
**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, 2023

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: 001-40824

Cue Health Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
4980 Carroll Canyon Rd.
Suite 100
San Diego, CA
(Address of principal executive offices)

27-1562193
(I.R.S. Employer
Identification No.)

92121
(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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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, 2023 the registrant had 154,632,057 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 Federal Drug Administration (the “FDA”) Emergency Use Authorizations (“EUAs”) for our COVID-19 test;
- our ability to accurately forecast demand for the Cue Health Monitoring System, our tests and other products;
- our ability to successfully build out our sales and marketing infrastructure, the costs and success of our marketing efforts, and our ability to promote our brand;
- our ability to increase demand for our products and services, obtain favorable coverage and reimbursement determinations from third-party payors and expand geographically;
- our ability to continue as a going concern;
- our expectations regarding our current or future litigation;
- 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, 2022 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, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 111,454	\$ 241,530
Restricted cash	800	800
Accounts receivable, net	1,320	18,751
Inventories, net - current	63,555	82,210
Prepaid expenses	9,862	15,728
Other current assets	5,248	12,134
Total current assets	192,239	371,153
Non-current inventories, net	27,640	25,436
Property and equipment, net	166,311	189,275
Operating lease right-of-use assets	80,829	85,321
Intangible assets, net	21,539	16,867
Other non-current assets	3,735	6,528
Total assets	\$ 492,293	\$ 694,580
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 11,109	\$ 7,150
Accrued liabilities and other current liabilities	39,920	52,378
Deferred revenue, current	623	1,566
Operating lease liabilities, current	5,109	7,739
Finance lease liabilities, current	1,646	2,362
Total current liabilities	58,407	71,195
Operating leases liabilities, net of current portion	42,961	44,045
Finance lease liabilities, net of current portion	—	849
Other non-current liabilities	2,091	1,997
Total liabilities	103,459	118,086
Commitments and contingencies (Note 14)		
Stockholders' Equity		
Common stock, \$0.00001 par value; 500,000,000 and 500,000,000 shares authorized, 154,601,335 and 150,406,014 issued and outstanding at September 30, 2023 and December 31, 2022, respectively	2	1
Additional paid-in-capital	831,938	794,567
Accumulated deficit	(443,106)	(218,074)
Total stockholders' equity	388,834	576,494
Total liabilities and stockholders' equity	\$ 492,293	\$ 694,580

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,	
	2023	2022	2023	2022
Revenue				
Product revenue	\$ 14,757	\$ 66,660	\$ 46,842	\$ 328,465
Grant and other revenue	2,720	2,929	5,296	8,234
Total revenue	17,477	69,589	52,138	336,699
Operating costs and expenses:				
Cost of product revenue	22,180	50,595	91,349	239,190
Sales and marketing	7,051	18,129	26,358	69,268
Research and development	37,103	42,516	118,372	115,303
General and administrative	15,848	25,625	47,489	77,946
Restructuring expense	—	137	14,518	2,020
Total operating costs and expenses	82,182	137,002	298,086	503,727
Loss from operations	(64,705)	(67,413)	(245,948)	(167,028)
Interest expense	(304)	(346)	(815)	(413)
Tax credits	20,939	—	20,939	—
Other income, net	1,833	409	5,525	458
Loss before income taxes	(42,237)	(67,350)	(220,299)	(166,983)
Income tax expense (benefit)	4,733	(1,047)	4,733	(4,433)
Net loss	\$ (46,970)	\$ (66,303)	\$ (225,032)	\$ (162,550)
Net loss per share – basic	\$ (0.31)	\$ (0.45)	\$ (1.48)	\$ (1.10)
Weighted-average number of shares used in computation of net loss per share – basic	153,699,408	148,582,721	152,226,999	147,443,196
Net loss per share – diluted	\$ (0.31)	\$ (0.45)	\$ (1.48)	\$ (1.10)
Weighted-average number of shares used in computation of net loss per share – diluted	153,699,408	148,582,721	152,226,999	147,443,196

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

Cue Health Inc.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)
(In thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at June 30, 2023	152,662,162	\$ 2	\$ 819,311	\$ (396,136)	\$ 423,177
Exercise of common stock options, including ESPP activity, 825,973 shares	825,973	—	259	—	259
Issuance of common stock upon vesting of restricted stock units	1,714,320	—	—	—	—
Tax withholding on stock option exercises and restricted stock unit issuance	(601,120)	—	(319)	—	(319)
Stock-based compensation	—	—	12,687	—	12,687
Net loss	—	—	—	(46,970)	(46,970)
Balance at September 30, 2023	154,601,335	\$ 2	\$ 831,938	\$ (443,106)	\$ 388,834

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at June 30, 2022	147,834,377	\$ 1	\$ 760,637	\$ (120,265)	\$ 640,373
Exercise of common stock options, including ESPP activity, 147,463 shares	790,530	—	1,468	—	1,468
Issuance of common stock upon vesting of restricted stock units	911,364	—	—	—	—
Tax withholding on stock option exercises and restricted stock unit issuance	(358,580)	—	(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

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

Cue Health Inc.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(Unaudited)
(In thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2022	150,406,014	\$ 1	\$ 794,567	\$ (218,074)	\$ 576,494
Exercise of common stock options, including ESPP activity, 1,299,053 shares	1,468,568	1	371	—	372
Issuance of common stock upon vesting of restricted stock units	4,243,128	—	—	—	—
Tax withholding on stock option exercises and restricted stock unit issuance	(1,516,375)	—	(1,585)	—	(1,585)
Stock-based compensation	—	—	38,597	—	38,597
Other	—	—	(12)	—	(12)
Net loss	—	—	—	(225,032)	(225,032)
Balance at September 30, 2023	154,601,335	\$ 2	\$ 831,938	\$ (443,106)	\$ 388,834

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2021	146,402,991	\$ 1	\$ 730,767	\$ (24,018)	\$ 706,750
Exercise of common stock options, including ESPP activity, 147,463 shares	1,306,235	—	1,980	—	1,980
Issuance of common stock upon vesting of restricted stock units	2,418,758	—	—	—	—
Tax withholding on stock option exercises and restricted stock unit issuance	(950,293)	—	(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

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,	
	2023	2022
Cash flows from operating activities		
Net loss	\$ (225,032)	\$ (162,550)
Adjustments to reconcile net loss to net cash, cash equivalents and restricted cash used in operations		
Depreciation and amortization	37,992	32,989
Allowance (recoveries) for credit losses provision	(308)	1,729
Stock-based compensation expense	38,597	48,515
Non-cash lease expense	7,186	6,215
Deferred income taxes	—	(3,478)
Interest on finance leases	65	137
Non-cash interest expense	202	319
Changes in operating assets and liabilities:		
Accounts receivable	17,739	78,081
Inventories	16,451	(44,921)
Prepaid expenses and other current assets	9,512	(7,151)
Other non-current assets	2,591	(1,912)
Accounts payable, accrued liabilities and other current liabilities	(13,092)	13,401
Income taxes payable	6,358	(11,331)
Deferred revenue	(943)	2,734
Operating lease liabilities	(6,408)	(12,996)
Net cash, cash equivalents and restricted cash used in operating activities	(109,090)	(60,219)
Cash flows from investing activities		
Purchase of property and equipment	(7,800)	(43,179)
Expenditures for software development and other intangible assets	(10,165)	(9,767)
Net cash, cash equivalents and restricted cash used in investing activities	(17,965)	(52,946)
Cash flows from financing activities		
Proceeds from exercise of common stock options	113	1,980
Tax withholding on stock option exercises and restricted stock unit issuance	(1,584)	(4,735)
Proceeds from employee stock purchase plan activity	372	977
Debt issuance and prepayment costs	—	(599)
Equity issuance costs	(292)	—
Payments for finance leases	(1,630)	(2,180)
Net cash, cash equivalents and restricted cash used in financing activities	(3,021)	(4,557)
Net change in cash, cash equivalents and restricted cash	(130,076)	(117,722)
Cash, cash equivalents and restricted cash, beginning balance	242,330	423,710
Cash, cash equivalents and restricted cash, ending balance	\$ 112,254	\$ 305,988
Reconciliation of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	\$ 111,454	\$ 304,654
Restricted cash, current	800	1,334
Total cash, cash equivalents and restricted cash	\$ 112,254	\$ 305,988

Supplemental disclosure for non-cash investing and financing matters

Right-of-use assets obtained in exchange for lease obligations	\$	—	\$	2,611
Prepaid rent reclassified to right-of-use assets	\$	—	\$	50
Purchase of property and equipment included in accounts payable	\$	2,594	\$	4,313
Software development costs included in accounts payable	\$	115	\$	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 that uses diagnostic-enabled care to empower people to live their healthiest lives. The Cue Health platform offers individuals and healthcare providers convenient and personalized access to lab-quality diagnostic tests at home and at the point-of-care, as well as on-demand telehealth consultations and treatment options for a wide range of health and wellness needs. 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, 2022. The unaudited interim condensed consolidated balance sheet as of December 31, 2022 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, 2023 are not necessarily indicative of the results for the fiscal year ending December 31, 2023 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.

