires business entities to disclose information about government assistance they receive if the transactions were accounted for by analogy to either a grant or a contribution accounting model. The disclosure requirements include the nature of the transaction and the related accounting policy used, the line items on the balance sheets and statements of operations that are affected and the amounts applicable to each financial statement line item and the significant terms and conditions of the transactions. The ASU is effective for annual periods beginning after December 15, 2021. The disclosure requirements can be applied either retrospectively or prospectively to all transactions in the scope of the amendments that are reflected in the financial statements at the date of initial application and new transactions that are entered into after the date of initial application. The Company adopted the ASU prospectively on January 1, 2022. The additional annual disclosures required are not expected to have a material impact on the financial statements.

NOTE 3. REVENUE

Product Revenue

Disaggregation of the product revenue by type of customer for the three and nine months ended September 30, 2022 and 2021, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Public sector entities	$ 780	$ 128,587	$ 6,213	$ 295,708
Private sector customers	65,880	94,007	322,252	128,808
Total product revenue	$ 66,660	$ 222,594	$ 328,465	$ 424,516

Product revenue for the three and nine months ended September 30, 2022 includes an immaterial amount of service revenue generated from telemedicine and proctoring services provided to customers. Revenue generated from proctoring is recognized over the term of the contracts with customers.

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, 2022 and 2021:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Product revenue	$ 66,660	$ 222,594	$ 328,465	$ 424,516
Cost of product revenue	50,595	88,569	239,190	173,746
Product gross profit	$ 16,065	$ 134,025	$ 89,275	$ 250,770
Product gross profit margin	24 %	60 %	27 %	59 %

During the three and nine months ended September 30, 2022, the Company recorded charges of $2.6 million and $45.5 million, respectively (the "inventory charge") primarily related to excess and obsolescent inventory that is reflected within the cost of product revenue line item of the condensed consolidated statements of operations. This inventory charge is primarily related to an overbuild of inventory and, in addition, identification of certain products which are not expected to perform in line with the Company's quality standards. The $2.6 million inventory charge recorded during the three months ended September 30, 2022 was recorded to inventory reserve. Of the $45.5 million inventory charge recorded

during the nine months ended September 30, 2022, $33.2 million was recorded to inventory reserve and $12.3 million was recorded to product warranty reserve.

DoD Agreement

In October 2020, the Company entered into a $480.9 million agreement with the U.S. government for the purchase of its Cue COVID-19 Test to meet the unprecedented demand for rapid and accurate molecular diagnostic testing (the "U.S. DoD Agreement"). The Company delivered all of the agreed upon products under the agreement prior to its expiration on December 31, 2021. The U.S. DoD Agreement provided for a $184.6 million upfront payment (the "U.S. DoD Advance") to facilitate the scaling of the Company's manufacturing capacity, which was received upon signing the contract. The U.S. DoD Agreement did not provide for the funds to be utilized in any specific manner beyond furthering the purposes of the agreement. The Company was not required to segregate, nor was the Company required to obtain the approval of the U.S. government to use the funds advanced to it under the agreement. The remaining $296.3 million of the agreement was due to the Company upon the delivery of Cue Readers, Cue COVID-19 Test Kits and Cue Control Swab Packs. The U.S. DoD Agreement also provided that, as soon as possible after the completion of the initial U.S. DoD Agreement, the Company and the U.S. government would negotiate in good faith to enter into a follow-on supply agreement based on federal acquisition regulations (a FAR-based contract). The U.S. DoD Agreement provides the U.S. DoD with the right to purchase no more than 45% of our production from the purchased equipment funded by the agreement for the duration of the follow-on contract at a specified discount, subject to a price floor as part of this follow-on contract. The U.S. government is also entitled to certain administrative reporting but does not receive the right to any intellectual property or know-how. The agreement term ended upon completion of the Company's performance obligations in December 2021.

Contract Assets and Liabilities

Contract assets primarily relate to the Company's conditional right to consideration for performance obligations satisfied through direct-to-consumer sales but not billed at the reporting date. Net contract assets were $0.4 million and $1.1 million as of September 30, 2022 and December 31, 2021, respectively, and were recorded in other current assets on the balance sheets.

Contract liabilities primarily relate to the U.S. DoD Advance and payments received from customers in advance of performance under the contracts. Contract liabilities are 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, 2022 is as follows:

	Amount
Balance at December 31, 2021	$ 92,448
Unearned revenue from cash received during the period, excluding amounts recognized as revenue during the period	2,734
Revenue recognized related to contract liability balance at the beginning of the period	—
Balance at September 30, 2022	$ 95,182

As of September 30, 2022, we continue to believe that the deferred revenue related to our satisfaction of estimated future performance obligations of a follow-on agreement with the U.S. DoD is appropriate. Several external factors such as the passage of time with no follow-on contract, the political climate in the U.S. government, the severity of the COVID-19 pandemic/flu season and others may reduce the likelihood of a follow-on contract. We continue to evaluate these factors quarterly and will recognize the deferred revenue over the term of a follow-on contract or when it becomes unlikely that a follow-on contract will be executed.

Grant and Other Revenue

Grant and other revenue relate to a cost reimbursement agreement with the Biomedical Advanced Research and Development Authority ("BARDA"). The Company generated $2.9 million and $8.2 million of revenue related to the agreement with BARDA during the three and nine months ended September 30, 2022, 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.

Accounts Receivable

The allowance for doubtful accounts represents the Company's estimate of probable credit losses relating to accounts receivable 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, 2022 and December 31, 2021, the Company's allowance for doubtful accounts was $2.0 million and $0.3 million, respectively.

