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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2023

OR

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

For the transition period from _____ to_____

Commission File Number: 001-40590

Cue Health Inc.

(Exact Name of Registrant as Specified in its Charter)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001 per share	**HLTH**	**Nasdaq Global Stock Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

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

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

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

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

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

As of May 3, 2023 the registrant had 151,618,769 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 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)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 178,201	$ 241,530
Restricted cash	800	800
Accounts receivable, net	9,799	18,751
Inventories, net - current	82,006	82,210
Prepaid expenses	11,617	15,728
Other current assets	4,574	12,134
Total current assets	286,997	371,153
Non-current inventories, net	27,718	25,436
Property and equipment, net	184,197	189,275
Operating lease right-of-use assets	84,542	85,321
Intangible assets, net	19,774	16,867
Other non-current assets	5,333	6,528
Total assets	$ 608,561	$ 694,580
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 16,644	$ 7,150
Accrued liabilities and other current liabilities	40,173	52,378
Deferred revenue, current	754	1,566
Operating lease liabilities, current	7,739	7,739
Finance lease liabilities, current	2,148	2,362
Total current liabilities	67,458	71,195
Operating leases liabilities, net of current portion	42,826	44,045
Finance lease liabilities, net of current portion	417	849
Other non-current liabilities	1,997	1,997
Total liabilities	112,698	118,086
Commitments and contingencies (Note 15)		
Stockholders' Equity		
Common stock, $0.00001 par value; 500,000,000 and 500,000,000 shares authorized, 151,567,650 and 150,406,014 issued and outstanding at March 31, 2023 and December 31, 2022, respectively	2	1
Additional paid-in-capital	808,133	794,567
Accumulated deficit	(312,272)	(218,074)
Total stockholders' equity	495,863	576,494
Total liabilities and stockholders' equity	$ 608,561	$ 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 March 31,	
	2023	**2022**
Revenue		
Product revenue	$ 24,494	$ 177,454
Grant and other revenue	271	1,956
Total revenue	24,765	179,410
Operating costs and expenses:		
Cost of product revenue	39,823	86,697
Sales and marketing	11,248	34,168
Research and development	44,733	28,787
General and administrative	16,938	26,910
Restructuring expense	7,873	—
Total operating costs and expenses	120,615	176,562
(Loss) income from operations	(95,850)	2,848
Interest expense	(220)	(51)
Other income, net	1,872	6
Net (loss) income before income taxes	(94,198)	2,803
Income tax (benefit) expense	—	—
Net (loss) income	$ (94,198)	$ 2,803
Net (loss) income per share – basic	$ (0.62)	$ 0.02
Weighted-average number of shares used in computation of net (loss) income per share – basic	151,083,716	146,526,370
Net (loss) income per share – diluted	$ (0.62)	$ 0.02
Weighted-average number of shares used in computation of net (loss) income per share – diluted	151,083,716	153,036,804

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, 473,080 shares	1,075,820	1	95	—	96
Issuance of common stock upon vesting of restricted stock units	398,470	—	—	—	—
Tax withholding on exercise of stock options and issuance of shares from restricted stock units	(312,654)	—	(924)	—	(924)
Stock-based compensation	—	—	14,407	—	14,407
Other	—	—	(12)	—	(12)
Net loss	—	—	—	(94,198)	(94,198)
Balance at March 31, 2023	151,567,650	$ 2	$ 808,133	$ (312,272)	$ 495,863

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, 2021	146,402,991	$ 1	$ 730,767	$ (24,018)	$ 706,750
Exercise of common stock options	294,856	—	270	—	270
Issuance of common stock upon vesting of restricted stock units	930,493	—	—	—	—
Tax withholding on exercise of stock options and restricted stock units	(670,044)	—	(720)	—	(720)
Stock-based compensation	—	—	16,035	—	16,035
Net income	—	—	—	2,803	2,803
Balance at March 31, 2022	146,958,296	$ 1	$ 746,352	$ (21,215)	$ 725,138

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)