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, long-lived assets, intangible assets and net deferred tax assets (net of 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. Revenues to customers located outside of the United States were not material and \$0.1 million for the three and nine months ended September 30, 2023, respectively. Revenues to customers located outside of the United States were \$1.8 million and \$9.3 million for the three and nine months ended September 30, 2022, respectively. Long-lived assets, which consist of property and equipment,

located outside of the United States were \$3.9 million and \$4.7 million as of September 30, 2023 and December 31, 2022, respectively.

COVID-19 Impact

COVID-19 was declared a global pandemic by the World Health Organization in March 2020 and adversely impacted global commercial activity. The Company began selling and recording product revenues for its Cue COVID-19 test in August 2020 after obtaining an EUA from the FDA in June 2020. Currently, the majority 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 EUAs and approvals for COVID-19 vaccines. The widely administered use of efficacious vaccines and therapeutic treatments for COVID-19 reduced 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

Transfers of Financial Assets

The Company accounts for transfers of financial assets as sales when it has surrendered control over the related assets. Whether control has been relinquished requires, among other things, an evaluation of relevant legal considerations and an assessment of the nature and extent of the Company's continuing involvement with the assets transferred. Gains and losses stemming from transfers reported as sales are included in other income, net in the condensed consolidated statements of operations. Assets obtained and liabilities incurred in connection with transfers reported as sales are initially recognized in the balance sheet at fair value.

Going Concern

The Company's operations have been primarily financed through a combination of its proceeds from its initial public offering, other financing activities, and product sales. The Company expects that its near and longer-term liquidity requirements will consist of working capital and general corporate expenses associated with its business, including, without limitation, expenses associated with product production, sales and marketing expense associated with increasing market awareness of its platform and brand generally to healthcare providers, individual consumers, enterprises and other target customers, research and development expenses associated with its test and care offerings, and expenses associated with being a public company.

The Company had an accumulated deficit of \$443.1 million as of September 30, 2023. During the year ended December 31, 2022, and the nine months ended September 30, 2023, the Company incurred negative cash flows. A tempering of COVID-19 testing demand has resulted in a loss from operations. Currently, the majority of our product revenue is related to sales of our Cue COVID-19 test, and while we have a number of tests submitted to the FDA for regulatory approval and in late stage technical development, the receipt of such approvals is outside the Company's control. These factors, underscored by the inherent uncertainty in timing of regulatory approvals, when considered in the aggregate, raise substantial doubt about the Company's ability to continue as a going concern.

Management's plans to alleviate the conditions that raise substantial doubt include obtaining regulatory approvals for additional test products, reduced spending, and the pursuit of additional capital. There can be no assurance that the current operating plan will be achieved, including the timing of additional products, or that additional funding will be available on terms acceptable to the Company, or at all. Accordingly, the Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern for a period of at least 12 months from the date of issuance of these condensed consolidated financial statements.

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Employee Retention Credit

Tax credits within the accompanying condensed consolidated statement of operations is attributable to the one-time receipt of the Employee Retention Tax Credit from the Internal Revenue Service (the "IRS"). As a response to the COVID-19 outbreak, the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which contained a number of programs to assist workers, families and businesses. Part of the CARES Act provides an Employee Retention Credit ("ERC"), which is a refundable tax credit against certain employment taxes equal to 50% of qualified wages paid, up to \$10,000 per employee annually, from March 12, 2020 through January 1, 2021. Additional relief provisions were passed by the United States government, which extended and expanded the qualified wage caps on these credits to 70% of qualified wages paid through June 30, 2021 and 100% of qualified wages paid through December 31, 2021, up to \$10,000 per employee per quarter.

The Company filed Form 941-X for the periods 2020-2021 to claim a refund for the ERC. The Company elected to account for the ERC under ASC 958-605 when the conditions had been substantially met, which was determined to be in the third quarter of 2023. During the three months ended September 30, 2023, the Company received payments from the IRS related to the ERC and recorded \$20.9 million within tax credits in the accompanying condensed consolidated statement of operations.

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 2016-13 also amends the accounting for credit losses on available-for-sale debt securities and purchased financial assets with credit deterioration. The Company adopted this standard effective January 1, 2023 under the modified retrospective method whereas comparative period information is not restated. The adoption of this standard did not have a significant impact on the Company's condensed consolidated financial statements, therefore no cumulative effect or catch up adjustment to the opening balance of retained earnings was recorded.

NOTE 3. REVENUE**Product Revenue**

Disaggregation of the product revenue by type of customer for the three and nine months ended September 30, 2023 and 2022, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Private sector customers	\$ 14,338	\$ 65,880	\$ 45,648	\$ 322,252
Public sector entities	419	780	1,194	6,213
Total product revenue	\$ 14,757	\$ 66,660	\$ 46,842	\$ 328,465

Product revenue for the three and nine months ended September 30, 2023 includes \$0.3 million and \$2.1 million, respectively, of service revenue generated from telemedicine and proctoring services provided to customers. Product revenue for the three and nine months ended September 30, 2022 includes \$2.6 million and \$6.4 million, respectively, 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 (loss) profit and product gross (loss) profit margin for the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Product revenue	\$ 14,757	\$ 66,660	\$ 46,842	\$ 328,465
Cost of product revenue	22,180	50,595	91,349	239,190
Product gross (loss) profit	\$ (7,423)	\$ 16,065	\$ (44,507)	\$ 89,275
Product gross (loss) profit margin	(50)%	24 %	(95)%	27 %

During the nine months ended September 30, 2023, a contract manufacturer vendor drew on a cash collateralized letter of credit in the amount of \$12.0 million (the "disputed payment charge") that was recorded in cost of product revenue. The Company disputes the validity of the payment and is pursuing recovery (See Note 14. *Commitments and Contingencies*).

Contract Assets and Liabilities

Contract assets primarily relate to the Company's conditional right to consideration for performance obligations satisfied but not billed at the reporting date. Net contract assets were \$0.3 million and \$0.3 million as of September 30, 2023 and December 31, 2022, respectively, and were recorded in other current assets on the balance sheets.

Contract liabilities are recorded when cash is received prior to recording revenue. Contract liabilities are recorded in deferred revenue on the balance sheets. The activity related to contract liabilities for the nine months ended September 30, 2023 and 2022 is as follows:

	Nine Months Ended September 30,	
	2023	2022
Balance at beginning of period	\$ 1,566	\$ 92,448
Unearned revenue from cash received during the period, excluding amounts recognized as revenue during the period	623	2,734
Revenue recognized related to contract liability balance at the beginning of the period	(1,566)	—
Balance at end of period	\$ 623	\$ 95,182

Grant and Other Revenue

Grant and other revenue primarily relates to a cost reimbursement agreement with the Biomedical Advanced Research and Development Authority ("BARDA"). The Company generated \$2.7 million and \$4.9 million of revenue related to an agreement with BARDA during the three and nine months ended September 30, 2023, respectively. 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.