NOTE 4. INVENTORIES

As of September 30, 2022 and December 31, 2021, the Company's inventories consisted of the following:

	September 30, 2022	December 31, 2021
Raw materials	$ 75,594	$ 46,273
Work-in-process	20,925	10,920
Finished goods	74,445	33,863
Reserve	(37,655)	(2,668)
Total inventories	$ 133,309	$ 88,388

During the three and nine months ended September 30, 2022, the Company recorded charges of $2.6 million and $45.5 million, respectively, primarily related to excess and obsolescent inventory that is reflected within the cost of product revenue line item of the condensed consolidated statements of operations. This inventory charge is primarily related to an overbuild of inventory and, in addition, identification of certain products which are not expected to perform in line with the Company's quality standards. The $2.6 million charge recorded during the three months ended September 30, 2022 was recorded to inventory reserve. Of the $45.5 million inventory charge recorded during the nine months ended September 30, 2022, $33.2 million was recorded to inventory reserve and $12.3 million was recorded to product warranty reserve.

NOTE 5. PREPAID EXPENSES

As of September 30, 2022 and December 31, 2021, the Company's prepaid expenses consisted of the following:

	September 30, 2022	December 31, 2021
Prepaid expense	$ 31,561	$ 30,153
Prepaid inventory	12,794	15,736
Total prepaid expenses	$ 44,355	$ 45,889

NOTE 6. PROPERTY AND EQUIPMENT, NET

As of September 30, 2022 and December 31, 2021, the Company's property and equipment, net consisted of the following:

	September 30, 2022	December 31, 2021
Construction in progress	$ 33,834	$ 4,082
Machinery and equipment	209,434	195,001
Leasehold improvements	21,611	19,302
Furniture and fixtures	1,703	740
Property and equipment	266,582	219,125
Accumulated depreciation and amortization	(72,323)	(41,669)
Total property and equipment, net	$ 194,259	$ 177,456

Depreciation and amortization expense related to property and equipment was $8.3 million and $11.4 million for the three months ended September 30, 2022 and 2021, respectively. Depreciation and amortization expense related to property and equipment was $28.6 million and $24.2 million for the nine months ended September 30, 2022 and 2021, respectively.

NOTE 7. INTANGIBLE ASSETS

As of September 30, 2022 and December 31, 2021, the Company's intangible assets consisted of the following:

	September 30, 2022	December 31, 2021
Capitalized software	$ 16,037	$ 5,638
Accumulated amortization	(4,459)	(2,067)
Capitalized software, net	11,578	3,571
In-process software development	4,466	4,102
Total intangible assets	$ 16,044	$ 7,673

Amortization expense related to intangible assets placed in service was $1.0 million and $2.4 million for the three and nine months ended September 30, 2022, respectively. Amortization expense related to intangible assets placed in service 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:

2022 (excluding the nine months ended September 30, 2022)	$ 1,099
2023	4,396
2024	3,955
2025	2,128
Total amortization expense	$ 11,578

NOTE 8. LEASES

The Company leases real estate and manufacturing and laboratory equipment which are used in the Company's manufacturing, research and development, and administrative activities. The Company identifies a contract that contains a lease as one which conveys a right, either explicitly or implicitly, to control the use of an identified asset in exchange for consideration. These arrangements are classified as finance leases and operating leases. Finance leases consist of laboratory and manufacturing equipment with remaining terms ranging from 1 year to 3 years. The Company's operating leases relate to the Company's manufacturing facilities and office space and have remaining terms from 7 years to 9 years.

There were no new material leases entered into during the three and nine months ended September 30, 2022.

The right-of-use assets and lease liabilities recognized on the Company's balance sheet as of September 30, 2022 and December 31, 2021 were as follows:

	Balance Sheet Location	September 30, 2022	December 31, 2021
Assets			
Right-of-use assets operating leases	*Operating lease right-of-use assets*	$ 85,284	$ 79,474
Right-of-use assets finance leases	*Property and equipment, net*	7,723	9,821
Liabilities			
Operating lease liabilities (current)	*Operating lease liabilities, current*	8,356	7,147
Finance lease liabilities (current)	*Finance lease liabilities, current*	2,581	2,621
Operating lease liabilities (non-current)	*Operating lease liabilities, net of current portion*	44,235	46,464
Finance lease liabilities (non-current)	*Finance lease liabilities, net of current portion*	1,268	3,271

The components of lease expense for the three and nine months ended September 30, 2022 and 2021 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating lease cost	$ 3,192	$ 2,398	$ 8,749	$ 5,365
Finance lease cost:				
Amortization of right-of-use assets	819	509	2,098	1,215
Interest on lease liabilities	43	54	137	154
Total lease cost	$ 4,054	$ 2,961	$ 10,984	$ 6,734

NOTE 9. ACCRUED LIABILITIES AND OTHER CURRENT LIABILITIES

Accrued liabilities and other current liabilities consisted of the following:

	September 30, 2022	December 31, 2021
Accrued purchases[(1)]	$ 4,535	$ 285
Accrued payroll and benefits	22,041	13,693
Accrued expenses	3,154	6,371
Accrued sales tax	6,484	4,284
Product warranty reserve (See Note 15. *Commitments and Contingencies*)	10,891	4,865
Total accrued liabilities and other current liabilities	$ 47,105	$ 29,498

(1) Accrued purchases primarily reflects receipts of goods and services for which we had not yet been invoiced. As we are invoiced for these goods and services, this balance will reduce and accounts payable will increase.

NOTE 10. DEBT

Revolving Credit Agreement

In February 2021, the Company entered into a loan and security agreement ("Revolving Credit Agreement") with a 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 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 May 2021, the Company repaid $63.2 million of debt outstanding under the Revolving Credit Agreement with a portion of the proceeds from the issuance and sale of the Convertible Notes. In June 2021, the Company terminated the Revolving Credit Agreement and was required to pay a fee 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 statements 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 $12.0 million, which was cash collateralized. In November 2021, East West Bank issued to us an additional letter of credit in the amount of $0.5 million. All other obligations under the Revolving Credit Agreement have otherwise been terminated.

Convertible Notes

In May 2021, the Company issued and sold convertible promissory notes (the "Convertible Notes") with a principal amount of $235.5 million. The Company recorded a loss of $23.3 million related to the change in estimated fair value of the Convertible Notes in its statement of operations for the six months ended June 30, 2021. All of the Convertible

Notes were converted upon the IPO, which was a qualified conversion event. The Convertible Notes' principal amount 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 December 31, 2021.

