Table of Contents

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, 2022

OR

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

For the transition period from _____ to_____

Commission File Number: 001-40590

Cue Health Inc.

(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

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

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

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

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

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

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

As of May 3, 2022 the registrant had 147,453,254 shares of common stock, $0.00001 par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

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

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

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

The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in the section titled "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and elsewhere in this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report on Form 10-Q. We cannot assure you that the results, events, and circumstances reflected in the forward-looking statements

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

The forward-looking statements made in this Quarterly Report on Form 10-Q relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Quarterly Report on Form 10-Q to reflect events or circumstances after the date of this report or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments we may make. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

TABLE OF CONTENTS

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Cue Health Inc.

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 426,465	$ 409,873
Restricted cash	13,838	13,837
Accounts receivable, net	75,830	104,589
Inventories	132,567	88,388
Prepaid expenses	42,902	45,889
Other current assets	9,807	7,446
Total current assets	701,409	670,022
Property and equipment, net	182,750	177,456
Prepaid rent	480	1,567
Operating lease right-of-use assets	84,212	79,474
Intangible assets, net	9,240	7,673
Other non-current assets	5,679	3,868
Total assets	$ 983,770	$ 940,060
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 48,842	$ 37,208
Accrued liabilities and other current liabilities	39,809	29,498
Income taxes payable	8,246	8,297
Deferred revenue, current	84,629	82,165
Operating lease liabilities, current	7,594	7,147
Finance lease liabilities, current	2,620	2,621
Total current liabilities	191,740	166,936
Deferred revenue, net of current portion	10,283	10,283
Operating leases liabilities, net of current portion	47,626	46,464
Finance lease liabilities, net of current portion	2,627	3,271
Other non-current liabilities	6,356	6,356
Total liabilities	258,632	233,310
Commitments and contingencies (Note 15)		
Stockholders' Equity (Deficit)		
Common stock, $0.00001 par value; 500,000,000 and 500,000,000 shares authorized, 146,958,296 and 146,402,991 issued and outstanding at March 31, 2022 and December 31, 2021, respectively	1	1
Additional paid-in-capital	746,352	730,767
Accumulated deficit	(21,215)	(24,018)
Total stockholders' equity (deficit)	725,138	706,750
Total liabilities and stockholders' equity (deficit)	$ 983,770	$ 940,060

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

Cue Health Inc.

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

	Three Months Ended March 31,	
	2022	**2021**
Revenue		
Product revenue	$ 177,454	$ 64,499
Grant and other revenue	1,956	—
Total revenue	179,410	64,499
Operating costs and expenses:		
Cost of product revenue	86,697	30,035
Sales and marketing	34,168	430
Research and development	28,787	7,409
General and administrative	26,910	11,870
Total operating costs and expenses	176,562	49,744
Income from operations	2,848	14,755
Interest expense	(51)	(535)
Other income, net	6	37
Net income before income taxes	2,803	14,257
Income tax expense	—	1,226
Net income	$ 2,803	$ 13,031
Net income per share attributable to common stockholders – basic	$ 0.02	$ 0.09
Weighted-average number of shares used in computation of net income per share attributable to common stockholders – basic	146,526,370	18,378,777
Net income per share attributable to common stockholders – diluted	$ 0.02	$ 0.08
Weighted-average number of shares used in computation of net income per share attributable to common stockholders – diluted	153,036,804	25,904,338

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

Cue Health Inc.

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2021	146,402,991	$ 1	$ 730,767	$ (24,018)	$ 706,750
Exercise of common stock options	294,231	—	270	—	270
Tax withholding on exercise of stock options and restricted stock units	—	—	(720)	—	(720)
Vesting of restricted stock units	261,074	—	—	—	—
Stock-based compensation, including employee stock purchase plan activity	—	—	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

Cue Health Inc.

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

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	8,350,743	$ 7,519	46,176,715	$66,186	28,998,607	$102,618	27,995,780	$ —	$ 9,036	$ (110,436)	$ (101,400)
Exercise of common stock options	—	—	—	—	—	—	622,749	—	32	—	32
Vesting of early exercised stock options	—	—	—	—	—	—	—	—	46	—	46
Stock-based compensation	—	—	—	—	—	—	—	—	3,021	—	3,021
Net income	—	—	—	—	—	—	—	—	—	13,031	13,031
Balance at March 31, 2021	8,350,743	$ 7,519	46,176,715	$66,186	28,998,607	$102,618	28,618,529	$ —	$ 12,135	$ (97,405)	$ (85,270)

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

Cue Health Inc.

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

	Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities		
Net income	$ 2,803	$ 13,031
Adjustments to reconcile net income to net cash, cash equivalents and restricted cash used in operations		
Depreciation and amortization	10,606	4,884
Stock-based compensation expense	16,035	3,021
Non-cash lease expense	1,996	625
Deferred income taxes	—	318
Non-cash interest expense	65	65
Changes in operating assets and liabilities:		
Accounts receivable	28,759	(9,410)
Inventory	(44,179)	(14,759)
Prepaid expenses and other current assets	1,618	(1,710)
Prepaid rent	—	983
Other non-current assets	(1,876)	(1,143)
Operating lease right-of-use assets	(4,073)	(2,024)
Accounts payable, accrued liabilities and other current liabilities	18,305	(13,082)
Income taxes payable	(51)	—
Deferred revenue	2,464	(15,989)
Operating lease liabilities	(1,002)	28
Interest on finance leases	51	49
Net cash, cash equivalents and restricted cash provided by (used in) operating activities	31,521	(35,113)
Cash flows from investing activities		
Purchase of property and equipment	(12,782)	(30,491)
Expenditures for software development	(1,273)	(1,350)
Net cash, cash equivalents and restricted cash used in investing activities	(14,055)	(31,841)
Cash flows from financing activities		
Proceeds from exercise of common stock options	270	32
Proceeds from debt	—	82,250
Tax withholding on exercise of stock options	(720)	—
Proceeds from employee stock purchase plan activity	273	—
Debt issuance and prepayment costs	—	(781)
Repayment of debt	—	(24,478)
Payments for finance leases	(696)	(382)
Net cash, cash equivalents and restricted cash (used in) provided by financing activities	(873)	56,641
Net change in cash, cash equivalents and restricted cash	16,593	(10,313)
Cash, cash equivalents and restricted cash, beginning balance	423,710	129,255
Cash, cash equivalents and restricted cash, ending balance	440,303	$ 118,942