In August 2023, the Company was awarded a new contract for \$28.3 million by BARDA to develop an Influenza A/B, RSV, and COVID-19 molecular multiplex test for both over-the-counter and point-of-care use. Income derived from reimbursement of direct out-of-pocket expenses, overhead allocations and fringe benefits for research costs associated with U.S. government contracts are recorded as grant revenue. We recognize revenue from our contracts and awards with BARDA at the gross amount of the reimbursement in the period during which the related costs are incurred, provided that the conditions under which the grants and contracts were provided have been met and only perfunctory performance obligations are outstanding. The direct costs associated with the contract are reflected as a component of research and development expense in our condensed consolidated statements of operations.

Accounts Receivable

Under ASU 2016-13, the Company is required to remeasure expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions and reasonable forecasts. The allowance for credit losses represents the Company's estimate of expected credit losses relating to these factors. Amounts are written off against the allowances for credit losses when the Company determines that a customer account is uncollectible.

The activity related to the allowance for credit losses for the nine months ended September 30, 2023 and 2022 is as follows:

	Nine Months Ended September 30,	
	2023	2022
Allowance for credit losses, beginning balance	\$ 2,311	\$ 318
Provision for doubtful accounts, net of recoveries	(308)	1,729
Write-offs	—	(20)
Allowance for credit losses, ending balance	<u>\$ 2,003</u>	<u>\$ 2,027</u>

Receivables Purchase Agreement

On June 1, 2023, the Company entered into a Receivables Purchase Agreement (the "Purchase Agreement") with East West Bank, a California state-chartered bank (the "Purchaser"), pursuant to which, among other things, the Company may sell certain of the indebtedness and other payment obligations owed to the Company to the Purchaser in an amount of up to \$20 million without recourse in exchange for cash. Transactions under the Purchase Agreement, which matures on June 1, 2024, are accounted for as sales under ASC 860, Transfers and Servicing of Financial Assets, with the sold receivables removed from the Company's balance sheet. Under the Purchase Agreement, the Company does not maintain any beneficial interest in the receivables sold. The Company performs limited administrative services on behalf of the Purchaser since the receivables are trade receivables, but otherwise maintains no significant continuing involvement with respect to the receivables. Sale proceeds that are representative of the fair value of factored receivables, less a factoring fee of the Wall Street Journal prime rate with a floor of 5.50%, are reflected in cash flows from operating activities on the condensed consolidated statements of cash flows.

During the nine months ended September 30, 2023 and 2022, the Company received cash proceeds of \$6.1 million and \$0, respectively, from the sales of accounts receivables under the Purchase Agreement. The Company's loss on these transactions, the cost of factoring such receivables, is reflected in other income, net on the condensed consolidated statements of operations, and were not material during the three and nine months ended September 30, 2023.

NOTE 4. INVENTORIES

As of September 30, 2023 and December 31, 2022, the Company's inventories consisted of the following:

	September 30, 2023	December 31, 2022
Raw materials	\$ 77,819	\$ 80,968
Work-in-process	9,136	14,305
Finished goods	39,182	37,867
Reserve	(34,942)	(25,494)
Total inventories	91,195	107,646
Non-current inventories	(27,640)	(25,436)
Total current inventories	<u>\$ 63,555</u>	<u>\$ 82,210</u>

NOTE 5. PREPAID EXPENSES

As of September 30, 2023 and December 31, 2022, the Company's prepaid expenses consisted of the following:

	September 30, 2023	December 31, 2022
Prepaid expense	\$ 6,409	\$ 11,523
Prepaid inventory	3,453	4,205
Total prepaid expenses	<u>\$ 9,862</u>	<u>\$ 15,728</u>

NOTE 6. PROPERTY AND EQUIPMENT, NET

As of September 30, 2023 and December 31, 2022, the Company's property and equipment, net consisted of the following:

	September 30, 2023	December 31, 2022
Construction in progress	\$ 33,400	\$ 32,412
Machinery and equipment	222,412	214,702
Leasehold improvements	23,830	23,233
Furniture and fixtures	2,009	1,883
Property and equipment	<u>281,651</u>	<u>272,230</u>
Accumulated depreciation and amortization	<u>(115,340)</u>	<u>(82,955)</u>
Total property and equipment, net	<u>\$ 166,311</u>	<u>\$ 189,275</u>

Depreciation and amortization expense related to property and equipment was \$11.2 million and \$8.3 million for the three months ended September 30, 2023 and 2022, respectively. Depreciation and amortization expense related to property and equipment was \$32.4 million and \$28.6 million for the nine months ended September 30, 2023 and 2022, respectively. The carrying value of assets under finance leases within property and equipment as of September 30, 2023 and December 31, 2022 was \$5.4 million and \$7.3 million, respectively.

As of September 30, 2023, the carrying value of manufacturing equipment not yet placed into service was \$23.2 million. The cost of this equipment is substantially complete and is included in construction in progress. Depreciation expense related to these assets will commence when they are placed into service and will be depreciated over their estimated useful lives.

NOTE 7. INTANGIBLE ASSETS

As of September 30, 2023, the Company's intangible assets consisted of the following:

	Gross Amount	Accumulated Amortization	Net Carrying Value
Capitalized software	\$ 27,735	\$ (11,140)	\$ 16,595
Other	920	(192)	728
Intangible assets, net	<u>28,655</u>	<u>(11,332)</u>	<u>17,323</u>
In-process software development	4,216	—	4,216
Total intangible assets	<u>\$ 32,871</u>	<u>\$ (11,332)</u>	<u>\$ 21,539</u>

As of December 31, 2022, the Company's intangible assets consisted of the following:

	Gross Amount	Accumulated Amortization	Net Carrying Value
Capitalized software	\$ 19,052	\$ (5,724)	\$ 13,328
In-process software development	3,539	—	3,539
Total intangible assets	<u>\$ 22,591</u>	<u>\$ (5,724)</u>	<u>\$ 16,867</u>

During the development stage, the Company capitalizes certain eligible costs associated with the software development, in accordance with ASC 350-40, Internal-Use Software. The capitalized costs primarily consist of direct labor and third-party contractor fees. In-process software development consists of software costs incurred in the development of internal-use software not yet implemented. The software is expected to be implemented no later than one year from the commencement date of development. Once the software is implemented and ready for its intended use, the Company will begin amortizing the capitalized costs on a straight-line basis over the software's estimated useful life.

Amortization expense related to intangible assets placed in service was \$2.4 million and \$5.6 million for the three and nine months ended September 30, 2023, respectively. 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. Estimated amortization expense for each of the years ending December 31 is as follows:

2023 (excluding the nine months ended September 30, 2023)	\$	2,309
2024		8,559
2025		5,116
2026		1,339
Total amortization expense	\$	<u>17,323</u>

TrustedMedRx Acquisition

On March 22, 2023, CHP HC, LLC, a wholly-owned subsidiary of the Company, entered into a definitive agreement to acquire TrustedMedRx, LLC, a privately-held pharmacy, which holds operating licenses in various jurisdictions. The purchase was completed on May 4, 2023, and is expected to enhance the Company's presence in the retail pharmacy market and expand its product and service offerings. The total purchase price was \$0.7 million and the Company incurred acquisition costs of \$0.2 million. The Company concluded the purchase qualified as an asset acquisition and the purchase price and acquisition costs related to the operating licenses have been capitalized as intangible assets. The capitalized operating licenses will be amortized on a straight-line basis over a period of two years, which represents the estimated useful life.

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 less than one year. The Company's operating leases relate to the Company's manufacturing facilities and office space and have remaining terms ranging from less than one year to eight years.

There were no new material leases entered into during the three and nine months ended September 30, 2023.