Secured Revolving Facility Agreement

On June 30, 2022, the Company entered into a loan and security agreement (the "2022 Revolving Facility Agreement") among the Company, the lenders from time to time party thereto and East West Bank, as collateral agent and administrative agent ("Agent"). The 2022 Revolving Facility Agreement provides for a $100.0 million secured revolving credit facility, with a $20.0 million letter of credit subfacility. As of September 30, 2022, there were no revolving loans outstanding and $12.5 million aggregate face amount of letters of credit outstanding under the 2022 Revolving Facility Agreement, which reduces the availability to borrow under the revolving credit facility to $87.5 million. The Company recorded $0.6 million in deferred financings costs in connection with the 2022 Revolving Facility Agreement. This balance will be amortized over two years and is classified in other non-current assets since no funds were drawn on the 2022 Revolving Facility Agreement.

The revolving loans are available subject to the Company maintaining an asset coverage ratio of not less than 1.20 to 1.00, measured as (x) the sum of specified cash and cash equivalents subject to liens in favor of Agent plus 80% of eligible accounts receivable less the amount of the Company's outstanding sales tax liability to (y) the principal amount of the outstanding obligations under the 2022 Revolving Facility Agreement. The revolving commitments terminate and the principal amount of outstanding revolving loans, together with accrued and unpaid interest, is due and payable on June 30, 2024.

The revolving loans accrue interest at the greater of the prime rate and 3.50%. Interest on the revolving loans is payable monthly in arrears. The Company may borrow, prepay and reborrow revolving loans, without premium or penalty. The Company is required to pay a prepayment fee of 1.0% if the revolving commitments are terminated prior to the maturity date. The Company is also obligated to pay other customary fees for a loan facility of this size and type.

The Company's obligations under the 2022 Revolving Facility Agreement are secured by substantially all of the Company's assets, and will be guaranteed by, and secured by substantially all of the assets of, its future domestic subsidiaries. As of the closing date, there were no guarantors.

The 2022 Revolving Facility Agreement requires the Company to maintain a current ratio of not less than 1.20 to 1.00, measured quarterly. The 2022 Revolving Facility Agreement also requires the Company to maintain at least six months remaining liquidity, determined as set forth in the 2022 Revolving Facility Agreement. Additionally, the 2022 Revolving Facility Agreement contains customary affirmative and negative covenants, including covenants limiting the ability of the Company and its subsidiaries to, among other things, dispose of assets, effect certain mergers, incur debt, grant liens, pay dividends and distributions on their capital stock, make investments and acquisitions, and enter into transactions with affiliates, in each case subject to customary exceptions for a loan facility of this size and type.

The events of default under the 2022 Revolving Facility Agreement include, among others, payment defaults, material misrepresentations, breaches of covenants, cross defaults with certain other material indebtedness, bankruptcy and insolvency events, the occurrence of a material adverse effect, a change of control and judgment defaults. The occurrence of an event of default could result in the acceleration of the Company's obligations under the 2022 Revolving Facility Agreement, the termination of the lenders' commitments, a 2% increase in the applicable rate of interest and the exercise by Agent and the lenders of other rights and remedies provided for under the 2022 Revolving Facility Agreement or applicable law.

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.

Common Stock Warrants

As of September 30, 2022, 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 were vested as of December 31, 2021.

NOTE 12. 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 incentive stock options, nonqualified stock options, stock appreciation rights, performance shares, awards of restricted stock and awards of restricted stock units.

As of December 31, 2021, with the introduction of a new stock incentive plan, shares are no longer available for future grants under the 2014 Plan.

2021 Stock Incentive Plan

In September 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 (incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards). The 2021 Plan initially authorized the issuance of a maximum of 22,399,691 shares of common stock. The number of shares of common stock available for issuance under the 2021 Plan were and will be increased on the first day of each fiscal year beginning with the 2022 fiscal year, in an amount equal to the least of (i) 5% of the number of shares of the Company's common stock outstanding on the first day of such fiscal year and (ii) the number of shares of the Company's common stock determined by the Company's board of directors. As of September 30, 2022, 3,619,826 shares of common stock were available for issuance under the 2021 Plan.

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 2021 ESPP initially allowed for the sale of 2,834,754 shares of common stock. The number of shares of the Company's common stock to be sold under the 2021 ESPP were and will be increased on the first day of each fiscal year beginning with the 2022 fiscal year, in an amount equal to the least of (i) 8,504,263 shares, (ii) 1% of the number of shares of the Company's common stock outstanding on the first day of such fiscal year and (ii) a number of shares of the Company's common stock determined by the Company's board of directors. The price at which stock is purchased under the 2021 ESPP is equal to 85% of the fair market value of the Company's common stock on the lesser of either (i) the first business day of the Plan Period or (ii) the Exercise Date. As of September 30, 2022, 4,151,321 shares of common stock were available for sale under the 2021 ESPP.

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, 2022 and 2021, was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Cost of product revenues	$ 865	$ 302	$ 2,267	$ 1,500
Sales and marketing	1,441	11	6,718	37
Research and development	6,212	294	17,780	884
General and administrative	7,172	19,359	21,750	23,136
Total stock-based compensation expense	$ 15,690	$ 19,967	$ 48,515	$ 25,558

In total, $0.9 million and $2.3 million of stock-based compensation expense was capitalized to inventory during the manufacturing process during the three and nine months ended September 30, 2022, respectively. An immaterial amount remained in inventory as of September 30, 2022.

Stock Options

A summary of stock option activity and related information for the nine months ended September 30, 2022 was as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at January 1, 2022	9,163,160	$ 5.13	6.40
Granted	—	—	
Exercised	(1,158,772)	0.52	
Forfeited	(188,209)	12.46	
Expired	(80,406)	14.62	
Outstanding at September 30, 2022	7,735,773	$ 5.55	6.33
Exercisable at September 30, 2022	5,823,768	$ 3.71	5.75
Vested and expected to vest at September 30, 2022	7,735,773	$ 5.55	6.33

There were no stock options granted during the nine months ended September 30, 2022.