Reconciliation of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	$ 426,465	$ 38,942
Restricted cash, current	13,838	—
Restricted cash, non-current	—	80,000
Total cash, cash equivalents and restricted cash	$ 440,303	118,942
Supplemental disclosure for cash flow information		
Cash paid for interest	$ —	$ 267
Supplemental disclosure for non-cash investing and financing matters		
Early exercised stock options liability	$ —	$ 46
Right-of-use assets obtained in exchange for lease obligations	$ 2,611	$ 18,621
Prepaid rent reclassified to right-of-use assets	$ 50	$ —
Purchase of property and equipment included in accounts payable	$ 9,235	$ 8,623
Initial public offering costs included in accounts payable	$ —	$ 547
Software development costs included in accounts payable	$ 897	$ —

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

Cue Health Inc.

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

NOTE 1. BUSINESS AND BASIS OF ACCOUNTING

Organization and Description of Business

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

Basis of Presentation

The accompanying unaudited interim condensed financial statements should be read in conjunction with the audited annual financial statements and notes thereto for the year ended December 31, 2021. The unaudited interim condensed balance sheet as of December 31, 2021 included herein was derived from the audited financial statements as of that date. The results of operations for the three months ended March 31, 2022 are not necessarily indicative of the results for the fiscal year ending December 31, 2022 or any future interim period. The Company's financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"), applicable rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for interim reporting and, in the opinion of management, include all adjustments necessary for the fair statement of the Company's financial position for the periods presented. All such adjustments are of a normal, recurring nature. Certain disclosures have been condensed or omitted from the interim condensed financial statements. The preparation of the accompanying financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, income and expenses as well as the related disclosure of contingent assets and liabilities.

Initial Public Offering

On September 28, 2021, the Company completed its initial public offering ("IPO") of 14,375,000 shares of the Company common stock at an offering price of $16.00 per share, including 1,875,000 shares purchased pursuant to the exercise in full of the underwriters' option to purchase additional shares. The Company received aggregate net proceeds of approximately $206.0 million after deducting underwriting commissions and legal, accounting, and consulting fees related to the IPO.

Upon completion of the IPO, Convertible Notes outstanding, see Note 10, *Debt*, in the principal amount of $235.5 million and accrued interest of $2.8 million were automatically converted into 18,611,914 shares of common stock. All outstanding shares of the Company's redeemable convertible preferred stock, see Note 11, *Capital Stock*, were converted into 83,605,947 shares of common stock. Immediately prior to the IPO, all of the Company's outstanding warrants to purchase redeemable convertible preferred stock were converted into the redeemable convertible preferred stock and the related warrant liabilities were reclassified to additional paid-in capital.

Use of Estimates

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

Significant estimates and assumptions made in the accompanying financial statements include, but are not limited to revenue recognition, net accounts receivable, equity-based compensation expense, product warranty reserve, the recoverability of its long-lived assets 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. All revenue to date is from customers located in the United States and all long-lived assets are located in the United States.

COVID-19 Impact

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

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

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

There have been no material changes to the Company's significant accounting policies from its Annual Report on Form 10-K for the fiscal year ended December 31, 2021, with the exception of the following:

Fair Value Measurements

At March 31, 2022, and December 31, 2021, we had $190.0 million and $0, respectively, of treasury securities that are classified within cash and cash equivalents on the balance sheet. The U.S. treasury securities are Level 1 securities that are traded by dealers or brokers in active over-the-counter markets.

Recent Accounting Pronouncements

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

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

of transition. The Company adopted this standard effective January 1, 2022, using the modified retrospective approach. The standard did not have a material impact on the financial statements for the three months ended March 31, 2022.

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

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

NOTE 3. REVENUE

Product Revenue

Disaggregation of the product revenue by type of customer for the three months ended March 31, 2022 and 2021, respectively:

	Three Months Ended March 31,	
	2022	**2021**
Public sector entities	$ 1,610	$ 62,091
Private sector customers	175,844	2,408
Total product revenue	$ 177,454	$ 64,499

Product revenue for the three months ended March 31, 2022 includes an immaterial amount of service revenue generated from telemedicine and proctoring services provided to customers. Revenue generated from proctoring is recognized over the term of the contracts with customers.

The following table sets forth the Company's product gross profit and product gross profit margin for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,	
	2022	**2021**
Product revenue	$ 177,454	$ 64,499
Cost of product revenue	86,697	30,035
Product gross profit	$ 90,757	$ 34,464
Product gross profit margin	51 %	53 %

DoD Agreement

In October 2020, the Company entered into a $480.9 million agreement with the U.S. government for the purchase of its Cue COVID-19 Test to meet the unprecedented demand for rapid and accurate molecular diagnostic testing (the

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

Refer to the Company's financial statements included in its 2021 10-K for further information on its revenue arrangements.