The right-of-use assets and lease liabilities recognized on the Company's balance sheet as of September 30, 2023 and December 31, 2022 were as follows:

	Balance Sheet Location	September 30,	
		2023	December 31, 2022
Assets			
Right-of-use assets operating leases	<i>Operating lease right-of-use assets</i>	\$ 80,829	\$ 85,321
Right-of-use assets finance leases	<i>Property and equipment, net</i>	5,437	7,264
Liabilities			
Operating lease liabilities (current)	<i>Operating lease liabilities, current</i>	5,109	7,739
Finance lease liabilities (current)	<i>Finance lease liabilities, current</i>	1,646	2,362
Operating lease liabilities (non-current)	<i>Operating lease liabilities, net of current portion</i>	42,961	44,045
Finance lease liabilities (non-current)	<i>Finance lease liabilities, net of current portion</i>	—	849

The components of lease expense for the three and nine months ended September 30, 2023 and 2022 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating lease cost	\$ 3,197	\$ 3,192	\$ 9,198	\$ 8,749
Finance lease cost:				
Amortization of right-of-use assets	896	819	2,127	2,098
Interest on lease liabilities	24	43	65	137
Total lease cost	\$ 4,117	\$ 4,054	\$ 11,390	\$ 10,984

NOTE 9. ACCRUED LIABILITIES AND OTHER CURRENT LIABILITIES

Accrued liabilities and other current liabilities consisted of the following:

	September 30, 2023	December 31, 2022
Accrued purchases ⁽¹⁾	\$ 1,127	\$ 4,488
Accrued payroll and benefits	17,428	26,350
Accrued expenses	6,070	5,553
Accrued sales tax	1,147	1,361
Product warranty reserve	2,966	6,660
Income tax payable	2,838	—
Accrued restructuring	107	—
Accrued purchase commitment loss ⁽²⁾	8,237	7,966
Total accrued liabilities and other current liabilities	\$ 39,920	\$ 52,378

⁽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.

⁽²⁾ Accrued purchase commitment loss reflects accrued loss on purchase obligations for inventory.

NOTE 10. DEBT

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, 2023, there were no revolving loans outstanding and \$1.0 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 \$99.0 million. The Company recorded \$0.6 million in deferred financings costs in connection with the 2022 Revolving Facility Agreement. This balance is 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 Company was in compliance with its covenants as of September 30, 2023.

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. STOCKHOLDERS' EQUITY

Preferred Stock Rights Agreement

On September 21, 2023, the Company's board of directors authorized and declared a dividend distribution of one right (each, a "Right") for each outstanding share of the Company's common stock to stockholders of record as of the close of business on October 2, 2023. Each Right entitles the registered holder to purchase from the Company one one-thousandth of a share of Series A Participating Preferred Stock, par value 0.00001 per share (the "Preferred Stock"), of the Company at an exercise price of \$8.00 per one one-thousandth of a share of Preferred Stock, subject to adjustment. The Rights expire on the earliest of (i) 5:00 p.m., New York City time, on September 20, 2024 (unless such date is extended) or (ii) the redemption or exchange of the Rights. The complete terms of the Rights are set forth in a Preferred Stock Rights Agreement (the "Rights Agreement"), dated as of September 21, 2023, between the Company and Computershare Trust Company, N.A., as rights agent. Given the nature of the Rights and their contingent activation, which has been deemed remote, no value is recognized in stockholders' equity.

At the Market Offering Program

On August 9, 2023, in connection with the launch of an "at the market" offering program, the Company entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC (the "Sales Agent"). Under the Sales Agreement, the Company may offer and sell its common stock from time to time having an aggregate offering price of up to \$50.0 million during the term of the Sales Agreement through the Sales Agent (the "Offering Program").

The Company did not issue any shares of common stock under the Offering Program during the nine months ended September 30, 2023.

Stock Incentive Plans

2021 Stock Incentive Plan

In September 2021, the Company adopted the 2021 Stock Incentive Plan (the "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.

2021 Employee Stock Purchase Plan

In September 2021, the Company adopted the 2021 Employee Stock Purchase Plan (the "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 (iii) 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.

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, 2023 and 2022, was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Cost of product revenues	\$ 650	\$ 865	\$ 1,995	\$ 2,267
Sales and marketing	1,793	1,441	5,068	6,718
Research and development	4,429	6,212	13,386	17,780
General and administrative	5,815	7,172	17,599	21,750
Restructuring	—	—	549	—
Total stock-based compensation expense	\$ 12,687	\$ 15,690	\$ 38,597	\$ 48,515

In total, \$0.7 million and \$2.0 million of stock-based compensation expense was capitalized to inventory during the manufacturing process during the three and nine months ended September 30, 2023, respectively. An immaterial amount remained in inventory as of September 30, 2023.

Stock Options

A summary of stock option activity and related information for the nine months ended September 30, 2023 was as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at January 1, 2023	7,102,853	\$ 5.92	6.4
Granted	3,473,387	\$ 2.15	
Exercised	(169,515)	\$ 0.66	
Forfeited	(1,084,592)	\$ 11.78	
Expired	(355,010)	\$ 10.27	
Outstanding at September 30, 2023	8,967,123	\$ 3.68	6.8
Exercisable at September 30, 2023	5,880,224	\$ 4.03	5.7
Vested and expected to vest at September 30, 2023	8,967,123	\$ 3.68	6.8

As of September 30, 2023, there was \$7.8 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.

The estimated fair value of each stock option award granted to employees was determined on the date of grant using the Black-Scholes option pricing model with the following assumptions for stock option grants for the nine months ended September 30, 2023.

	2023
Expected volatility	85%
Expected term (years)	6.5
Expected dividend yield	0.0%
Risk-free interest rate	4.3%
Grant date fair value	\$ 1.58

During the nine months ended September 30, 2023, the Company modified certain stock options previously granted to non-employees. The modification included changes to the exercise price of 622,323 unvested options. As a result of these modifications, the Company will recognize an additional \$0.4 million in stock-based compensation expense over the remaining vesting period of the affected options.

Restricted Stock Units

Under the 2014 and 2021 Plans, restricted stock units (“RSUs”) are generally subject to a four-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, 2023 was as follows:

	Underlying Shares	Weighted-average Grant Date Fair Value	Aggregate Fair Value
Outstanding, January 1, 2023	18,681,701	\$ 9.51	\$ 177,739
Granted	9,754,451	\$ 1.63	15,910
Vested	(4,243,128)	\$ 7.47	(31,686)
Forfeited	(5,260,776)	\$ 6.70	(35,225)
Outstanding, September 30, 2023	<u>18,932,248</u>	<u>\$ 6.69</u>	<u>\$ 126,738</u>

As of September 30, 2023, there was \$80.7 million of total unrecognized compensation cost related to outstanding RSUs, which is expected to be recognized over a remaining weighted-average vesting period of 2.3 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, 2023 was as follows:

	Underlying Shares	Weighted-average Grant Date Fair Value	Aggregate Fair Value
Outstanding, January 1, 2023	3,335,300	\$ 12.82	\$ 42,759
Granted	—	\$ —	—
Vested	—	\$ —	—
Forfeited	—	\$ —	—
Outstanding, September 30, 2023	<u>3,335,300</u>	<u>\$ 12.82</u>	<u>\$ 42,759</u>

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, 2023 was as follows:

	Underlying Shares	Weighted-average Grant Date Fair Value	Aggregate Fair Value
Outstanding, January 1, 2023	798,635	\$ 16.00	\$ 12,778
Granted	266,212	\$ 2.48	660
Vested	—	\$ —	—
Forfeited	(532,425)	\$ 9.24	(4,919)
Outstanding, September 30, 2023	<u>532,422</u>	<u>\$ 16.00</u>	<u>\$ 8,519</u>

Common Stock Warrants

As of September 30, 2023, 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, 2022.

NOTE 12. LOSS PER SHARE

Basic net loss per share is computed by dividing net loss by the weighted-average common shares outstanding during the period. Diluted net loss per share 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net loss	\$ (46,970)	\$ (66,303)	\$ (225,032)	\$ (162,550)
Denominator:				
Basic and diluted weighted-average common shares outstanding	153,699,408	148,582,721	152,226,999	147,443,196
Net loss per share				
Basic	\$ (0.31)	\$ (0.45)	\$ (1.48)	\$ (1.10)
Diluted	\$ (0.31)	\$ (0.45)	\$ (1.48)	\$ (1.10)

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

Outstanding anti-dilutive securities not included in the diluted net 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,	
	2023	2022	2023	2022
Restricted stock units	18,932,248	18,596,751	18,932,248	18,596,751
Stock options	8,967,123	7,735,773	8,967,123	7,735,773
Employee stock purchase plan – shares projected to be issued	2,305,712	314,531	2,305,712	314,531
Common stock warrants	75,744	75,744	75,744	75,744
Total	30,280,827	26,722,799	30,280,827	26,722,799

NOTE 13. INCOME TAXES

The Company's effective income tax rate for the three and nine months ended September 30, 2023 was 11.2% and 2.1%, respectively. The Company's effective income tax rate for the three and nine months ended September 30, 2022 was benefits of 1.6% and 2.7%, respectively.