As of September 30, 2022, there was approximately $9.4 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 2.2 years, on a straight-line basis.

Restricted Stock Units

Under the 2014 and 2021 Plans, 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, but may be subject to other vesting conditions such as performance or market based conditions. Compensation expense is recognized ratably over the requisite service period.

A summary of RSU activity and related information for the nine months ended September 30, 2022 was as follows:

	Underlying Shares	Weighted-average Grant Date Fair Value	Aggregate Fair Value
Outstanding, January 1, 2022	11,264,235	$ 14.62	$ 164,683
Granted	10,484,399	6.28	65,842
Vested	(2,418,758)	14.54	(35,169)
Forfeited	(733,125)	11.63	(8,526)
Outstanding, September 30, 2022	18,596,751	$ 10.05	$ 186,830

As of September 30, 2022, there was approximately $150.2 million of total unrecognized compensation cost related to outstanding RSUs, which is expected to be recognized over a remaining weighted-average vesting period of 3.4 years, on a straight-line basis.

Market-Based Performance-Vesting RSUs

In September 2021, the Company issued 3,335,300 RSUs that vest based on the satisfaction of both a continued employment condition and the achievement of certain market-based performance goals. Market-based performance-vesting RSUs vest upon the achievement of certain stock price performance over a performance period. There are seven stock price targets which can be achieved over the performance period and are based on an average closing price of the Company’s common stock.

Market-based performance-vesting RSU activity for the nine months ended September 30, 2022 was as follows:

	Underlying Shares	Weighted-average Grant Date Fair Value	Aggregate Fair Value
Outstanding, January 1, 2022	$ 3,335,300	$ 12.82	$ 42,759
Granted	—	—	—
Vested	—	—	—
Forfeited	—	—	—
Outstanding, September 30, 2022	$ 3,335,300	$ 12.82	42,759

Operational-Based Performance-Vesting RSUs

In September 2021, the Company issued 1,597,272 operational-based performance-vesting RSUs that vest based on the satisfaction of both a continued employment condition and the achievement of certain performance goals including meeting certain annual revenue targets and product development milestones.

The grant date fair value of operational-based performance-vesting RSUs was estimated based on the fair value of the Company's common stock on the date of grant. Compensation costs are recorded when achievement of the performance goals is determined to be probable.

Operations-based performance-vesting RSU activity for the nine months ended September 30, 2022 was as follows:

	Underlying Shares	Weighted-average Grant Date Fair Value	Aggregate Fair Value
Outstanding, January 1, 2021	1,597,272	$ 16.00	$ 25,556
Granted	—	—	—
Vested	(532,424)	16.00	(8,519)
Forfeited	—	—	—
Outstanding, September 30, 2022	1,064,848	$ 16.00	$ 17,037

NOTE 13. 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, convertible notes, restricted stock and similar equity instruments granted by the Company. Some restricted stock units vest upon certain performance and market conditions and as they vest, the shares will be included in outstanding common shares. 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 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,	
	2022	2021	2022	2021
Numerator:				
Net (loss) income	$ (66,303)	$ 19,348	$ (162,550)	$ 52,188
Minus: Income allocated to participating securities	—	14,926	—	43,670
Net (loss) income attributable to common stockholders – basic	$ (66,303)	$ 4,422	$ (162,550)	$ 8,518
Plus: Income allocated to non-participating securities	—	701	—	2,142
Net (loss) income attributable to common stockholders - diluted	$ (66,303)	$ 5,123	$ (162,550)	$ 10,660
Denominator:				
Basic weighted-average common shares outstanding	148,285,721	31,554,720	147,443,196	22,997,311
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	148,285,721	39,304,978	147,443,196	30,747,569
Net (loss) income attributable to common stockholders per share				
Basic	$ (0.45)	$ 0.14	$ (1.10)	$ 0.37
Diluted	$ (0.45)	$ 0.13	$ (1.10)	$ 0.35

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,	
	2022	2021	2022	2021
Stock options	7,735,773	2,767,821	7,735,773	2,767,821
Restricted stock units	18,596,751	9,747,566	18,596,751	9,747,566
Employee stock purchase plan – shares projected to be issued	314,531	—	314,531	—
Total	26,647,055	12,515,387	26,647,055	12,515,387

NOTE 14. INCOME TAXES

The Company's effective income tax rate for the three and nine months ended September 30, 2022 was 1.6% and 2.7%, respectively. The Company's effective income tax rate for the three and nine months ended September 30, 2021 was 60.9% and 45.4%, respectively.

The effective tax rate for the nine months ended September 30, 2022, differs from the statutory rate due to changes in the amount of the valuation allowance recorded against the Company's deferred tax assets and the impact of certain state tax credits recorded in the period ended September 30, 2022.

The effective tax rate for the nine months ended September 30, 2021, differs from the statutory rate due to the non-tax deductible items including the charges related to the Convertible Notes and the forgiveness of the promissory notes.

During the nine months ended September 30, 2022, the Company completed the application process to obtain income tax credits from the state of California related to the California Competes program and recorded a benefit of approximately $1.7 million.

During the nine months ended September 30, 2022, the Company recorded amounts related to uncertain tax positions of approximately $0.3 million.

NOTE 15. 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.

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 choose to replace Cue Cartridges that result in cancelled tests and invalid test results. All warranties are classified as current liabilities 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 based on 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 following table provides a reconciliation of the change in estimated warranty liabilities:

	Amount
Balance, December 31, 2021	$ 4,865
Provision for warranties	7,080
Provision for warranties related to the inventory charge (see Note 4, *Inventories*)	12,263
Settlements	(13,317)
Balance, September 30, 2022	$ 10,891

Restructuring

Restructuring actions were taken in the second quarter of 2022 in order to reduce costs and improve operations and manufacturing efficiency. As a result of these actions, for the three and nine months ended September 30, 2022, the Company recorded $0.1 million and $2.0 million of charges, respectively, which were reported as restructuring expense in the accompanying condensed consolidated statements of operations. This was accounted for as a one-time termination benefit communicated by period end without an additional service component, so the charge represents the total amount expected to be incurred. As of September 30, 2022, all of the charges have been paid.