Contract Assets and Liabilities

Contract assets primarily relate to the Company's conditional right to consideration for performance obligations satisfied through direct-to-consumer sales but not billed at the reporting date. Net contract assets were $0.6 million and $1.1 million as of March 31, 2022 and December 31, 2021, respectively, and were recorded in other current assets on the balance sheets.

Contract liabilities primarily relate to the U.S. DoD Advance and payments received from customers in advance of performance under the contracts. Contract liabilities are recorded in current and non-current deferred revenue on the balance sheets. The activity related to contract liabilities for the three months ended March 31, 2022 is as follows:

	Amount
Balance at December 31, 2021	$ 92,448
Unearned revenue from cash received during the period, excluding amounts recognized as revenue during the period	2,464
Revenue recognized related to contract liability balance at the beginning of the period	—
Balance at March 31, 2022	$ 94,912

Grant and Other Revenue

Grant and other revenue relate to a cost reimbursement agreement with the Biomedical Advanced Research and Development Authority ("BARDA"). The Company generated $2.0 million and $0 of revenue related to the agreement with BARDA during the three months ended March 31, 2022 and 2021, respectively.

Accounts Receivable

The allowance for doubtful accounts represents the Company's estimate of probable credit losses relating to accounts receivable and is determined based on historical experience and other specific account data. Amounts are written off against the allowances for doubtful accounts when the Company determines that a customer account is uncollectible. As of March 31, 2022 and December 31, 2021, the Company's allowance for doubtful accounts was $0.5 million and $0.3 million, respectively.

NOTE 4. INVENTORIES

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

	March 31, 2022	December 31, 2021
Raw materials	$ 57,223	$ 46,273
Work-in-process	16,014	10,920
Finished goods	60,775	33,863
Reserve	(1,445)	(2,668)
Total inventories	$ 132,567	$ 88,388

The Company has revised the above information as of December 31, 2021 to correct an immaterial misclassification by increasing raw materials by $12.2 million and decreasing finished goods by the same amount. This revision only impacted the classification within inventories.

NOTE 5. PREPAID EXPENSES

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

	March 31, 2022	December 31, 2021
Prepaid expense	$ 28,635	$ 30,153
Prepaid inventory	14,267	15,736
Total prepaid expenses	$ 42,902	$ 45,889

NOTE 6. PROPERTY AND EQUIPMENT, NET

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

	March 31, 2022	December 31, 2021
Construction in progress	$ 10,515	$ 4,082
Machinery and equipment	202,493	195,001
Leasehold improvements	20,444	19,302
Furniture and fixtures	970	740
Property and equipment	234,422	219,125
Accumulated depreciation and amortization	(51,672)	(41,669)
Total property and equipment, net	$ 182,750	$ 177,456

Depreciation and amortization expense related to property and equipment was $10.0 million and $4.8 million for the three months ended March 31, 2022 and 2021, respectively. The carrying value of assets under finance leases within property and equipment as of March 31, 2022 and December 31, 2021 was $9.2 million and $9.8 million, respectively.

NOTE 7. INTANGIBLE ASSETS

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

	March 31, 2022	December 31, 2021
Capitalized software	$ 9,741	$ 5,638
Accumulated amortization	(2,671)	(2,067)
Capitalized software, net	7,070	3,571
In-process software development	2,170	4,102
Total intangible assets	$ 9,240	$ 7,673

Amortization expense related to intangible assets placed in service was $0.6 million and $0.2 million for the three months ended March 31, 2022 and 2021, respectively. Estimated amortization expense for each of the years ending December 31 is as follows:

2022 (excluding the three months ended March 31, 2022)	$ 2,064
2023	2,705
2024	1,884
2025	417
Total amortization expense	$ 7,070

NOTE 8. LEASES

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

Refer to the Company's financial statements included in its 2021 10-K for further information on its lease arrangements. There were no new material leases entered into during the three months ended March 31, 2022.

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

	Balance Sheet Location	March 31, 2022	December 31, 2021
Assets			
Right-of-use assets operating leases	*Operating lease right-of-use assets*	$ 84,212	$ 79,474
Right-of-use assets finance leases	*Property and equipment, net*	9,182	9,821
Liabilities			
Operating lease liabilities (current)	*Operating lease liabilities, current*	7,594	7,147
Finance lease liabilities (current)	*Finance lease liabilities, current*	2,620	2,621
Operating lease liabilities (non-current)	*Operating lease liabilities, net of current portion*	47,626	46,464
Finance lease liabilities (non-current)	*Finance lease liabilities, net of current portion*	2,627	3,271

The components of lease expense for the three months ended March 31, 2022 and 2021 were as follows:

	Three Months Ended March 31,	
	2022	2021
Operating lease cost	$ 2,762	$ 1,117
Finance lease cost:		
Amortization of right-of-use assets	639	335
Interest on lease liabilities	51	49
Total lease cost	$ 3,452	$ 1,501

NOTE 9. ACCRUED LIABILITIES AND OTHER CURRENT LIABILITIES

Accrued liabilities and other current liabilities consisted of the following:

	March 31, 2022	December 31, 2021
Accrued purchases (1)	$ 6,882	$ 285
Accrued payroll and benefits	12,165	13,693
Accrued expenses	8,535	6,371
Accrued sales tax	6,992	4,284
Product warranty reserve	5,235	4,865
Total accrued liabilities and other current liabilities	$ 39,809	$ 29,498