The effective tax rate for the three and nine months ended September 30, 2023 differs from the statutory rate primarily due to the Company maintaining a full valuation allowance against its net deferred tax assets and the impact of tax credits recorded during the three and nine months ended September 30, 2023.

The effective tax rate for the three and nine months ended September 30, 2022 differs from the statutory rate primarily due to the Company maintaining a full valuation allowance against its net deferred tax assets and the impact of certain state tax credits recorded during the nine months ended September 30, 2022.

NOTE 14. 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. Subject to certain limitations, the Company currently provides customers with the right to receive a replacement Cue Cartridge for unexpired tests that do not produce a valid result, for a period of up to ninety days from the date the test is performed. 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, 2022	\$ 6,660
Provision for warranties	1,315
Settlements	(5,009)
Balance, September 30, 2023	<u>\$ 2,966</u>

Cost Reduction Plan

On January 5, 2023, the Company announced that it was implementing a new cost reduction plan (the “January CRP”). Management, with the oversight and guidance of the Company’s board of directors, determined to implement the January CRP following a review of the Company’s business, operating expenses and the macroeconomic environment. The January CRP is intended to reduce the Company’s cost structure and improve its operational efficiency. The January CRP includes a reduction in the Company’s employee base.

On April 28, 2023, the Company announced a further cost reduction plan (the “April CRP”, and together with the January CRP, the “CRP”), which included a reduction in the Company’s employee base.

Cash expenditures in connection with the CRP consist of payments for salary, benefits, and unused paid time off for the affected employees. The CRP also consists of a severance package that includes a cash severance payment and payments to cover the employer premiums and administration fees for continuation of healthcare coverage for a limited period. The severance package, in some cases, also included an acceleration of the vesting of certain outstanding restricted stock units and stock options to affected employees.

Each affected employee’s eligibility for the severance benefits is contingent upon such employee’s execution (and no revocation) of a separation agreement, which includes a general release of claims against the Company. The Company expects payments relating to the CRP to be completed by the end of the fourth quarter of 2023.

In connection with the CRP, the Company recorded restructuring charges of \$0 and \$14.5 million during the three and nine months ended September 30, 2023, respectively, related to one-time termination benefits.

The following table summarizes the total amount incurred and accrued related to these restructuring activities:

	Amount
Accrued restructuring as of December 31, 2022	\$ —
Restructuring charges incurred during the period	14,518
Cash payments	(13,862)
Non-cash settlements and other adjustments	(549)
Accrued restructuring as of September 30, 2023	<u>\$ 107</u>

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, 2023.

Purchase Commitments

Purchase commitments are comprised of the Company's commitments for goods and services in the normal course of business. These purchase commitments relate to goods and services which have not yet been delivered or performed and therefore have not been reflected in our condensed consolidated balance sheets and condensed consolidated statements of operations. These commitments typically become due after the delivery and completion of such goods or services.

Legal Proceedings

On May 5, 2023, Sanmina Corporation ("Sanmina"), a contract manufacturer, filed a complaint against us in the Superior Court of California, Santa Clara County. Sanmina alleges breach of contract, breach of implied covenant of good faith and fair dealing and promissory estoppel. In connection with this allegation, in March 2023, Sanmina unilaterally drew against a \$12.0 million collateralized letter of credit with Sanmina (the "Letter of Credit") that we had posted as a partial security for our obligations under our agreement with Sanmina, and which we have recorded as cost of product revenue. Sanmina is seeking damages in the amount of approximately \$24.2 million. We believe the claims are without merit, and we dispute both the incurrence of the costs alleged and that Sanmina lawfully drew on the Letter of Credit. We intend to defend ourselves vigorously and on July 25, 2023, we filed a cross-complaint alleging, among other claims, that Sanmina is in breach of contract for improperly over-ordering components and we are seeking recovery of wrongfully retained funds, components, and manufacturing equipment rightfully due to us.

Legal fees and expenses are expensed as incurred.

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, 2022 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 empower 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, Cue Ecosystem Integrations and Apps, and access to additional Cue-branded and third-party diagnostic products, enables lab-quality diagnostics-led care at home, at work or at the point of care. Our platform offers individuals and healthcare providers convenient and personalized access to lab-quality diagnostic tests at home and at the point-of-care, as well as on-demand telehealth consultations and treatment options for a wide range of health and wellness needs. 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 multiple hardware, software, and diagnostic components: (1) our revolutionary, proprietary 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 capabilities; (3) our Cue Virtual Care Delivery Apps, including our consumer-friendly Cue Health App, the clinician-facing Cue Clinic, and our Cue Enterprise Dashboard; and (4) our Cue

Ecosystem Integrations and Apps, including integration with: electronic medical record (“EMR”) systems (enabling seamless connection between a clinician, their EMR, and Cue’s diagnostics); pharmacies and last-mile delivery (enabling e-Rx and on-demand delivery), clinician networks (enabling virtual care and prescription) and laboratories (enabling mail-in panel testing).

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.

COVID-19 Impact

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 efficacious vaccines and the availability of therapeutic treatments for COVID-19 reduced the demand for our COVID-19 test and, as a result, the COVID-19 diagnostic testing market may not develop or grow substantially. 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.

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 a portion related to the sale of non-COVID-19 test kits, component parts, telehealth and other services.

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 as appropriate in our business to drive growth and to deliver our business strategies. We plan to invest in research and development to enhance our platform and bring additional tests to market. In addition to continuing to develop our own test kits, we have also expanded the Cue Care experience to allow users of third-party test results to continue to receive the same virtual care and e-prescription process we offer to users of our Cue COVID-19 tests.

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, Henry Schein, Inc., McKesson Corporation, Cardinal Health, Inc., Medline Industries, LP and the Minnesota Department of Health. 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

We currently offer our molecular COVID-19 test, molecular mpox test, as well as other mail-in at-home test kits which address general health and wellness conditions across a wide range of health concerns, such as sexually transmitted infections, heart health and food sensitivities. In May 2023, we announced a new pharmacy offering with over-the-counter and prescription medication options for common health and wellness needs. A key part of our growth strategy is to continue 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. We have filed De Novo submission to the FDA for full clearance of our Flu A/B standalone molecular test and our Respiratory Syncytial Virus ("RSV") molecular test and filed an EUA submission to the FDA for our Flu A/B + COVID molecular multiplex test. We have two test kits in clinical studies, covering Strep Throat and Chlamydia + Gonorrhea (swab collection method), as well as two test kits in late stage technical development: Chlamydia + Gonorrhea (urine collection method) molecular multiplex test and Mpox + Herpes molecular multiplex test. In August 2022, 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 and in February 2023 we further expanded our Cue Care capabilities to include other at-home test kits. In March 2023, the FDA issued an EUA for the Company's molecular test to detect the mpox virus for use in a point-of-care setting. In June 2023, the Company received De Novo authorization for the Company's molecular test to detect COVID-19. In August 2023, the Company was awarded a new contract for \$28.3 million by BARDA to develop an Influenza A/B, RSV, and COVID-19 molecular multiplex test for both over-the-counter and point-of-care use.