Standby Letters of Credit

During the year ended December 31, 2021, the Company was party to certain letters of credit, primarily related to a letter of credit with Comerica Bank as collateral required by one of the Company's vendors. During the year ended December 31, 2021, the Company entered into a Revolving Credit Agreement with a capacity of $130.0 million and all but one of the letters of credits were no longer required by the counterparties. The one letter of credit, totaling $6.0 million, was 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 June 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. The letter of credit was increased to $12.0 million in July 2021. In November 2021, East West Bank issued an additional letter of credit in the amount of $0.5 million. All other obligations under the Revolving Credit Agreement have otherwise been terminated.

On June 30, 2022, these letters of credit were re-issued under the 2022 Revolving Facility Agreement. The 2022 Revolving Facility Agreement provides for a $100.0 million secured revolving credit facility, with a $20.0 million letter of credit subfacility. As of September 30, 2022, there were no revolving loans outstanding and $12.5 million aggregate face amount of letters of credit outstanding under the 2022 Revolving Facility Agreement, which reduces the availability to borrow under the revolving credit facility to $87.5 million.

Restricted Cash

In November 2021, $0.8 million of cash was restricted in relation to a customs surety on international imports which remains restricted as of September 30, 2022. The Company also has outstanding cash collateralized letters of credit with Comerica Bank related to its real estate leases totaling $0.5 million as of September 30, 2022.

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 consolidated 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, 2021 included in our Annual Report on Form 10-K. 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, 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 pursuant to the exercise in full of the underwriters' option to purchase additional shares. The Company received aggregate net proceeds of approximately $206.0 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 $2.8 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, the majority of our product revenue is related to sales of our Cue COVID-19 test with an immaterial portion related to the sale of component parts.

In December 2020, the FDA issued 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 even after effective vaccines have been widely distributed and administered. We also believe COVID-19 will remain endemic for the foreseeable future and demand for a fast and accurate test to confirm a diagnosis and seek timely and appropriate treatment may fluctuate based on COVID-19 infection rates and variants. 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

Manufacturing Capacity

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 third-party contract manufacturers. We continue to optimize 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. Our performance will depend on our ability to manufacture products efficiently at the quantities required to meet customer demand and quality to meet our internal standards.

Investments in Our Growth

We expect to make continued investments in our business to drive growth and to deliver our business strategies. We plan to invest 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 to invest in our supply chain and logistics operations to meet customer demand. 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

Following the completion of our obligations under the U.S. DoD Agreement in December 2021, the future commercial success of our diagnostic products is dependent on our ability to broaden our customer base beyond the U.S. government and public sector to include enterprise employers, healthcare providers and direct-to-consumer. As a result, our long term growth depends on our ability to renew and acquire new customers. Current key strategic relationships include BARDA, Google LLC, or Google, the Mayo Clinic, the National Basketball Association, Major League Baseball, 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.

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. We have filed de novo submission to the FDA for full clearance of our molecular COVID-19 test, filed de novo submission to the FDA for full clearance of our Flu A/B standalone molecular test, and filed an emergency use authorization submission to the FDA for our Flu A/B + COVID multiplex molecular test. We completed our launch of Cue Care, our test-to-treat solution for patients who test positive on any COVID-19 test, including at-home antigen tests

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, regulatory approval from CDSCO, authorization from Singapore Health Sciences Authority, and registration with the Qatar Ministry of Health, 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 Cue 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.

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,	
	2022	2021	2022	2021
(dollars in thousands)		(unaudited)		
Revenue:				
Product revenue	$ 66,660	$ 222,594	$ 328,465	$ 424,516
Grant and other revenue	2,929	1,085	8,234	1,085
Total revenue	69,589	223,679	336,699	425,601
Operating costs and expenses:				
Cost of product revenue	50,595	88,569	239,190	173,746
Sales and marketing	18,129	5,572	69,268	7,531
Research and development	42,516	9,079	115,303	21,150
General and administrative	25,625	33,084	77,946	56,336
Restructuring expense	137	—	2,020	—
Total operating costs and expenses	137,002	136,304	503,727	258,763
(Loss) Income from operations	(67,413)	87,375	(167,028)	166,838
Interest expense	(346)	(1,786)	(413)	(9,752)
Change in fair value of redeemable convertible preferred stock warrants	—	243	—	53
Change in fair value of convertible notes	—	(36,306)	—	(59,560)
Loss on extinguishment of debt	—	—	—	(1,998)
Other income, net	409	(80)	458	(19)
Net (loss) income before income taxes	(67,350)	49,446	(166,983)	95,562
Income tax (benefit) expense	(1,047)	30,098	(4,433)	43,374
Net (loss) income	$ (66,303)	$ 19,348	$ (162,550)	$ 52,188
Net (loss) income per share attributable to common stockholders – diluted	$ (0.45)	$ 0.13	$ (1.10)	$ 0.35

Comparison of the Three Months Ended September 30, 2022 and 2021

The following table sets forth a summary of our results of operations for the three months ended September 30, 2022 and 2021 and the changes between periods:

	Three Months Ended September 30,			
	2022	**2021**	**$ Change**	**% Change**
(dollars in thousands)		**(unaudited)**		
Revenue:				
Product revenue	$ 66,660	$ 222,594	$ (155,934)	(70)%
Grant and other revenue	2,929	1,085	1,844	170%
Total revenue	69,589	223,679	(154,090)	(69%)
Operating costs and expenses:				
Cost of product revenue	50,595	88,569	(37,974)	(43)%
Sales and marketing	18,129	5,572	12,557	225%
Research and development	42,516	9,079	33,437	368%
General and administrative	25,625	33,084	(7,459)	(23%)
Restructuring expense	137	—	137	n.m
Total operating costs and expenses	137,002	136,304	698	1%
(Loss) Income from operations	(67,413)	87,375	(154,788)	(177%)
Interest expense	(346)	(1,786)	1,440	(81%)
Change in fair value of redeemable convertible preferred stock warrants	—	243	(243)	(100%)
Change in fair value of convertible notes	—	(36,306)	36,306	(100%)
Other income, net	409	(80)	489	(611%)
Net (loss) income before income taxes	(67,350)	49,446	(116,796)	(236)%
Income tax (benefit) expense	(1,047)	30,098	(31,145)	(103)%
Net (loss) income	$ (66,303)	$ 19,348	$ (85,651)	(443)%
Net (loss) income per share attributable to common stockholders – diluted	$ (0.45)	$ 0.13	$ (0.58)	(443)%

n.m. = not meaningful

Revenue was $69.6 million in the three months ended September 30, 2022, compared to $223.7 million in the three months ended September 30, 2021. The decrease was primarily due to the completion of our obligations under the U.S. DoD Agreement in December 2021 combined with a tempering of COVID-19 testing during 2022. Revenue during the three months ended September 30, 2022 was primarily driven by product sales to private sector customers of $65.9 million.

Cost of Product Revenue was $50.6 million in the three months ended September 30, 2022, compared to $88.6 million in the three months ended September 30, 2021. This decrease was primarily due to the completion of our obligations under the U.S. DoD Agreement in December 2021. Our product gross profit margin, or product gross profit as a percentage of product revenue, was approximately 24% in the three months ended September 30, 2022 compared to approximately 60%, in the three months ended September 30, 2021. This decrease was primarily due to the inventory charge, supply chain constraints and associated higher component, transport costs, customer mix and a reduction in overall production volume relative to our manufacturing capacity.

Sales and Marketing Expense was $18.1 million in the three months ended September 30, 2022, compared to $5.6 million in the three months ended September 30, 2021. This increase related to increased sales and marketing personnel costs to support a broadening of our customer base, planned additions to our product offering and higher expenses related to our overall marketing and brand expansion efforts.

Research and Development Expense was $42.5 million in the three months ended September 30, 2022, compared to $9.1 million in the three months ended September 30, 2021. This increase was primarily driven by additional headcount,

materials and other resource utilization associated with the expansion of our platform, including new test development and overall enhancement of our software platform for products under development, as well as costs related to the clinical studies conducted for our submissions to the FDA requiring 510(k) clearances for our Flu A/B standalone molecular test and EUA of our Flu A/B + COVID multiplex molecular test.

General and Administrative Expense was $25.6 million in the three months ended September 30, 2022 compared to $33.1 million in the three months ended September 30, 2021. This decrease was primarily related to 2021 IPO-related stock based compensation activity which did not occur in 2022, offset by expenses related to headcount growth to support our overall expansion.

Interest Expense was $0.3 million in the three months ended September 30, 2022 compared to $1.8 million in the three months ended September 30, 2021. The interest expense in the three months ended September 30, 2021 was primarily related to our Convertible Notes which were converted into common stock as part of the IPO. We did not incur any expense associated with the Convertible Notes during the three months ended September 30, 2022 as the Convertible Notes were not outstanding during that period.

Change in Fair Value of Convertible Notes was $0 and $36.3 million in the three months ended September 30, 2022 and 2021, 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 the fair value of the Convertible Notes during the three months ended September 30, 2022 as the Convertible Notes were not outstanding during that period.

Income Tax (Benefit) Expense was $(1.0) million in the three months ended September 30, 2022 compared to $30.1 million in the three months ended September 30, 2021. Our effective tax rate was a benefit of 1.6% in the three months ended September 30, 2022, compared to 60.9% in the three months ended September 30, 2021. The fluctuation in our provision/(benefit) and effective tax rate was primarily due to the net pre-tax loss generated by the Company during the three months ended September 30, 2022, and the benefit from the approval of the California Competes state income tax credits. The tax expense recorded for the three months ended September 30, 2021 was primarily related to the tax liability arising from income from operations which exceeded available net operating loss carryforwards and the discrete impact of the non-deductible items.

Comparison of the Nine Months Ended September 30, 2022 and 2021

The following table sets forth a summary of our results of operations for the nine months ended September 30, 2022 and 2021 and the changes between periods:

	Nine Months Ended September 30,			
	2022	**2021**	**$ Change**	**% Change**
(dollars in thousands)		**(unaudited)**		
Revenue:				
Product revenue	$ 328,465	$ 424,516	$ (96,051)	(23)%
Grant and other revenue	8,234	1,085	7,149	659 %
Total revenue	336,699	425,601	(88,902)	(21)%
Operating costs and expenses:				
Cost of product revenue	239,190	173,746	65,444	38 %
Sales and marketing	69,268	7,531	61,737	820 %
Research and development	115,303	21,150	94,153	445 %
General and administrative	77,946	56,336	21,610	38 %
Restructuring expense	2,020	—	2,020	n.m
Total operating costs and expenses	503,727	258,763	244,964	95 %
(Loss) income from operations	(167,028)	166,838	(333,866)	(200)%
Interest expense	(413)	(9,752)	9,339	(96)%
Change in fair value of redeemable convertible preferred stock warrants	—	53	(53)	(100)%
Change in fair value of convertible notes	—	(59,560)	59,560	(100)%
Loss on extinguishment of debt	—	(1,998)	1,998	(100)%
Other income (expense), net	458	(19)	477	(2,511)%
Net (loss) income before income taxes	(166,983)	95,562	(262,545)	(275)%
Income tax (benefit) expense	(4,433)	43,374	(47,807)	(110)%
Net (loss) income	$ (162,550)	$ 52,188	$ (214,738)	(411)%
Net (loss) income per share attributable to common stockholders – diluted	$ (1.10)	$ 0.35	$ (1.45)	(418)%

n.m. = not meaningful

Revenue was $336.7 million in the nine months ended September 30, 2022, compared to $425.6 million in the nine months ended September 30, 2021. This decrease was primarily due to the completion of our obligations under the U.S. DoD Agreement in December 2021 which was offset by an increase in sales to private customers. Revenue during the nine months ended September 30, 2022 was primarily driven by product sales to private sector customers of $322.3 million.