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

NOTE 10. DEBT

Revolving Credit Agreement

In February 2021, the Company entered into a loan and security agreement ("Revolving Credit Agreement") with a group of lenders with East West Bank, acting as administrative agent and collateral agent for the lenders. In connection with entering into the Revolving Credit Agreement, the Company repaid outstanding amounts of $5.4 million and terminated the prior Loan and Security Agreement with Comerica Bank ("2015 Credit Agreement") that was initially entered into in May 2015. The 2015 Credit Agreement, as amended, provided for a revolving line with a credit extension of up to $4.0 million and a Growth Capital A Line with a credit extension of up to $6.0 million. The Revolving Credit Agreement provided for a revolving credit facility with an aggregate maximum principal amount of $130.0 million and a letter of credit subfacility of $20.0 million. In connection with entering into the Revolving Credit Agreement, the Company repaid outstanding amounts of $5.4 million and terminated an existing loan agreement with Comerica Bank.

In May 2021, the Company repaid $63.2 million of debt outstanding under the Revolving Credit Agreement with a portion of the proceeds from the issuance and sale of Convertible Notes. In June 2021, the Company terminated the Revolving Credit Agreement and was required to pay a fee equal to 1.00% of the amount of the outstanding revolving commitment. The Company also wrote-off issuance costs of $0.7 million for a total loss on extinguishment of debt of $2.0 million. These amounts were recorded in loss on extinguishment of debt in the statements of operations during the year ended December 31, 2021. Upon agreement with East West Bank and the other lenders to the Revolving Credit Agreement, the Company kept in place its outstanding letter of credit in the amount of $12.0 million, which is cash collateralized. In November 2021, East West Bank issued to us an additional letter of credit in the amount of $0.5 million. All other obligations under the Revolving Credit Agreement have otherwise been terminated.

Convertible Notes

In May 2021, the Company issued and sold convertible promissory notes ("Convertible Notes") with a principal amount of $235.5 million. All of the Convertible Notes were converted upon the IPO, which was a qualified conversion event. The Convertible Notes' principal amount of $235.5 million and accrued interest of $2.8 million was converted into

18,611,914 shares of common stock at a fair value of $297.8 million using a 20% discount to the initial public offing price of $16.00 per share. The Company no longer had outstanding Convertible Notes as of December 31, 2021.

NOTE 11. CAPITAL STOCK

Amended and Restated Certificate of Incorporation

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

Common Stock Warrants

As of March 31, 2022, the Company had an outstanding warrant to purchase 75,744 shares of common stock at a purchase price of $0.40 per share. The warrant was issued on August 22, 2017 and expires on August 22, 2027. All shares subject to the warrant were vested as of December 31, 2021.

NOTE 12. STOCK-BASED COMPENSATION

Stock Incentive Plans

2014 Equity Incentive Plan

In August 2014, the Company adopted the 2014 Equity Incentive Plan ("2014 Plan") under which employees, non-employee directors and consultants of the Company may be granted incentive stock options, nonqualified stock options, stock appreciation rights, performance shares, awards of restricted stock and awards of restricted stock units.

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

2021 Stock Incentive Plan

In September 2021, the Company adopted the 2021 Stock Incentive Plan ("2021 Plan") under which employees, officers and directors, as well as consultants and advisors to the Company are eligible to be granted awards (incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards). The 2021 Plan initially authorized the issuance of a maximum of 22,399,691 shares of common stock. The number of shares of common stock available for issuance under the 2021 Plan were and will be increased on the first day of each fiscal year beginning with the 2022 fiscal year, in an amount equal to the least of (i) 5% of the number of shares of the Company's common stock outstanding on the first day of such fiscal year and (ii) the number of shares of the Company's common stock determined by the Company's board of directors. As of March 31, 2022, 8,755,861 shares of common stock were available for issuance under the 2021 Plan.

2021 Employee Stock Purchase Plan

In September 2021, the Company adopted the 2021 Employee Stock Purchase Plan ("2021 ESPP") under which employees of the Company can purchase shares of the Company's common stock commencing on such time and such dates as the board of directors of the Company determine. The 2021 ESPP initially allowed for the sale of 2,834,754 shares of common stock. The number of shares of the Company's common stock to be sold under the 2021 ESPP were and will be increased on the first day of each fiscal year beginning with the 2022 fiscal year, in an amount equal to the least of (i) 8,504,263 shares, (ii) 1% of the number of shares of the Company's common stock outstanding on the first day of such fiscal year and (ii) a number of shares of the Company's common stock determined by the Company's board of directors. As of March 31, 2022, 4,298,784 shares of common stock were available for sale under the 2021 ESPP. 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, 2022 and 2021, was as follows:

	Three Months Ended March 31,	
	2022	2021
Cost of product revenues	$ 518	$ 854
Sales and marketing	2,813	15
Research and development	5,145	396
General and administrative	7,559	1,756
Total stock-based compensation expense	$ 16,035	$ 3,021

In total, $0.5 million and $0.9 million of stock-based compensation expense was capitalized to inventory during the manufacturing process during the three months ended March 31, 2022 and 2021, respectively. An immaterial amount remained in inventory as of March 31, 2022.