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. In June 2023, the Company received De Novo authorization for the Company's molecular test to detect COVID-19. However, 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

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. We also anticipate fluctuation in demand associated with the emergence of novel variants and the degree of severity of the existing and any new variants. 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,	
	2023	2022	2023	2022
<i>(dollars in thousands)</i>	(unaudited)			
Revenue:				
Product revenue	\$ 14,757	\$ 66,660	\$ 46,842	\$ 328,465
Grant and other revenue	2,720	2,929	5,296	8,234
Total revenue	17,477	69,589	52,138	336,699
Operating costs and expenses:				
Cost of product revenue	22,180	50,595	91,349	239,190
Sales and marketing	7,051	18,129	26,358	69,268
Research and development	37,103	42,516	118,372	115,303
General and administrative	15,848	25,625	47,489	77,946
Restructuring expense	—	137	14,518	2,020
Total operating costs and expenses	82,182	137,002	298,086	503,727
Loss from operations	(64,705)	(67,413)	(245,948)	(167,028)
Interest expense	(304)	(346)	(815)	(413)
Tax credits	20,939	—	20,939	—
Other income, net	1,833	409	5,525	458
Net loss before income taxes	(42,237)	(67,350)	(220,299)	(166,983)
Income tax expense (benefit)	4,733	(1,047)	4,733	(4,433)
Net loss	\$ (46,970)	\$ (66,303)	\$ (225,032)	\$ (162,550)

Comparison of the Three Months Ended September 30, 2023 and 2022

The following table sets forth a summary of our results of operations for the three months ended September 30, 2023 and 2022 and the changes between periods:

	Three Months Ended September 30,			
	2023	2022	\$ Change	% Change
(dollars in thousands)				
Revenue:				
Product revenue	\$ 14,757	\$ 66,660	\$ (51,903)	(78)%
Grant and other revenue	2,720	2,929	(209)	(7)%
Total revenue	17,477	69,589	(52,112)	(75)%
Operating costs and expenses:				
Cost of product revenue	22,180	50,595	(28,415)	(56)%
Sales and marketing	7,051	18,129	(11,078)	(61)%
Research and development	37,103	42,516	(5,413)	(13)%
General and administrative	15,848	25,625	(9,777)	(38)%
Restructuring expense	—	137	(137)	(100)%
Total operating costs and expenses	82,182	137,002	(54,820)	(40)%
Loss from operations	(64,705)	(67,413)	2,708	(4)%
Interest expense	(304)	(346)	42	(12)%
Tax credits	20,939	—	20,939	n.m
Other income, net	1,833	409	1,424	348%
Net loss before income taxes	(42,237)	(67,350)	25,113	(37)%
Income tax expense (benefit)	4,733	(1,047)	5,780	(552)%
Net loss	\$ (46,970)	\$ (66,303)	\$ 19,333	(29)%

Revenue was \$17.5 million in the three months ended September 30, 2023, compared to \$69.6 million in the three months ended September 30, 2022. The decrease was primarily volume related due to the tempering of COVID-19 testing during 2022 which continued into 2023. Revenue during the three months ended September 30, 2023 was primarily driven by sales to private sector customers of \$14.4 million.

Cost of Product Revenue was \$22.2 million in the three months ended September 30, 2023, compared to \$50.6 million in the three months ended September 30, 2022. This decrease was primarily due to lower material costs of \$18.8 million and lower labor and overhead costs of \$2.3 million associated with decreased revenue volume as well as a reduction in excess inventory reserves and warranty costs of \$3.9 million. Our product gross profit margin, or product gross profit as a percentage of product revenue was a loss of 50% in the three months ended September 30, 2023, compared to 24% in the three months ended September 30, 2022. The decrease in product gross profit margin was primarily due to a reduction in overall production volume relative to our manufacturing capacity which impacted product gross profit margin by 88%.

Sales and Marketing Expense was \$7.1 million in the three months ended September 30, 2023, compared to \$18.1 million in the three months ended September 30, 2022. This decrease was primarily due to a decrease in digital and marketing costs of \$6.4 million as we shifted marketing strategies, a decrease in personnel costs of \$3.7 million related to the CRP, workforce realignment and optimization efforts, and a decrease in professional services costs of \$0.5 million from additional efforts in cost reduction.

Research and Development Expense was \$37.1 million in the three months ended September 30, 2023, compared to \$42.5 million in the three months ended September 30, 2022. This decrease was primarily driven by decreased personnel costs of \$5.0 million related to the CRP, as well as workforce realignment and optimization efforts to decrease materials and other costs of \$5.2 million. The decrease was offset by a shift in usage of facility and support costs by research and development of \$2.2 million and increased regulatory and clinical costs of \$3.7 million. These increases were driven by the investment in and expansion of our test menu including our Flu A/B standalone, RSV standalone, Flu A/B + COVID multiplex and Chlamydia + Gonorrhea molecular tests.

General and Administrative Expense was \$15.8 million in the three months ended September 30, 2023 compared to \$25.6 million in the three months ended September 30, 2022. This decrease was primarily related to a decrease in personnel costs of \$2.8 million related to the CRP, workforce realignment and optimization efforts and a decrease in accounting, support and other consulting-related costs of \$4.8 million, as we invested in our central team to support our operations as a public company in order to reduce consulting-related costs.

Interest Expense was \$0.3 million in the three months ended September 30, 2023, compared to \$0.3 million in the three months ended September 30, 2022.

Tax Credits was \$20.9 million in the three months ended September 30, 2023, compared to \$0 in the three months ended September 30, 2022. This increase was related to the receipt of employee retention credits of \$20.9 million.

Income Tax Expense (Benefit) was \$4.7 million and \$(1.0) million in the three months ended September 30, 2023 and 2022, respectively. Our effective income tax rate for the three months ended September 30, 2023 and 2022 was 11.2% and a benefit of 1.6%, respectively. The effective tax rate for the three months ended September 30, 2023 differs from the statutory rate primarily due to the Company maintaining a full valuation allowance against its net deferred tax assets and the impact of tax credits recorded during the three months ended September 30, 2023. The effective tax rate for the three months ended September 30, 2022 differs from the statutory rate primarily due to the Company maintaining a full valuation allowance against its net deferred tax assets and the impact of certain state tax credits recorded during the three months ended September 30, 2022.

Comparison of the Nine Months Ended September 30, 2023 and 2022

The following table sets forth a summary of our results of operations for the nine months ended September 30, 2023 and 2022 and the changes between periods:

	Nine Months Ended September 30,			
	2023	2022	\$ Change	% Change
(dollars in thousands)				
Revenue:				
Product revenue	\$ 46,842	\$ 328,465	\$ (281,623)	(86)%
Grant and other revenue	5,296	8,234	(2,938)	(36)%
Total revenue	52,138	336,699	(284,561)	(85)%
Operating costs and expenses:				
Cost of product revenue	91,349	239,190	(147,841)	(62)%
Sales and marketing	26,358	69,268	(42,910)	(62)%
Research and development	118,372	115,303	3,069	3%
General and administrative	47,489	77,946	(30,457)	(39)%
Restructuring expense	14,518	2,020	12,498	619%
Total operating costs and expenses	298,086	503,727	(205,641)	(41)%
Loss from operations	(245,948)	(167,028)	(78,920)	47%
Interest expense	(815)	(413)	(402)	97%
Tax credits	20,939	—	20,939	n.m
Other income, net	5,525	458	5,067	1,106%
Net loss before income taxes	(220,299)	(166,983)	(53,316)	32 %
Income tax expense (benefit)	4,733	(4,433)	9,166	(207)%
Net loss	\$ (225,032)	\$ (162,550)	\$ (62,482)	38 %

Revenue was \$52.1 million in the nine months ended September 30, 2023, compared to \$336.7 million in the nine months ended September 30, 2022. The decrease was primarily volume related due to the tempering of COVID-19 testing during 2022 which continued into 2023. Revenue during the nine months ended September 30, 2023 was primarily driven by sales to private sector customers of \$46.0 million.

Cost of Product Revenue was \$91.3 million in the nine months ended September 30, 2023, compared to \$239.2 million in the nine months ended September 30, 2022. This decrease was primarily due to lower material costs of \$93.5 million and lower labor and overhead costs of \$35.7 million associated with decreased revenue volume, offset by the disputed payment charge of \$12.0 million (see Note 3. *Revenue*, to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q). Our product gross profit margin, or product gross profit as a percentage of product revenue was a loss of 95% in the nine months ended September 30, 2023, compared to 27% in the nine months ended September 30, 2022. The decrease in product gross profit margin was primarily due to the aforementioned \$12.0 million charge which impacted product gross profit margin by 26% and an increase in excess inventory reserves and scrap of \$11.5 million which impacted product gross profit margin by 25%. In addition, a reduction in overall production volume relative to our manufacturing capacity impacted product gross profit margin by 77%. These decreases were offset by a prior year charge of \$45.5 million related to an overbuild of inventory and identification of certain products which are not expected to perform in line with the Company's quality standards which impacted product gross profit margin by 14%.