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities		
Net (loss) income	$ (94,198)	$ 2,803
Adjustments to reconcile net (loss) income to net cash, cash equivalents and restricted cash (used in) provided by operations		
Depreciation and amortization	12,064	10,606
Allowance for doubtful accounts provision	312	(229)
Stock-based compensation expense	14,407	16,035
Non-cash lease expense	2,278	1,996
Interest on finance leases	24	51
Non-cash interest expense	79	65
Changes in operating assets and liabilities:		
Accounts receivable	8,640	28,988
Inventories	(2,078)	(44,179)
Prepaid expenses and other current assets	11,659	1,618
Other non-current assets	1,116	(1,876)
Accounts payable, accrued liabilities and other current liabilities	(4,656)	18,254
Deferred revenue	(812)	2,464
Operating lease liabilities	(2,718)	(5,075)
Net cash, cash equivalents and restricted cash (used in) provided by operating activities	(53,883)	31,521
Cash flows from investing activities		
Purchase of property and equipment	(3,906)	(12,782)
Expenditures for software development	(4,412)	(1,273)
Net cash, cash equivalents and restricted cash used in investing activities	(8,318)	(14,055)
Cash flows from financing activities		
Proceeds from exercise of common stock options	96	270
Tax withholding on exercise of stock options	(924)	(720)
Proceeds from employee stock purchase plan activity	370	273
Payments for finance leases	(670)	(696)
Net cash, cash equivalents and restricted cash used in financing activities	(1,128)	(873)
Net change in cash, cash equivalents and restricted cash	(63,329)	16,593
Cash, cash equivalents and restricted cash, beginning balance	242,330	423,710
Cash, cash equivalents and restricted cash, ending balance	$ 179,001	$ 440,303
Reconciliation of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	$ 178,201	$ 426,465
Restricted cash, current	800	13,838
Total cash, cash equivalents and restricted cash	$ 179,001	$ 440,303
Supplemental disclosure for cash flow information		
Cash paid for taxes	$ —	$ —

Cash paid for interest	$ —	$ —
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	$ 2,548	$ 9,235
Software development costs included in accounts payable	$ —	$ 897

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

Cue Health Inc.

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

NOTE 1. BUSINESS AND BASIS OF ACCOUNTING

Organization and Description of Business

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

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements should be read in conjunction with the audited annual financial statements and notes thereto for the year ended December 31, 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 months ended March 31, 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 and long-lived assets and net deferred tax assets (and related valuation allowance). The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

Segment Reporting

Operating segments are identified as components of an enterprise about which discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. In addition, the guidance for segment reporting indicates certain quantitative materiality thresholds. The Company views its operations and manages its business in one operating segment which is consistent with how the Chief Executive Officer, who is the chief operating decision-maker, reviews the business, makes investment and resource allocation decisions, and assesses operating performance. The majority of revenue to date is from customers located in the United States and the majority of long-lived assets are located in the United States. Revenues to customers located outside of the United States were not material and $3.5 million for the three months ended March 31, 2023 and 2022, respectively.

Long-lived assets, which consist of property and equipment, located outside of the United States were $4.4 million and $4.7 million as of March 31, 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 but served as a catalyst to accelerating the Company's product pipeline. 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 an efficacious vaccine or new therapeutic treatment for COVID-19 may reduce the demand for the Cue COVID-19 test and, as a result, the COVID-19 diagnostic testing market may not develop or grow substantially. Given the rapid development of events surrounding the pandemic, there is uncertainty to the Company's future results and performance.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

There have been no material changes to the Company's significant accounting policies from its Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

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 months ended March 31, 2023 and 2022, respectively:

	Three Months Ended March 31,	
	2023	**2022**
Private sector customers	$ 24,013	$ 175,844
Public sector entities	481	1,610
Total product revenue	$ 24,494	$ 177,454

Product revenue for the three months ended March 31, 2023 includes an immaterial amount of service revenue generated from telemedicine and proctoring services provided to customers. Revenue generated from proctoring is recognized over the term of the contracts with customers.

The following table sets forth the Company's product gross (loss) profit and product gross (loss) profit margin for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,	
	2023	2022
Product revenue	$ 24,494	$ 177,454
Cost of product revenue	39,823	86,697
Product gross (loss) profit	$ (15,329)	$ 90,757
Product gross (loss) profit margin	(63)%	51 %

During the three months ended March 31, 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.

Contract Assets and Liabilities

Contract assets primarily relate to the Company's conditional right to consideration for performance obligations satisfied through direct-to-consumer sales but not billed at the reporting date. Net contract assets were not material and $0.3 million as of March 31, 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 three months ended March 31, 2023 and 2022 is as follows:

	Three Months Ended March 31,	
	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	556	2,464
Revenue recognized related to contract liability balance at the beginning of the period	(1,368)	—
Balance at end of period	$ 754	$ 94,912

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 $0.1 million and $2.0 million of revenue related to the agreement with BARDA during the three months ended March 31, 2023 and 2022, respectively.

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 doubtful accounts represents the Company's estimate of expected credit losses relating to these factors. Amounts are written off against the allowances for doubtful accounts when the Company determines that a customer account is uncollectible. As of March 31, 2023 and December 31, 2022, the Company's allowance for doubtful accounts was $2.0 million and $2.3 million, respectively.