Stock Options

A summary of stock option activity and related information for the three months ended March 31, 2022 was as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at January 1, 2022	9,163,160	$ 5.13	6.40
Granted	—	—	
Exercised	(294,856)	0.38	
Forfeited	(74,964)	11.77	
Expired	(14,833)	15.61	
Outstanding at March 31, 2022	8,778,507	$ 5.22	6.50
Exercisable at March 31, 2022	6,151,757	$ 2.89	5.70
Vested and expected to vest at March 31, 2022	8,778,507	$ 5.22	6.50

There were no stock options granted during the three months ended March 31, 2022.

As of March 31, 2022, there was approximately $12.3 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.

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, 2022 was as follows:

	Underlying Shares	Weighted-average Grant Date Fair Value	Aggregate Fair Value
Outstanding, January 1, 2022	11,264,235	$ 14.62	$ 164,683
Granted	5,003,537	8.10	40,529
Vested	(930,493)	15.93	(14,823)
Forfeited	(5,204)	13.98	(73)
Outstanding, March 31, 2022	15,332,075	$ 12.41	$ 190,316

As of March 31, 2022, there was approximately $171.5 million of total unrecognized compensation cost related to outstanding RSUs.

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, 2022 was as follows:

	Underlying Shares	Weighted-average Grant Date Fair Value	Aggregate Fair Value
Outstanding, January 1, 2022	$ 3,335,300	$ 12.82	$ 42,759
Granted	—	—	—
Vested	—	—	—
Forfeited	—	—	—
Outstanding, March 31, 2022	$ 3,335,300	$ 12.82	42,759

Operational-Based Performance-Vesting RSUs

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

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

Operations-based performance-vesting RSU activity for the three months ended March 31, 2022 was as follows:

	Underlying Shares	Weighted-average Grant Date Fair Value	Aggregate Fair Value
Outstanding, January 1, 2021	1,597,272	$ 16.00	$ 25,556
Granted	—	—	—
Vested	(532,424)	16.00	(8,519)
Forfeited	—	—	—
Outstanding, March 31, 2022	1,064,848	$ 16.00	$ 17,037

NOTE 13. INCOME (LOSS) PER SHARE

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

Basic and diluted net income (loss) attributable to common holders per share is presented in conformity with the two- class method required for participating securities as the redeemable convertible preferred stock, common stock subject to restricted stock purchase agreements, early exercised options, and restricted shares are considered participating

securities. Under the two-class method, distributed and undistributed income allocated to participating securities are excluded from net income (loss) attributable to common stockholders for purposes of calculating basic and diluted income (loss) per share.

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

	Three Months Ended March 31,	
	2022	2021
Numerator:		
Net income (loss)	$ 2,803	$ 13,031
Minus: Income allocated to participating securities	—	11,366
Net income (loss) attributable to common stockholders – basic	$ 2,803	$ 1,665
Plus: Income allocated to non-participating securities	—	525
Net income (loss) attributable to common stockholders - diluted	$ 2,803	$ 2,190
Denominator:		
Basic weighted-average common shares outstanding	146,526,370	18,378,777
Dilutive potential common stock issuable:		
Common stock warrants	72,395	73,804
Preferred stock warrants	—	74,149
Stock options	5,813,101	7,377,608
Restricted stock units	624,938	—
Diluted weighted-average shares outstanding	153,036,804	25,904,338
Net income (loss) attributable to common stockholders per share		
Basic	$ 0.02	$ 0.09
Diluted	$ 0.02	$ 0.08

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,	
	2022	2021
Stock options	2,701,855	2,926,821
Restricted stock units	9,634,182	—
Employee stock purchase plan – shares projected to be issued	110,935	—
Total	12,446,972	2,926,821

NOTE 14. INCOME TAXES

The Company's effective income tax rate was 0% and 8.6% for the three months ended March 31, 2022 and 2021, respectively. The effective tax rate for the three months ended March 31, 2022 and 2021 differed from the statutory tax rate primarily due to the Company maintaining a full valuation allowance against its net deferred tax assets.

Refer to the Company's financial statements included in its 2021 10-K for further information on income taxes.

NOTE 15. COMMITMENTS AND CONTINGENCIES

Product Liability

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

Product Warranty Reserve

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

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

	Amount	
Balance, December 31, 2021	$	4,865
Provision for warranties		1,211
Settlements		(841)
Balance, March 31, 2022	$	5,235

Standby Letters of Credit

As of December 31, 2020, the Company was party to certain letters of credit, primarily related to a letter of credit with Comerica Bank as collateral required by one of the Company's vendors. During the year ended December 31, 2021, the Company entered into a Revolving Credit Agreement with a capacity of $130.0 million and all but one of the letters of credits were no longer required by the counterparties. The one letter of credit, totaling $6.0 million, was re-issued under the Revolving Credit Agreement.

In May 2021, the Company repaid the debt outstanding under the Revolving Credit Agreement and terminated the agreement in June 2021. Upon agreement with East West Bank and the other lenders to the Revolving Credit Agreement, the Company kept in place its outstanding letter of credit in the amount of $6.0 million. The letter of credit was increased to $12.0 million in July 2021. In November 2021, East West Bank issued an additional letter of credit in the amount of $0.5 million. All other obligations under the Revolving Credit Agreement have otherwise been terminated. In November 2021, $0.8 million of cash was restricted in relation to a customs surety on international imports. The Company also has outstanding letters of credit with Comerica Bank related to its real estate leases totaling $0.5 million as of March 31, 2022. All letters of credit are cash collateralized.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and the related notes and the discussion under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" for the fiscal year ended December 31, 2021 included in our Annual Report on Form 10-K. This discussion, particularly information with respect to our future results of operations or financial condition, business strategy and plans and objectives of management for future operations, includes forward-looking statements that involve risks and uncertainties as described under the heading "Forward-Looking Statements" in this Quarterly Report on Form 10-Q for a discussion of important factors that could cause our actual results to differ materially from those anticipated in these forward-looking statements.