Sales and Marketing Expense was \$26.4 million in the nine months ended September 30, 2023, compared to \$69.3 million in the nine months ended September 30, 2022. This decrease was primarily due to a decrease in digital and marketing costs of \$33.4 million as we shifted marketing strategies, a decrease in personnel costs of \$8.1 million related to the CRP, workforce realignment and optimization efforts, and a decrease in professional services costs of \$3.3 million from additional efforts in cost reduction.

Research and Development Expense was \$118.4 million in the nine months ended September 30, 2023, compared to \$115.3 million in the nine months ended September 30, 2022. This increase was primarily driven by a shift in usage of facility and support costs by research and development of \$7.4 million and increased regulatory and clinical costs

of \$5.8 million. The increase was driven by investment and expansion of our test menu including our Flu A/B standalone, RSV standalone, Flu A/B + COVID multiplex and Chlamydia + Gonorrhea molecular tests. These increases were offset by a decrease of personnel costs of \$7.4 million related to the CRP, as well as workforce realignment and optimization efforts to decrease professional service and other costs of \$5.2 million.

General and Administrative Expense was \$47.5 million in the nine months ended September 30, 2023 compared to \$77.9 million in the nine months ended September 30, 2022. This decrease was primarily related to a decrease in personnel costs of \$9.9 million related to the CRP, workforce realignment and optimization efforts, and a decrease in accounting, consulting-related and other support costs of \$13.3 million, as we invested in our central team to support our operations as a public company in order to reduce consulting and external-related costs.

Interest Expense was \$0.8 million in the nine months ended September 30, 2023, compared to \$0.4 million in the nine months ended September 30, 2022.

Tax Credits was \$20.9 million in the nine months ended September 30, 2023, compared to \$0 in the nine months ended September 30, 2022. This increase was related to the receipt of employee retention credits of \$20.9 million.

Income Tax Expense (Benefit) was \$4.7 million and \$(4.4) million in the nine months ended September 30, 2023 and 2022, respectively. Our effective income tax rate for the nine months ended September 30, 2023 and 2022 was 11.2% and a benefit of 2.7%, respectively. The effective tax rate for the nine months ended September 30, 2023 differs from the statutory rate primarily due to the Company maintaining a full valuation allowance against its net deferred tax assets and the impact of tax credits recorded during the nine months ended September 30, 2023. The effective tax rate for the nine months ended September 30, 2022 differs from the statutory rate primarily due to the Company maintaining a full valuation allowance against its net deferred tax assets and the impact of certain state tax credits recorded during the nine months ended September 30, 2022.

Liquidity and Capital Resources

Overview

As of September 30, 2023, we held \$111.5 million of cash and cash equivalents. Our primary cash needs are for the funding of day-to-day operations 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, we 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, 2023, there were no revolving loans outstanding and \$1.0 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 \$99.0 million. 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.

We had an accumulated deficit of \$443.1 million as of September 30, 2023. During the year ended December 31, 2022, and the nine months ended September 30, 2023, we incurred negative cash flows. A tempering of COVID-19 testing demand has resulted in a loss from operations. Currently, the majority of our product revenue is related to sales of our Cue COVID-19 test, and while we have a number of tests submitted to the FDA for regulatory approval and in late stage technical development, the receipt of such approvals is outside our control. These factors, underscored by the inherent uncertainty in timing of regulatory approvals, when considered in the aggregate, raise substantial doubt about our ability to continue as a going concern.

In August 2023, we filed with the SEC a new shelf registration statement on Form S-3, pursuant to which we may offer debt securities, preferred stock, common stock and certain other securities from time to time up to a maximum aggregate amount of \$250,000,000. Additionally, on August 9, 2023, in connection with the launch of an “at the market” offering program, we entered into a sales agreement (the “Sales Agreement”) with Cowen and Company, LLC (the “Sales Agent”). Under the Sales Agreement, we may offer and sell our common stock from time to time having an aggregate offering price of up to \$50,000,000 during the term of the Sales Agreement through the Sales Agent (the “Offering Program”). We did not issue any shares of our common stock under the Offering Program during the nine months ended September 30, 2023.

Management's plans to alleviate the conditions that raise substantial doubt include obtaining regulatory approvals for additional test products, reduced spending, and the pursuit of additional capital. There can be no assurance that the current operating plan will be achieved, including the timing of additional products, or that additional funding will be available on terms acceptable to us, or at all. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of these condensed consolidated financial statements.

Cash Flows

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

	Nine Months Ended September 30,	
	2023	2022
<i>(dollars in thousands)</i>	(unaudited)	
Net cash, cash equivalents and restricted cash used in operating activities	\$ (109,090)	\$ (60,219)
Net cash, cash equivalents and restricted cash used in investing activities	(17,965)	(52,946)
Net cash, cash equivalents and restricted cash used in financing activities	(3,021)	(4,557)
Net change in cash, cash equivalents and restricted cash	<u>\$ (130,076)</u>	<u>\$ (117,722)</u>

Cash Flows from Operating Activities

Net cash, cash equivalents and restricted cash used in operating activities was \$109.1 million in the nine months ended September 30, 2023, primarily reflecting our net loss of \$225.0 million, net of non-cash cost items and changes in operating working capital. Non-cash cost adjustments were primarily driven by stock-based compensation expense of \$38.6 million and depreciation and amortization expenses of \$38.0 million. The timing of our revenue and collections decreased our accounts receivable.

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 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.

Cash Flows from Investing Activities

Net cash, cash equivalents and restricted cash used in investing activities was \$18.0 million for the nine months ended September 30, 2023, reflecting purchases of property and equipment of \$7.8 million and investments of \$10.2 million primarily related to the development of internal-use software.

Net cash, cash equivalents and restricted cash used in investing activities was \$52.9 million in the nine months ended September 30, 2022, reflecting purchases of property and equipment of \$43.2 million to expand our research and development and production capabilities and investments of \$9.8 million in the development of internal-use software.

Cash Flows from Financing Activities

Net cash, cash equivalents and restricted cash used in financing activities for the nine months ended September 30, 2023 of \$3.0 million was primarily driven by \$1.6 million in tax withholding on stock option exercises and RSU vesting and \$1.6 million in payments for finance leases. These cash outflows were offset by proceeds of \$0.4 million from the 2021 ESPP and \$0.1 million from stock options exercised.

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 2021 ESPP and \$2.0 million from stock options exercised.

Commitments and Contingencies

See Note 14. *Commitments and Contingencies*, to our unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for a summary of our commitments as of September 30, 2023.

Our material cash commitments at September 30, 2023 related to real estate leases under non-cancelable operating lease agreements in the amount of \$48.1 million that expire at various dates through 2031 and finance leases of manufacturing equipment totaling \$1.6 million. We expect to fund these commitments using our existing cash on hand.

Critical Accounting Estimates

For a description of our critical accounting estimates, refer to Part II, Item 7, Critical Accounting Estimates in our Annual Report on Form 10-K for the year ended December 31, 2022. There have been no material changes to our critical accounting estimates from our Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

Recently Adopted and Issued Accounting Pronouncements

Recently issued and adopted accounting pronouncements are described in Note 2 to our condensed consolidated 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 (“CEO”) and Chief Financial Officer (“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, 2022, the CEO and CFO concluded that our disclosure controls and procedures were not effective at a reasonable assurance level as of September 30, 2023.

In light of this fact, our management has performed additional analyses, reconciliations and other post-closing procedures and has concluded that, notwithstanding the identified material weakness, management believes the condensed consolidated 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. GAAP.