NOTE 4. INVENTORIES

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

	March 31, 2023	December 31, 2022
Raw materials	$ 80,939	$ 80,968
Work-in-process	12,647	14,305
Finished goods	45,061	37,867
Reserve	(28,923)	(25,494)
Total inventories	$ 109,724	$ 107,646
Non-current inventories	$ (27,718)	$ (25,436)
Total inventories, current	$ 82,006	$ 82,210

NOTE 5. PREPAID EXPENSES

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

	March 31, 2023	December 31, 2022
Prepaid expense	$ 7,892	$ 11,523
Prepaid inventory	3,725	4,205
Total prepaid expenses	$ 11,617	$ 15,728

NOTE 6. PROPERTY AND EQUIPMENT, NET

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

	March 31, 2023	December 31, 2022
Construction in progress	$ 36,101	$ 32,412
Machinery and equipment	216,355	214,702
Leasehold improvements	23,343	23,233
Furniture and fixtures	1,911	1,883
Property and equipment	277,710	272,230
Accumulated depreciation and amortization	(93,513)	(82,955)
Total property and equipment, net	$ 184,197	$ 189,275

Depreciation and amortization expense related to property and equipment was $10.6 million and $10.0 million for the three months ended March 31, 2023 and 2022, respectively. The carrying value of assets under finance leases within property and equipment as of March 31, 2023 and December 31, 2022 was $6.6 million and $7.3 million, respectively.

As of March 31, 2023, the carrying value of manufacturing equipment not yet placed into service was $23.8 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 March 31, 2023 and December 31, 2022, the Company's intangible assets consisted of the following:

	March 31, 2023	December 31, 2022
Capitalized software	$ 18,658	$ 19,052
Accumulated amortization	(7,229)	(5,724)
Capitalized software, net	11,429	13,328
In-process software development	8,345	3,539
Total intangible assets	$ 19,774	$ 16,867

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 $1.6 million and $0.6 million for the three months ended March 31, 2023 and 2022, respectively. Estimated amortization expense for each of the years ending December 31 is as follows:

2023 (excluding the three months ended March 31, 2023)	$ 4,409
2024	5,073
2025	1,937
2026	10
Total amortization expense	$ 11,429

NOTE 8. LEASES

The Company leases real estate and manufacturing and laboratory equipment which are used in the Company's manufacturing, research and development, and administrative activities. The Company identifies a contract that contains a lease as one which conveys a right, either explicitly or implicitly, to control the use of an identified asset in exchange for consideration. These arrangements are classified as finance leases and operating leases. Finance leases consist of laboratory and manufacturing equipment with remaining terms ranging from under 1 year to 2 years. The Company's operating leases relate to the Company's manufacturing facilities and office space and have remaining terms from under 1 year to 9 years.

There were no new material leases entered into during the three months ended March 31, 2023.

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

	Balance Sheet Location	March 31, 2023	December 31, 2022
Assets			
Right-of-use assets operating leases	*Operating lease right-of-use assets*	$ 84,542	$ 85,321
Right-of-use assets finance leases	*Property and equipment, net*	6,624	7,264
Liabilities			
Operating lease liabilities (current)	*Operating lease liabilities, current*	7,739	7,739
Finance lease liabilities (current)	*Finance lease liabilities, current*	2,148	2,362
Operating lease liabilities (non-current)	*Operating lease liabilities, net of current portion*	42,826	44,045
Finance lease liabilities (non-current)	*Finance lease liabilities, net of current portion*	417	849

The components of lease expense for the three months ended March 31, 2023 and 2022 were as follows:

	Three Months Ended March 31,	
	2023	2022
Operating lease cost	$ 2,988	$ 2,762
Finance lease cost:		
Amortization of right-of-use assets	640	639
Interest on lease liabilities	24	51
Total lease cost	$ 3,652	$ 3,452

NOTE 9. ACCRUED LIABILITIES AND OTHER CURRENT LIABILITIES

Accrued liabilities and other current liabilities consisted of the following:

	March 31, 2023	December 31, 2022
Accrued purchases[(1)]	$ 2,517	$ 4,488
Accrued payroll and benefits	14,211	26,350
Accrued expenses	7,894	5,553
Accrued sales tax	385	1,361
Product warranty reserve (See Note 15. *Commitments and Contingencies*)	6,584	6,660
Accrued restructuring	365	—
Accrued purchase commitment loss [(2)]	8,217	7,966
Total accrued liabilities and other current liabilities	$ 40,173	$ 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 expected to be reserved.

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 March 31, 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 March 31, 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. CAPITAL STOCK

Common Stock Warrants

As of March 31, 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. STOCK-BASED COMPENSATION

Stock Incentive Plans

2021 Stock Incentive Plan

In September 2021, the Company adopted the 2021 Stock Incentive Plan ("2021 Plan") under which employees, officers and directors, as well as consultants and advisors to the Company are eligible to be granted awards (incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards). The 2021 Plan initially authorized the issuance of a maximum of 22,399,691 shares of common stock. The number of shares of common stock available for issuance under the 2021 Plan were and will be increased on the first day of each fiscal year beginning with the 2022 fiscal year, in an amount equal to the least of (i) 5% of the number of shares of the Company's common stock outstanding on the first day of such fiscal year and (ii) the number of shares of the Company's common stock determined by the Company's board of directors.