Overview

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

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

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

Initial Public Offering

The Company's registration statement related to its initial public offering ("IPO") was declared effective on September 23, 2021, and the Company's common stock began trading on the Nasdaq Global Stock Market ("Nasdaq") on September 24, 2021. On September 28, 2021, the Company completed its IPO of 14,375,000 shares of the Company common stock at an offering price of $16.00 per share, including 1,875,000 shares purchased pursuant to the exercise in full of the underwriters' option to purchase additional shares. The Company received aggregate net proceeds of approximately $206.0 million after deducting underwriting commissions and legal, accounting, and consulting fees related to the IPO.

Upon completion of the IPO, Convertible Notes outstanding in the principal amount of $235.5 million and accrued interest of $2.8 million were automatically converted into 18,611,914 shares of common stock. All outstanding shares of the Company's redeemable convertible preferred stock were converted into 83,605,947 shares of common stock. Immediately prior to the IPO, all of the Company's outstanding warrants to purchase redeemable convertible preferred stock were converted into the redeemable convertible preferred stock and the related warrant liabilities were reclassified to additional paid-in capital.

COVID-19 Impact

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

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

Certain Key Factors Affecting Our Performance

Manufacturing Capacity

We manufacture all of our Cue Cartridges in our vertically integrated facilities in San Diego, California. We also produce all of our biochemistry in-house, including critical enzymes, antibodies and primers for our Cue Cartridges. Production of our Cue Readers is performed for us by third-party contract manufacturers and production of our Cue Wands is performed by both us and 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.

Investments in Our Growth

We expect to make continued significant investments in our business to drive growth, and therefore we expect our expenses to increase going forward. We expect to invest significant resources in sales and marketing to drive demand for our products and services as well as research and development to enhance our platform and bring additional tests to market. We also intend to continue investing in our supply chain and logistics operations. As we continue to scale our business, we expect to hire additional personnel and incur additional expenses, including those expenses in connection with our becoming a public company.

Expanding Our Customer Base

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, and Henry Schein, Inc. We intend to leverage our success with our COVID-19 test and the expansion of our manufacturing capabilities to enable broad distribution of our Cue Readers and awareness of our platform across different groups of customers and to enhance pull-through of our future tests.

Enhancing and Expanding Our Menu of Tests and Software Capabilities

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

Regulatory Clearance of Our Diagnostic Products

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

Reimbursement and Insurance Coverage

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

Seasonality

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

First Quarter 2022 Summary (on a comparative basis)

Key GAAP financial results for the three months ended March 31, 2022 were as follows as compared to the three months ended March 31, 2021:

- Revenue was $179.4 million compared to $64.5 million;
- Product gross margin was 51% compared to 53%;
- Net income was $2.8 million compared to $13.0 million and;
- Earnings per diluted share was $0.02 compared to $0.08

Results of Operations

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

	Three Months Ended March 31,	
	2022	2021
(dollars in thousands)	(unaudited)	
Revenue:		
Product revenue	$ 177,454	$ 64,499
Grant and other revenue	1,956	—
Total revenue	179,410	64,499
Operating costs and expenses:		
Cost of product revenue[(1)]	86,697	30,035
Sales and marketing	34,168	430
Research and development	28,787	7,409
General and administrative	26,910	11,870
Total operating costs and expenses	176,562	49,744
Income from operations	2,848	14,755
Interest expense	(51)	(535)
Other income, net	6	37
Net income before income taxes	2,803	14,257
Income tax expense	—	1,226
Net income	$ 2,803	$ 13,031
Net income per share attributable to common stockholders – diluted	$ 0.02	$ 0.08

(1) Includes $9.6 million and $4.1 million of depreciation and amortization expense for the three months ended March 31, 2022 and 2021, respectively.

Comparison of the Three months ended March 31, 2022 and 2021

The following table sets forth a summary of our results of operations for the three months ended March 31, 2022 and 2021 and the changes between periods:

	Three Months Ended March 31,			
	2022	**2021**	**$ Change**	**% Change**
(dollars in thousands)		**(unaudited)**		
Revenue:				
Product revenue	$ 177,454	$ 64,499	$ 112,955	175%
Grant and other revenue	1,956	—	1,956	n.m
Total revenue	179,410	64,499	114,911	178%
Operating costs and expenses:				
Cost of product revenue	86,697	30,035	56,662	189%
Sales and marketing	34,168	430	33,738	7,846%
Research and development	28,787	7,409	21,378	289%
General and administrative	26,910	11,870	15,040	127%
Total operating costs and expenses	176,562	49,744	126,818	255%
Income from operations	2,848	14,755	(11,907)	(81%)
Interest expense	(51)	(535)	484	(90%)
Other income, net	6	37	(31)	(84%)
Net income before income taxes	2,803	14,257	(11,454)	(80)%
Income tax expense	—	1,226	(1,226)	n.m.
Net income	$ 2,803	$ 13,031	$ (10,228)	(78)%
Net income per share attributable to common stockholders – diluted	$ 0.02	$ 0.08	$ —	(78)%

n.m. = not meaningful

Revenue increased to $179.4 million in the three months ended March 31, 2022, from $64.5 million in the three months ended March 31, 2021. The increase was primarily due to the continued expansion of our customer base and increases in production capacity. Revenue during the three months ended March 31, 2022 was primarily driven by product sales to private sector customers of $175.8 million along with product sales to public sector clients of $1.6 million.