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 Annual Report on Form 10-K for the year ended December 31, 2022, 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, 2022, we began to take steps to address our material weaknesses through our remediation plan, which included the hiring of a Chief Financial Officer, Chief Accounting Officer, Assistant Controller, Director of Tax, and Senior Director of SOX Compliance. We walked through and updated our documentation of key financial business processes and financial systems and identified areas of improvement and relevant risks. On the basis of these risks, we assessed the design and implementation of internal controls, identified relevant gaps, and prepared a detailed project plan to address noted internal control weaknesses. Such actions include redesigning certain controls, documenting and implementing formalized processes and procedures, testing controls for which the design and implementation was deemed to be effective, and delivering targeted training to process/control owners, related to, but not limited to, financial accounting, manual journal entries, segregation of duties and information technology general controls. During the first three quarters of 2023, we focused on advancing management action plans targeting processes and controls most critical to our material weaknesses.

We have dedicated resources and continue to engage external advisors to 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.

While we believe that these efforts will improve our internal control over financial reporting, the implementation of our remediation actions is ongoing and the material 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.

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, 2023 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.

For information regarding our legal proceedings, see Note 14 - *Commitments and Contingencies* to our unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

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, 2022 other than as set forth below:

If we do not regain compliance with or continue to satisfy the Nasdaq continued listing requirements, our common stock could be delisted from the Nasdaq.

The listing of our common stock on the Nasdaq Global Stock Market ("Nasdaq") is contingent on our compliance with the Nasdaq's conditions for continued listing. We are currently not in compliance with Nasdaq listing requirements, specifically the minimum bid price requirement, and must regain compliance on or prior to December 4, 2023. If we are unable to regain such compliance, we will cease to be eligible to trade on Nasdaq and will likely be delisted by Nasdaq.

If we were to fail to meet a Nasdaq listing requirement, we may be subject to delisting by the Nasdaq. In the event our common stock is no longer listed for trading on Nasdaq, our trading volume and share price may decrease and we may experience further difficulties in raising capital which could materially affect our operations and financial results. Further, delisting from the Nasdaq could also have other negative effects, including potential loss of confidence by partners, lenders, suppliers and employees and could also trigger various defaults under our financing arrangements and other outstanding agreements. Finally, delisting could make it harder for us to raise capital and sell securities. You may experience future dilution as a result of future equity offerings. In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock.

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

The trading price of our common stock has been and may in the future continue to be subject to extreme volatility. For example, from September 27, 2021, the date our common stock began trading on the Nasdaq, through September 30, 2023, our common stock has experienced an intra-day trading high of \$22.20 per share and an intra-day trading low of \$0.31 per share. At certain times during such period, the daily fluctuations in the trading price of our common stock were greater than 10%. We cannot predict the magnitude of future fluctuations in the trading price of our common stock. The trading price of our common stock may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control, including events described in the risk factors set forth in this Quarterly Report on Form 10-Q and in our other reports filed with the SEC from time to time, as well as our operating results, financial condition and other events or factors.

We might not be able to continue as a going concern.

We had an accumulated deficit of \$443.1 million as of September 30, 2023. During the year ended December 31, 2022, and the nine months ended September 30, 2023, we incurred negative cash flows. A tempering of COVID-19 testing demand has resulted in a loss from operations. Currently, the majority of our product revenue is related to sales of our Cue COVID-19 test, and while we have a number of tests submitted to the FDA for regulatory approval and in late state technical development, the receipt of such approvals is outside our control. These factors, underscored by the inherent uncertainty of obtaining timely regulatory approvals, when considered in the aggregate, raise substantial doubt about our ability to continue as a going concern. If we cannot continue as a viable entity, our stockholders would likely lose most or all of their investment in us.

If we are unable to generate sustainable operating profit and sufficient cash flows, then our future success will depend on our ability to raise capital. We are seeking additional financing and evaluating financing alternatives in order to

meet our cash requirements for the next twelve months. We cannot be certain that raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current stockholders may experience dilution. If we are unable to obtain funds when needed or on acceptable terms, we may be required to curtail our current product development programs, cut operating costs, forego future development and other opportunities or even terminate our operations.

Product liability, product recall or personal injury issues could damage our reputation and have a significant adverse effect on our businesses, operating results, cash flows and/or financial condition.

The products that we sell could become subject to contamination, product tampering, mislabeling, recall or other damage. In addition, errors in the dispensing, packaging or administration of drugs or other products and consuming drugs in a manner that is not prescribed could lead to serious injury or death. Product liability or personal injury claims may be asserted against us with respect to any of the drugs or other products we sell or services we provide. Should a product or other liability issue arise, the coverage available under our insurance programs and the indemnification amounts available to us from third parties may not be adequate to protect us against the financial impact of the related claims. We also may not be able to maintain our existing levels of insurance on acceptable terms in the future. A product liability or personal injury issue or judgment against us or a product recall, tampering, or mislabeling could damage our reputation and have a significant adverse effect on our businesses, operating results and/or financial condition.

Shareholder activism could cause us to incur significant expense, disrupt our business, result in a proxy contest or litigation and impact our stock price.

We have been subject to shareholder activism and may be subject to such activism in the future, which could result in substantial costs and divert management's and our board of director's attention and resources from our business. Such shareholder activism could give rise to perceived uncertainties as to our future, adversely affect our relationships with our employees, customers, or suppliers and make it more difficult to attract and retain qualified personnel. We may be required to incur significant fees and other expenses related to activist shareholder matters, including for third party advisors. We may be subjected to a proxy contest or to litigation by activist investors. Our stock price has been and could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any shareholder activism.

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

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

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

- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

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

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

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

Sales of our common stock in the public market could lower the market price for our common stock and adversely impact the trading price of our securities.

Future sales by the Company of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then prevailing market price of our common stock and could make it more difficult for the Company to raise funds in the future through a public offering of our securities.

On March 16, 2023, we filed with the SEC a "shelf" registration statement on Form S-3, and an amendment thereto on August 1, 2023. The registration statement registers certain securities that may be issued by us in a maximum aggregate amount of up to \$250,000,000. Shares of our common stock may be sold from time to time under this registration statement for up to three years from the filing date. On August 9, 2023, we filed a prospectus supplement for the sale of up to \$50,000,000 of shares of our common stock in an "at the market" offering under the shelf registration statement.

The issuance of additional shares of our common stock, or issuances of additional securities, could dilute the ownership interest of our common stockholders and could depress the market price of shares of our common stock and impair our ability to raise capital through the sale of additional equity securities. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock.

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

Our operations, or those of our suppliers or third-party contract manufacturers, could become subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and pandemics, including the COVID-19 pandemic, acts of terrorism, acts of war or other geopolitical unrest, including Russia's invasion of Ukraine and the Israel-Hamas conflict, and other natural or man-

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

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

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

Securities Trading Plans of Directors and Executive Officers

Clint Sever, our Chief Product Officer, adopted a Rule 10b5-1 trading arrangement on September 15, 2023. The duration of the trading arrangement begins on January 2, 2024, and ends on May 31, 2024. The Rule 10b5-1 trading arrangement provides for the sale of 295,900 shares of our common stock upon the exercise of stock options. The trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c).

Item 6. Exhibits**EXHIBIT INDEX**

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed Herewith
3.1	Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock	8-K	001-40824	3.1	September 22, 2023	
4.1	Preferred Stock Rights Agreement, dated as of September 21, 2023, by and between Cue Health Inc. and Computershare Trust Company, N.A., as rights agent	8-K	001-40824	4.1	September 22, 2023	
10.1	Sales Agreement, dated August 9, 2023, by and between Cue Health Inc. and Cowen and Company, LLC	8-K	001-40824	1.1	August 9, 2023	
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					X
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					X
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)					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
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 8, 2023

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

Date: November 8, 2023

By: /s/ Aasim Javed
Aasim Javed
Chief Financial Officer
(Principal Financial Officer)

Date: November 8, 2023

By: /s/ Randall Pollard
Randall Pollard
Chief Accounting Officer and
Controller
(Principal Accounting Officer)

**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 8, 2023

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

**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, Aasim Javed, 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 8, 2023

By: /s/ Aasim Javed
Aasim Javed
Chief Financial Officer
(Principal Financial Officer)

**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, 2023 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 8, 2023

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

Date: November 8, 2023

By: /s/ Aasim Javed
Aasim Javed
Chief Financial Officer
(Principal Financial 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.