2021 Employee Stock Purchase Plan

In September 2021, the Company adopted the 2021 Employee Stock Purchase Plan ("2021 ESPP") under which employees of the Company can purchase shares of the Company's common stock commencing on such time and such dates as the board of directors of the Company determine. The 2021 ESPP initially allowed for the sale of 2,834,754 shares of common stock. The number of shares of the Company's common stock to be sold under the 2021 ESPP were and will be increased on the first day of each fiscal year beginning with the 2022 fiscal year, in an amount equal to the least of (i) 8,504,263 shares, (ii) 1% of the number of shares of the Company's common stock outstanding on the first day of such fiscal year and (ii) a number of shares of the Company's common stock determined by the Company's board of directors. The price at which stock is purchased under the 2021 ESPP is equal to 85% of the fair market value of the Company's common stock on the lesser of either (i) the first business day of the Plan Period or (ii) the Exercise Date.

Stock-Based Compensation

Stock-based compensation expense related to awards issued under the Company's incentive compensation plans for the three months ended March 31, 2023 and 2022, was as follows:

	Three Months Ended March 31,	
	2023	2022
Cost of product revenues	$ 636	$ 518
Sales and marketing	1,528	2,813
Research and development	5,069	5,145
General and administrative	6,855	7,559
Restructuring	319	—
Total stock-based compensation expense	$ 14,407	$ 16,035

In total, $0.6 million of stock-based compensation expense was capitalized to inventory during the manufacturing process during the three months ended March 31, 2023. An immaterial amount remained in inventory as of March 31, 2023.

Stock Options

A summary of stock option activity and related information for the three months ended March 31, 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	(142,141)	0.70	
Forfeited	(754,996)	14.37	
Expired	(5,500)	15.61	
Outstanding at March 31, 2023	9,673,603	$ 3.97	7.4
Exercisable at March 31, 2023	5,587,957	$ 4.42	5.7
Vested and expected to vest at March 31, 2023	9,673,603	$ 3.97	7.4

As of March 31, 2023, there was approximately $11.3 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 2.6 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 BSM option pricing model with the following assumptions for stock option grants for the three months ended March 31, 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 three months ended March 31, 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, RSUs are generally subject to a 4-year vesting period, with 25% of the shares vesting one year from the vesting commencement date and quarterly thereafter over the remaining vesting term, but may be subject to other vesting conditions such as performance or market based conditions. Compensation expense is recognized ratably over the requisite service period.

A summary of RSU activity and related information for the three months ended March 31, 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	6,821,951	2.11	14,370
Vested	(864,455)	10.29	(8,893)
Forfeited	(2,038,728)	6.28	(12,797)
Outstanding, March 31, 2023	22,600,469	$ 7.54	$ 170,419

As of March 31, 2023, there was approximately $123.5 million of total unrecognized compensation cost related to outstanding RSUs, which is expected to be recognized over a remaining weighted-average vesting period of 2.9 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 three months ended March 31, 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, March 31, 2023	$ 3,335,300	$ 12.82	$ 42,759

Operational-Based Performance-Vesting RSUs

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

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

Operations-based performance-vesting RSU activity for the three months ended March 31, 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	(266,212)	2.48	(660)
Outstanding, March 31, 2023	798,635	$ 16.00	$ 12,778

NOTE 13. INCOME (LOSS) PER SHARE

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted-average common shares outstanding during the period. Diluted net income (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) income and the weighted-average shares used in computing basic and diluted earnings per share:

	Three Months Ended March 31,	
	2023	2022
Numerator:		
Net (loss) income	$ (94,198)	$ 2,803
Denominator:		
Basic weighted-average common shares outstanding	151,083,716	146,526,370
Dilutive potential common stock issuable:		
Common stock warrants	—	72,395
Stock options	—	5,813,101
Restricted stock units	—	624,938
Diluted weighted-average shares outstanding	151,083,716	153,036,804
Net (loss) income per share		
Basic	$ (0.62)	$ 0.02
Diluted	$ (0.62)	$ 0.02

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

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

	Three Months Ended March 31,	
	2023	2022
Stock options	9,673,603	2,701,855
Restricted stock units	22,600,469	9,634,182
Employee stock purchase plan – shares projected to be issued	564,413	110,935
Total	32,838,485	12,446,972

NOTE 14. INCOME TAXES

The Company's effective income tax rate for each of the three months ended March 31, 2023 and 2022 was 0%.