Cost of Product Revenue increased to $86.7 million in the three months ended March 31, 2022, from $30.0 million in the three months ended March 31, 2021. This increase was primarily due to a substantial increase in the sales of our products. Our product gross profit margin, or product gross profit as a percentage of product revenue was approximately 51% in the three months ended March 31, 2022 compared to approximately 53%, in the three months ended March 31, 2021. This decrease was primarily related to supply chain constraints and associated higher component, transport costs as well as customer mix.

Sales and Marketing Expense increased to $34.2 million in the three months ended March 31, 2022, from $0.4 million in the three months ended March 31, 2021. This increase related to increased sales and marketing personnel costs to support a broadening of our customer base, planned additions to our product offering and higher expenses related to our overall marketing and brand expansion efforts.

Research and Development Expense increased to $28.8 million in the three months ended March 31, 2022, from $7.4 million in the three months ended March 31, 2021. This increase was primarily driven by additional headcount, materials and other resource utilization associated with the expansion of our platform, including new test development and overall enhancement of our software platform for products under development, as well as costs related to clinical studies for 510(k) approval of our COVID-19 and influenza tests.

General and Administrative Expense increased to $26.9 million in the three months ended March 31, 2022 from $11.9 million in the three months ended March 31, 2021. This increase was primarily related to an increase in stock-based

compensation expenses, headcount growth to support our overall expansion as well as accounting and other consulting-related costs to support our operations as a public company.

Interest Expense decreased to $0.1 million in the three months ended March 31, 2022 from $0.5 million in the three months ended March 31, 2021. This decrease was primarily driven by debt repayment activity in the prior year. Our interest expense prior to February 2021 primarily consisted of expense related to our prior loan and security agreement with Comerica Bank. In February 2021, we entered into the Revolving Credit Agreement. In connection with the Revolving Credit Agreement, we repaid outstanding amounts of $5.4 million and terminated the 2015 Credit Agreement we initially entered into in May 2015. In May 2021, we repaid the outstanding balance under the Revolving Credit Agreement. In June 2021, we terminated the Revolving Credit Agreement.

Income Tax Expense was $0 in the three months ended March 31, 2022 compared to $1.2 million in the three months ended March 31, 2021, and our effective tax rate was 0% in the three months ended March 31, 2022, compared to 8.6% in the three months ended March 31, 2021. The fluctuation in our provision and effective tax rate was primarily due to the Company maintaining a full valuation allowance against its net deferred tax assets. The tax expense recorded for the three months ended March 31, 2021 was related to deferred tax liabilities arising from accelerated depreciation deductions for federal tax purposes and current state income taxes in jurisdictions for which the Company did not have available tax attributes.

Liquidity and Capital Resources

Overview

As of March 31, 2022, we held $426.5 million of cash and cash equivalents as a result of our IPO proceeds and other financing activities. Our primary cash needs are for the funding of day-to-day operations, financing capital investments and to address our working capital needs. Our largest source of operating cash generation is from sales to our customers. Our primary uses of cash from operating activities are for personnel-related expenses, material and supply costs for manufacturing, direct costs to deliver our products, and sales and marketing expenses and research and development initiatives.

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

We expect that our near and longer-term liquidity requirements will consist of working capital and general corporate expenses associated with the growth of our business, including, without limitation, expenses associated with scaling up our operations and continuing to increase our manufacturing capacity, sales and marketing expense associated with rollout of our over-the-counter, at home COVID-19 test to commercial customers, including directly to consumers, increasing market awareness of our platform and brand generally to individual consumers, enterprises and other target customers, additional research and development expenses associated with expanding our care offerings, expenses associated with continuing to build out our corporate infrastructure and expenses associated with being a public company. Our short-term capital expenditure needs relate primarily to the expansion of our research and development capabilities, expanding production capacity and optimization of existing business processes.

Cash Flows

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

	Three Months Ended March 31,	
	2022	2021
(dollars in thousands)	(unaudited)	
Net cash, cash equivalents and restricted provided by (used in) operating activities	$ 31,521	$ (35,113)
Net cash, cash equivalents and restricted cash used in investing activities	(14,055)	(31,841)
Net cash, cash equivalents and restricted cash (used in) provided by financing activities	(873)	56,641
Net change in cash, cash equivalents and restricted cash	$ 16,593	$ (10,313)

Cash Flows from Operating Activities

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.

Net cash, cash equivalents and restricted cash used in operating activities was $35.1 million in the three months ended March 31, 2021, primarily reflecting our net income of $13.0 million offset by increases in inventory and accounts receivable of $14.8 million and $9.4 million, respectively. In addition, there were decreases in accounts payable and deferred revenue of $14.8 million and $16.0 million, respectively. These fluctuations were due to the expansion of production facilities and increases in product revenue.

Cash Flows from Investing Activities

Net cash, cash equivalents and restricted cash used in investing activities was $14.1 million for the three months ended March 31, 2022, reflecting purchases of property and equipment of $12.8 million to expand our R&D 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.

Net cash, cash equivalents and restricted cash used in investing activities was $31.8 million in the three months ended March 31, 2021, primary reflecting purchases of property and equipment of $30.5 million to expand our production capabilities of our COVID-19 Test Kits in relation to the U.S. DoD Agreement.

Cash Flows from Financing Activities

Net cash used in financing activities for the three months ended March 31, 2022 of $0.9 million was 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.