Cost of Product Revenue was $239.2 million in the nine months ended September 30, 2022, compared to $173.7 million in the nine months ended September 30, 2021. This increase was primarily driven by the inventory charge of $45.5 million. Our product gross profit margin, or product gross profit as a percentage of product revenue was approximately 27% in the nine months ended September 30, 2022 compared to approximately 59% in the nine months ended September 30, 2021. This decrease was primarily due to the inventory charge, as well as supply chain constraints and associated higher component, transport costs, customer mix and a reduction in overall production volume relative to our manufacturing capacity.

Sales and Marketing Expense was $69.3 million in the nine months ended September 30, 2022, compared to $7.5 million in the nine months ended September 30, 2021. This increase related to increased sales and marketing personnel costs to support a broadening of our customer base, planned additions to our product offering and higher expenses related to our overall marketing and brand expansion efforts.

Research and Development Expense was $115.3 million in the nine months ended September 30, 2022, compared to $21.2 million in the nine months ended September 30, 2021. This increase was primarily driven by additional

headcount, materials and other resource utilization associated with the expansion of our platform, including new test development and overall enhancement of our software platform for products under development, as well as costs related to the clinical studies conducted for our submissions to the FDA requiring 510(k) clearance for our COVID-19 test and Flu A/B standalone molecular test and EUA for our Flu A/B + COVID multiplex molecular test.

General and Administrative Expense was $77.9 million in the nine months ended September 30, 2022, compared to $56.3 million in the nine months ended September 30, 2021. This increase was primarily related to compensation increase related to headcount growth to support our overall expansion as well as accounting and other consulting-related costs to support our operations as a public company.

Interest Expense was $0.4 million in the nine months ended September 30, 2022, from $9.8 million in the nine months ended September 30, 2021. This decrease was primarily driven by debt repayment activity in the prior year. Our interest expense prior to February 2021 primarily consisted of expense related to our prior loan and security agreement with Comerica Bank. In February 2021, we entered into the Revolving Credit Agreement. In connection with entering into the Revolving Credit Agreement, we repaid outstanding amounts under and terminated the 2015 Credit Agreement. In May 2021, we repaid the outstanding balance under the Revolving Credit Agreement. In June 2021, we terminated the Revolving Credit Agreement. Interest expense related to the Convertible Notes was $1.7 million during the nine months ended September 30, 2021. We did not incur any expense associated with the Convertible Notes during the nine months ended September 30, 2022 as the Convertible Notes were not outstanding during that period.

Change in Fair Value of Convertible Notes was $0 and $59.6 million in the nine months ended September 30, 2022 and 2021, 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, 2022 as the Convertible Notes were not outstanding during that period.

Income Tax (Benefit) Expense was $(4.4) million in the nine months ended September 30, 2022 compared to $43.4 million in the nine months ended September 30, 2021. Our effective tax rate was a benefit of 2.7% in the nine months ended September 30, 2022, compared to 45.4% in the nine months ended September 30, 2021. The fluctuation in our provision/(benefit) and effective tax rate was primarily due to the net pre-tax loss generated by the Company during the nine months ended September 30, 2022, and the benefit from the approval of the California Competes state income tax credits. The tax expense recorded for the nine months ended September 30, 2021 was primarily related to the tax liability arising from income from operations which exceeded available net operating loss carryforwards and the discrete impact of the non-deductible items.

Liquidity and Capital Resources

Overview

As of September 30, 2022, we held $304.7 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.

On June 30, 2022, the Company entered into the 2022 Revolving Facility Agreement. The 2022 Revolving Facility Agreement provides for a $100.0 million secured revolving credit facility, with a $20.0 million letter of credit subfacility. As of September 30, 2022, there were no revolving loans outstanding and $12.5 million aggregate face amount of letters of credit outstanding under the 2022 Revolving Facility Agreement, which reduces the availability to borrow under the revolving credit facility to $87.5 million.

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 sales and marketing expense associated with 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 being a public company. Our short-term capital expenditure needs

relate primarily to the expansion of our research and development capabilities and optimization of existing business processes.

Cash Flows

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

	Nine Months Ended September 30,	
	2022	2021
(dollars in thousands)	(unaudited)	
Net cash, cash equivalents and restricted used in operating activities	$ (60,219)	$ (18,298)
Net cash, cash equivalents and restricted cash used in investing activities	(52,946)	(78,161)
Net cash, cash equivalents and restricted cash (used in) provided by financing activities	(4,557)	425,793
Net change in cash, cash equivalents and restricted cash	$ (117,722)	$ 329,334

Cash Flows from Operating Activities

Net cash, cash equivalents and restricted cash used in operating activities was $60.2 million in the nine months ended September 30, 2022, primarily reflecting our net loss of $162.6 million, net of non-cash cost items and changes in operating working capital. Non-cash cost adjustments were primarily driven by inventory charges of $45.5 million, stock-based compensation expense of $48.5 million and depreciation and amortization expenses of $33.0 million. The timing of our revenue and collections decreased our accounts receivable. Inventory increase was driven by our effort to limit the effects of a potential future supply chain disruption combined with a tempering of COVID-19 testing demand in the latter part of the first quarter.

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. 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. The increase in deferred revenue recognized was due to the increase in product deliveries to the U.S. government.

Cash Flows from Investing Activities

Net cash, cash equivalents and restricted cash used in investing activities was $52.9 million for the nine months ended September 30, 2022, reflecting purchases of property and equipment of $43.2 million to expand our R&D and production capabilities. We also invested $9.8 million in the development of internal-use software.

Net cash, cash equivalents and restricted cash used in investing activities was $78.2 million in the nine months ended September 30, 2021, primarily reflecting purchases of property and equipment of $74.6 million to expand our production capabilities of our COVID-19 Test Kits in relation to the U.S. DoD Agreement.