The effective tax rate for the three months ended March 31, 2023 and 2022, differs from the statutory rate primarily due to the Company maintaining a full valuation allowance against its net deferred tax assets.

NOTE 15. COMMITMENTS AND CONTINGENCIES

Product Liability

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

Product Warranty Reserve

The Company provides its customers with the right to receive a replacement of defective or nonconforming Cue Readers for a period of up to twelve months from the date of shipment. Subject to certain limitations, the Company currently provides customers with the right to receive a replacement Cue Cartridge for 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	3,322
Settlements	(3,398)
Balance, March 31, 2023	$ 6,584

Cost Reduction Plan

On January 5, 2023, the Company announced that it was implementing a new cost reduction plan (the "CRP"). Management, with the oversight and guidance of the Company's board of directors, determined to implement the CRP following a review of the Company's business, operating expenses and the macroeconomic environment. The CRP is

intended to reduce the Company's cost structure and improve its operational efficiency. The CRP includes 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 will also consist 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, will also include 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 second quarter of 2023.

In connection with the CRP, the Company recorded a $7.9 million restructuring charge related to one-time termination benefits during the three months ended March 31, 2023.

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	7,873
Cash payments	(7,247)
Non-cash settlements and other adjustments	(261)
Accrued restructuring as of March 31, 2023	$ 365

On April 28, 2023, the Company announced a further cost reduction plan, which will include a reduction in the Company's employee base. In connection with this cost reduction plan, the Company estimates that it will record an aggregate restructuring charge related to one-time termination benefits in the range of approximately $5.0 million to $7.0 million during the three months ended June 30, 2023. The substantial majority of these charges will result in cash expenditures. The Company expects payments relating to the further cost reduction plan to be completed by the end of the fourth quarter of 2023.

Standby Letters of Credit

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 March 31, 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.

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 March 31, 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.

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. The acquisition 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 for the acquisition is approximately $0.7 million, which will be funded through the Company's existing cash resources.

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 is designed to empower stakeholders across the healthcare ecosystem, including consumers, providers, enterprises and payors with paradigm-shifting access to diagnostic and health data to inform care decisions. We are helping pioneer a new continuous care model that we believe has the potential to significantly improve the user experience, provide measurable and actionable clinical insights, and increase efficiency within the healthcare ecosystem. We believe this model, powered by our platform, will allow users to actively manage their health, which we believe will lead to improved health outcomes and a more resilient, connected, and efficient healthcare ecosystem for all stakeholders.

The Cue Integrated Care Platform consists of 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 an efficacious vaccine or the availability of therapeutic treatments for COVID-19 may reduce the demand for our COVID-19 test and could cause the COVID-19 diagnostic testing market to fail to grow or to decline. However, we believe the need for ongoing detection and monitoring will continue even after effective vaccines have been widely distributed and administered. We also believe COVID-19 will remain endemic for the foreseeable future and demand for a fast and accurate test to confirm a diagnosis and seek timely and appropriate treatment may fluctuate based on COVID-19 infection rates and variants. Even while vaccine efforts are underway, public health measures, like testing, will likely need to stay in effect to protect against COVID-19. However, given the unpredictable nature of the COVID-19 pandemic, the development and potential size of the COVID-19 diagnostic testing market is highly uncertain.

While the ongoing global COVID-19 pandemic has adversely impacted global commercial activity, it served as a catalyst to accelerate our product pipeline and commercialization of our platform. We began selling and recording product revenue for our COVID-19 test in August 2020 after obtaining our first FDA EUA in June 2020. Currently, the majority of our product revenue is related to sales of our Cue COVID-19 test with an immaterial portion related to the sale of 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. For example, in February 2023, we further expanded our Cue Care capabilities and our product lines by launching the sale of thirteen at-home test kits, allowing users to test for general health and wellness conditions across a wide range of health concerns, such as sexually transmitted infections, heart health and food sensitivities. We are continuing to enhance these service offerings and anticipate introducing solutions for additional conditions. In addition to continuing to develop our own test kits, we are also expanding 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 product lines.

Expanding Our Customer Base

Following the completion of our obligations under the U.S. DoD Agreement in December 2021, the future commercial success of our diagnostic products is dependent on our ability to broaden our customer base beyond the U.S. government and public sector to include enterprise employers, healthcare providers and direct-to-consumer. As a result, our long term growth depends on our ability to renew and acquire new customers. Current key strategic relationships include BARDA, Google LLC, or Google, the Mayo Clinic, the National Basketball Association, Major League Baseball, and Henry Schein, Inc. We intend to leverage our success with our COVID-19 test and the expansion of our manufacturing capabilities to enable broad distribution of our Cue Readers and awareness of our platform across different groups of customers and to enhance pull-through of our future tests.

Enhancing and Expanding Our Menu of Tests and Software Capabilities

We currently offer our molecular COVID-19 test, molecular mpox test, as well as thirteen other 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. 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. Investing in research and development will allow us to develop new tests as well as enhance our current product offerings and our Cue Integrated Care Platform. We have filed de novo submission to the FDA for full clearance of our molecular COVID-19 test, filed de novo submission to the FDA for full clearance of our Flu A/B standalone molecular test, and filed an EUA submission to the FDA for our Flu A/B + COVID multiplex molecular test. We have finished our clinical studies for Respiratory Syncytial Virus (“RSV”) and also have two test kits in clinical studies, covering Strep Throat and Chlamydia + Gonorrhea (swab collection method), as well as one test kit in late stage technical development for Chlamydia + Gonorrhea (urine collection method). 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 thirteen 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.

Regulatory Clearance of Our Diagnostic Products

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

Reimbursement and Insurance Coverage

We have been granted two EUAs by the FDA for our COVID-19 test for point-of-care and at-home and over-the-counter indications. The commercial success of our COVID-19 test, and any of our subsequently developed tests, is dependent on a customer's ability to be able to pay for or otherwise be reimbursed for the purchase of a test, whether out-of-pocket, by insurance or from a governmental or other third-party payor. We believe payment for our products, including our Cue COVID-19 Test Kits, will be billable by a physician, reimbursable by government payors or insurance companies, paid for by a self-insured employer, or eligible under FSA and HSA guidelines. For example, most of our contemplated future tests that are currently offered by others through central labs are reimbursable by health plans and governmental payors if properly ordered by a physician. These third-party payors decide which products will be covered and establish reimbursement levels for those products. Coverage criteria and reimbursement rates for clinical laboratory tests are subject to adjustment by payors, and current reimbursement rates could be reduced, or coverage criteria restricted in the future. If the Cue Health Monitoring System, including any of our current or future tests, are not reimbursable or covered by insurance, our business may be materially and adversely impacted.

Seasonality

We anticipate that fluctuations in customer and user demand for our COVID-19 test may be similar to those related to influenza, which typically increases during the fall and winter seasons. Although our products will be available throughout the year, we anticipate that we may experience higher sales during the fall and winter seasons, relative to the spring and summer seasons. 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 March 31,	
	2023	**2022**
(dollars in thousands)	**(unaudited)**	
Revenue:		
Product revenue	$ 24,494	$ 177,454
Grant and other revenue	271	1,956
Total revenue	24,765	179,410
Operating costs and expenses:		
Cost of product revenue	39,823	86,697
Sales and marketing	11,248	34,168
Research and development	44,733	28,787
General and administrative	16,938	26,910
Restructuring expense	7,873	—
Total operating costs and expenses	120,615	176,562
(Loss) Income from operations	(95,850)	2,848
Interest expense	(220)	(51)
Other income, net	1,872	6
Net (loss) income before income taxes	(94,198)	2,803
Income tax (benefit) expense	—	—
Net (loss) income	$ (94,198)	$ 2,803
Net (loss) income per share attributable to common stockholders – diluted	$ (0.62)	$ 0.02

Comparison of the Three Months Ended March 31, 2023 and 2022

The following table sets forth a summary of our results of operations for the three months ended March 31, 2023 and 2022 and the changes between periods:

	Three Months Ended March 31,			
	2023	**2022**	**$ Change**	**% Change**
(dollars in thousands)		**(unaudited)**		
Revenue:				
Product revenue	$ 24,494	$ 177,454	$ (152,960)	(86)%
Grant and other revenue	271	1,956	(1,685)	(86%)
Total revenue	24,765	179,410	(154,645)	(86%)
Operating costs and expenses:				
Cost of product revenue	39,823	86,697	(46,874)	(54)%
Sales and marketing	11,248	34,168	(22,920)	(67%)
Research and development	44,733	28,787	15,946	55%
General and administrative	16,938	26,910	(9,972)	(37%)
Restructuring expense	7,873	—	7,873	n.m
Total operating costs and expenses	120,615	176,562	(55,947)	(32%)
(Loss) Income from operations	(95,850)	2,848	(98,698)	(3,466%)
Interest expense	(220)	(51)	(169)	331%
Other income, net	1,872	6	1,866	31,100%
Net (loss) income before income taxes	(94,198)	2,803	(97,001)	(3,461)%
Income tax (benefit) expense	—	—	—	n.m
Net (loss) income	$ (94,198)	$ 2,803	$ (97,001)	(3,461)%
Net (loss) income per share – diluted	$ (0.62)	$ 0.02	$ (0.64)	(3,504)%

n.m. = not meaningful

Revenue was $24.8 million in the three months ended March 31, 2023, compared to $179.4 million in the three months ended March 31, 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 March 31, 2023 was primarily driven by sales to private sector customers of $24.1 million.