Cash Flows from Financing Activities

Net cash, cash equivalents and restricted cash used in financing activities for the nine months ended September 30, 2022 of $4.6 million was primarily driven by $4.7 million in tax withholding on stock option exercises and RSU vesting and $2.2 million in payments for finance leases. These cash outflows were offset by proceeds of $1.0 million from the employee stock purchase plan and $2.0 million from stock options exercised.

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

Commitments and Contingencies

See Note 15, *Commitments and Contingencies*, to our unaudited interim condensed consolidated financial statements included elsewhere in this quarterly report for a summary of our commitments as of September 30, 2022.

Our material cash commitments at September 30, 2022 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. We expect to fund these commitments using our existing cash on hand.

As of September 30, 2022, there were no revolving loans outstanding and $12.5 million aggregate face amount of letters of credit outstanding under the 2022 Revolving Facility Agreement, which reduces the availability to borrow under the revolving credit facility from $100 million to $87.5 million. We also had outstanding cash collateralized letters of credit with Comerica Bank related to our real estate leases totaling $0.5 million which is reflected on the balance sheet as restricted cash. In November 2021, $0.8 million of cash was restricted in relation to a customs surety on international imports.

Critical Accounting Policies and Estimates

For a description of our critical accounting policies and estimates, refer to Part II, Item 7, Critical Accounting Policies and Estimates in our Annual Report on Form 10-K for the year ended December 31, 2021. There have been no material changes to the Company's critical accounting policies and estimates from its Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

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.

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 disclosed in our

Annual Report on Form 10-K for the year ended December 31, 2021, the CEO and CFO concluded that our disclosure controls and procedures were not effective at a reasonable assurance level as of September 30, 2022.

Notwithstanding the identified material weaknesses, management believes the financial statements included in this Quarterly Report on Form 10-Q fairly present, in all material respects, our financial condition, results of operations and cash flows as of and for the periods presented in accordance with U.S. generally accepted accounting principles.

Previously Reported Material Weaknesses

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.

As disclosed in Item 9A. “Controls and Procedures” of our Form 10-K for the year ended December 31, 2021, we continue to have material weaknesses in internal controls over financial reporting related to i) information technology general controls, ii) a lack of segregation of duties, iii) documentation and design of formalized processes and procedures, iv) experience and training important to our financial reporting requirements; and v) 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.

Remediation Plan

As previously described in Part II, Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2021, 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, the hiring of a Vice President and Treasurer in the second quarter of 2021, the hiring of an Interim Controller, an Assistant Controller and a Director of Tax in the fourth quarter of 2021. During the first quarter of 2022, we recruited a Chief Accounting Officer and a Vice President of Internal Audit who joined the Company in the second quarter of 2022. During the second quarter of 2022, we hired a Director of Internal Audit and a Senior Director of SOX Compliance. During the third quarter of 2022, we walked through and updated our documentation of key financial business processes and financial systems and identified areas of improvement. In addition, we have dedicated resources and continue to engage 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 have evaluated the longer-term resource needs of our various financial functions and have expanded the size of the financial organization to help address these material weaknesses. The weaknesses will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

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, 2021 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.

Changes in Internal Control over Financial Reporting

Except for the remediation measures in connection with the material weaknesses described above, there were no other changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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.

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

Item 1A. Risk Factors.

There have been no material changes from the risk factors as previously disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 other than as set forth below:

Our operations are subject to the effects of a rising rate of inflation.

The United States has recently experienced historically high levels of inflation. According to the U.S. Department of Labor, the annual inflation rate for the United States was approximately 7.0% for 2021. If the inflation rate continues to increase, such as increases in the costs of labor, it will likely affect all of our expenses, especially employee compensation expenses. Additionally, the United States is experiencing an acute workforce shortage, which in turn, has created a hyper-competitive wage environment that may increase our operating costs. To the extent inflation results in rising interest rates and has other adverse effects on the market, it may adversely affect our consolidated financial condition and results of operations.

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

From January 1, 2020 to December 31, 2021, the number of our employees increased from 99 to 1,585 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 forecast 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.

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.

As disclosed in Item 9A. "Controls and Procedures" of our Form 10-K for the year ended December 31, 2021, we continue to have material weaknesses in internal controls over financial reporting related to i) information technology general controls, ii) a lack of segregation of duties, iii) documentation and design of formalized processes and procedures, iv) experience and training important to our financial reporting requirements; and v) 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.

As previously described in Part II, Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2021, 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, the hiring of a Vice President and Treasurer in the second quarter of 2021, the hiring of an Interim Controller, an Assistant Controller and a Director of Tax in the fourth quarter of 2021. During the first quarter of 2022, we recruited a Chief Accounting Officer and a Vice President of Internal Audit who joined the Company in the second quarter of 2022. During the second quarter of 2022, we hired a Director of Internal Audit and a Senior Director of SOX Compliance. During the third quarter of 2022, we walked through and updated our documentation of our key financial business processes and financial systems and identified areas of improvement. In addition, we have dedicated resources and continue to engage 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 have evaluated the longer-term resource needs of our various financial functions and have expanded the size of the financial organization to help address these material weaknesses. The weaknesses will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

If we fail to remediate the identified material weaknesses or identify new misstatements or misclassifications 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 have hired a large number of employees to support such growth. 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.

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

Unregistered Sales of Equity Securities

None.

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 $206.0 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. 333259250), 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, 2022, we have paid approximately $24.0 million of expenses incurred in connection with our IPO and no further expenses in connection with our IPO are expected.

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 Bylaws of Cue Health Inc. dated November 3, 2022	8-K	001-40824	3.1	November 8, 2022
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				

* 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 9, 2022

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

Date: November 9, 2022

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 9, 2022

By: /s/ Ayub Khattak
Ayub Khattak
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 9, 2022

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, 2022 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 results of operations of the Company.

Date: November 9, 2022

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

Date: November 9, 2022

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.