Cost of Product Revenue was $39.8 million in the three months ended March 31, 2023, compared to $86.7 million in the three months ended March 31, 2022. This decrease was primarily due to lower material costs of $47.4 million and lower labor and overhead costs of $19.9 million associated with decreased revenue volume, offset by the disputed payment charge of $12.0 million (see Note 3. *Revenue*). Our product gross profit margin, or product gross profit as a percentage of product revenue was a loss of approximately 63% in the three months ended March 31, 2023, compared to approximately 51%, in the three months ended March 31, 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 approximately 49%, as well as a reduction in overall production volume relative to our manufacturing capacity which impacted product gross profit margin by approximately 41%.

Sales and Marketing Expense was $11.2 million in the three months ended March 31, 2023, compared to $34.2 million in the three months ended March 31, 2022. This decrease was primarily due to a decrease in digital and marketing costs of $23.1 million as we shifted to account-based marketing strategies.

Research and Development Expense was $44.7 million in the three months ended March 31, 2023, compared to $28.8 million in the three months ended March 31, 2022. This increase was primarily driven by increased material costs of $5.1 million, increased personnel costs of $4.6 million and increased regulatory and clinical costs of $2.7 million related to clinical studies. The increase was driven by investment in our software stack as well as expansion of our test menu including our Flu A/B standalone, RSV standalone, Flu A/B + COVID multiplex and Chylamydia + Gonorrhea molecular tests.

General and Administrative Expense was $16.9 million in the three months ended March 31, 2023 compared to $26.9 million in the three months ended March 31, 2022. This decrease was primarily related to a decrease in accounting and other consulting-related costs of $4.7 million, as we invested in our central team to support our operations as a public company in order to reduce consulting-related costs. In addition, we had a decrease in personnel costs of $3.4 million related to the CRP, workforce realignment and optimization efforts.

Interest Expense was $0.2 million in the three months ended March 31, 2023 compared to $0.1 million in the three months ended March 31, 2022.

Income Tax (Benefit) Expense was $0 in each of the three months ended March 31, 2023 and 2022. Our effective income tax rate for each of the three months ended March 31, 2023 and 2022 was 0.0%. The effective tax rate for the three months ended March 31, 2023 and 2022, differs from the statutory rate primarily due to the Company maintaining a full valuation allowance against its net deferred tax assets.

Liquidity and Capital Resources

Overview

As of March 31, 2023, we held $178.2 million of cash and cash equivalents. Our primary cash needs are for the funding of day-to-day operations, financing capital investments and to address our working capital needs. Our largest source of operating cash generation is from sales to our customers. Our primary uses of cash from operating activities are for personnel-related expenses, material and supply costs for manufacturing, direct costs to deliver our products, and sales and marketing expenses and research and development initiatives.

On June 30, 2022, 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 March 31, 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.

Our operations have been primarily financed through a combination of our proceeds from our initial public offering, other financing activities, and product sales. Prior to August 2020, we had never generated any revenue from the commercial sale of products, and we had devoted substantially all of our resources to the research and development of our Cue Health Monitoring System. We only first started realizing revenue from commercial product sales in August 2020 following receipt of our first EUA from the FDA in June 2020 for our COVID-19 test. Our COVID-19 test includes a Cue Reader and a Cue COVID-19 Test Kit comprised of a Cue COVID-19 Cartridge and a Cue Wand. Since receiving our first FDA EUA, we have incurred significant additional expenses in connection with the commercial scale up of our business, including costs associated with scaling up our manufacturing operations, costs associated with the production of our COVID-19 test, sales and marketing expenses, and costs associated with the hiring of new employees, the growth of our business and building out our corporate infrastructure.

We expect that our near and longer-term liquidity requirements will consist of working capital and general corporate expenses associated with our business, including, without limitation, expenses associated with sales and marketing expense associated with increasing market awareness of our platform and brand generally to individual consumers, enterprises and other target customers, research and development expenses associated with our test and care offerings, and expenses associated with being a public company. Our short-term capital expenditure needs relate primarily to our research and development initiatives and optimization of existing business processes.

We had an accumulated deficit of $312.3 million as of March 31, 2023. During the year ended December 31, 2022, we incurred negative cash flows as a result of expending significant resources in expanding its activities combined with a tempering of COVID-19 test demand. This has resulted in a loss from operations, which is expected to continue for at least the next twelve months. Our ability to regain profitability is based on numerous factors, many of which are beyond our control, including, among other factors, market acceptance of our products, the length of the COVID-19 pandemic or future epidemics or public health emergencies, future product development, and our ability to expand our menu of tests. Our inability to achieve and maintain profitability, whether in the near term or longer term, may make it difficult to continue to grow our business and accomplish our strategic objectives, and could materially adversely affect our business, financial condition, results of operations and future prospects.

The Company believes that its existing cash and cash equivalents and availability under the revolving facility agreement are sufficient for the Company to meet its obligations through at least one year from the date of issuance of the consolidated condensed financial statements. If the Company is unable to achieve and maintain profitability, it will need additional financing to support its continuing operations and pursue its strategic objectives. Additional financing may be achieved through a combination of equity offerings, and debt financings. The Company may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all.

Cash Flows

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

	Three Months Ended March 31,	
	2023	2022
(dollars in thousands)	(unaudited)	
Net cash, cash equivalents and restricted cash (used in) provided by operating activities	$ (53,883)	$ 31,521
Net cash, cash equivalents and restricted cash used in investing activities	(8,318)	(14,055)
Net cash, cash equivalents and restricted cash used in financing activities	(1,128)	(873)
Net change in cash, cash equivalents and restricted cash	$ (63,329)	$ 16,593

Cash Flows from Operating Activities

Net cash, cash equivalents and restricted cash used in operating activities was $53.9 million in the three months ended March 31, 2023, primarily reflecting our net loss of $94.2 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 $14.4 million and depreciation and amortization expenses of $12.1 million. The timing of our revenue and collections decreased our accounts receivable and other current assets.

Net cash, cash equivalents and restricted cash provided by operating activities was $31.5 million in the three months ended March 31, 2022, primarily reflecting our net income of $2.8 million, net of non-cash cost items and changes in operating working capital. Non-cash cost adjustments were primarily driven by depreciation and amortization expenses of $10.6 million and stock-based compensation expense of $16.0 million. The timing of our revenue and collections decreased our accounts receivable. Inventory increase was driven by our effort to limit the effects of a potential future supply chain disruption combined with a tempering of COVID-19 testing demand in the latter part of the first quarter.

Cash Flows from Investing Activities

Net cash, cash equivalents and restricted cash used in investing activities was $8.3 million for the three months ended March 31, 2023, reflecting purchases of property and equipment of $3.9 million and investments of $4.4 million in the development of internal-use software.

Net cash, cash equivalents and restricted cash used in investing activities was $14.1 million in the three months ended March 31, 2022, reflecting purchases of property and equipment of $12.8 million to expand our research and development and production capabilities. We also invested $1.3 million in the development of internal-use software related to COVID-19 Testing apps for commercial customers.

Cash Flows from Financing Activities

Net cash, cash equivalents and restricted cash used in financing activities for the three months ended March 31, 2023 of $1.1 million was primarily driven by $0.9 million in tax withholding on stock option exercises and RSU vesting and $0.7 million in payments for finance leases. These cash outflows were offset by proceeds of $0.4 million from the employee stock purchase plan and $0.1 million from stock options exercised.

Net cash, cash equivalents and restricted cash used in financing activities was $0.9 million for the three months ended March 31, 2022, primarily driven by $0.7 million in tax withholding on stock option exercises and RSU vesting and $0.7 million in payments for finance leases. These cash outflows were offset by proceeds of $0.3 million from stock options exercised and $0.3 million from the employee stock purchase plan.

Commitments and Contingencies

See Note 15. *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 March 31, 2023.

Our material cash commitments at March 31, 2023 related to real estate leases under non-cancelable operating lease agreements in the amount of $50.6 million that expire at various dates through 2031 and finance leases of manufacturing equipment totaling $2.6 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, or CEO, and Chief Financial Officer, or CFO, as appropriate to allow timely decisions regarding required disclosure. Pursuant to in Rules 13(a)-13(e) and 15(d)-15(e) under the Exchange Act, our management, with the participation of our CEO and CFO, performed an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation and as a result our material weaknesses previously identified and disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022, the CEO and CFO concluded that our disclosure controls and procedures were not effective at a reasonable assurance level as of March 31, 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, Director of Internal Audit 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 quarter 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 March 31, 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.

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

Item 1A. Risk Factors.

There have been no material changes from the risk factors as previously disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 other than as set forth below:

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 March 31, 2023, our common stock has experienced an intra-day trading high of $22.20 per share and an intra-day trading low of $1.63 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.

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

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date
10.1	Employment Agreement, dated February 28, 2023, by and between Aasim Javed and the Company.	8-K/A	001-40824	10.1	March 6, 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				
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101				

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Cue Health Inc.

Date: May 10, 2023

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

Date: May 10, 2023

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

Date: May 10, 2023

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

Exhibit 31.1

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

I, Ayub Khattak, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: May 10, 2023

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

Exhibit 31.2

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

I, 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: May 10, 2023

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q for the quarterly period ended March 31, 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: May 10, 2023

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

Date: May 10, 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.