Net cash, cash equivalents and restricted cash provided by financing activities was $56.6 million for the three months ended March 31, 2021, primarily reflecting proceeds received from the Revolving Credit Agreement in February 2021 partially offset by repayment of the borrowings under the 2015 Credit Agreement.

Commitments and Contingencies

See Note 15, *Commitments and Contingencies*, to our unaudited interim condensed financial statements included elsewhere in this quarterly report for a summary of our commitments as of March 31, 2022. Our material cash commitments at March 31, 2022 related to finance leases of manufacturing equipment totaling $6.5 million, real estate leases under non-cancelable operating lease agreements in the amount of $69.9 million, that expire at various dates through 2031 and a legal settlement of a contract dispute totaling $9.0 million, of which $4.5 million has not been paid. We expect to fund these commitments using our existing cash on hand.

As of March 31, 2022, we had outstanding letters of credit totaling $12.5 million with East West Bank. We also had outstanding letters of credit with Comerica Bank related to our real estate leases totaling $0.5 million. All letters of credit are cash collateralized and reflected on the balance sheet as restricted cash. In November 2021, $0.8 million of cash was restricted in relation to a customs surety on international imports

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

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

material changes to the Company's critical accounting policies and estimates from its Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Recently Adopted and Issued Accounting Pronouncements

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

Emerging Growth Company Status

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. To date, we have not been exposed to material risks related to market instruments in the ordinary course of our business, but we may in the future.

Item 4. Controls and Procedures

Evaluation of Disclosure and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. In addition, they are designed to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, as appropriate to allow timely decisions regarding required disclosure. Pursuant to in Rules 13(a)-13(e) and 15(d)-15(e) under the Exchange Act, our management, with the participation of our CEO and CFO, performed an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation and as a result our material weaknesses previously identified and disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021, the CEO and CFO concluded that our disclosure controls and procedures were not effective at a reasonable assurance level as of March 31, 2022.

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

Previously Reported Material Weaknesses

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

As disclosed in Item 9A. "Controls and Procedures" of our Form 10-K for the year ended December 31, 2021, we continue to have material weaknesses in internal controls over financial reporting related to i) information technology general controls, ii) a lack of segregation of duties, iii) documentation and design of formalized processes and procedures, iv) experience and training important to our financial reporting requirements; and v) the review of journal entries. These material weaknesses could result in material misstatements of our financial statement account balances or disclosures of our annual or interim financial statements that would not be prevented or detected.

Remediation Plan

As previously described in Part II, Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2021, we began to take steps to address our material weaknesses through our remediation plan, which included the hiring of advisors in the fourth quarter of 2020 and a Chief Financial Officer in the first quarter of 2021, the hiring of a Vice President and Treasurer in the second quarter of 2021, the hiring of an Interim Controller, an Assistant Controller and a Director of Tax in the fourth quarter of 2021. During the first quarter of 2022, we recruited a Chief Accounting Officer and a Vice President of Internal Audit who joined the Company in the second quarter of 2022. We have dedicated resources to capturing and documenting current state processes while identifying opportunities for process improvement. In addition, we continue to engage external advisors to evaluate and document the design and operating effectiveness of our internal controls and assist with the remediation and implementation of our internal controls as required. We have evaluated the longer-term resource needs of our various financial functions and plan to significantly expand the size of the financial organization to help address these material weaknesses, while utilizing external advisor in the short term to bridge this gap. The weaknesses will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

We and our independent registered public accounting firm were not required to, and did not, perform an evaluation of our internal controls over financial reporting as of December 31, 2021 or any prior period in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses. Material weaknesses may still exist when we report on the effectiveness of our internal controls over financial reporting as required under Section 404 of the Sarbanes-Oxley Act.

Changes in Internal Control over Financial Reporting

Except for the remediation measures in connection with the material weaknesses described above, there were no other changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

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

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

Item 1A. Risk Factors.

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

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

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

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

From January 1, 2020 to December 31, 2021, the number of our employees increased from 99 to 1,585 as we have been rapidly scaling up our manufacturing and corporate infrastructure during this time. We anticipate continued growth in our business operations. Our recent rapid growth has, and our continued growth is expected to, place significant strain across our organizational, administrative, and operational infrastructure. Our ability to manage our growth properly will require us to implement additional operational, financial, and managerial controls, as well as our reporting systems and procedures, and to continuously improve these controls, systems and procedures.

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

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

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

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

We were a private company from our inception until the closing of our IPO on September 28, 2021, and, as such, we previously had not had the internal control and financial reporting requirements that are required of a publicly-traded company. We are required to comply with the requirements of The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, following the date we are deemed to be an "accelerated filer" or a "large accelerated filer," each as defined in the Exchange Act, which could be as early as our next fiscal year. As a result of becoming a public company, we are required, under Section 404 of the Sarbanes-Oxley Act to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with our Annual Report on Form 10-K for the year ended December 31, 2022. This assessment will need to include disclosure of any material weaknesses identified in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis.

As disclosed in Item 9A. "Controls and Procedures" of our Form 10-K for the year ended December 31, 2021, we continue to have material weaknesses in internal controls over financial reporting related to i) information technology general controls, ii) a lack of segregation of duties, iii) documentation and design of formalized processes and procedures, iv) experience and training important to our financial reporting requirements; and v) the review of journal entries. These material weaknesses could result in material misstatements of our financial statement account balances or disclosures of our annual or interim financial statements that would not be prevented or detected.

As previously described in Part II, Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2021, we began to take steps to address our material weaknesses through our remediation plan, which included the hiring of advisors in the fourth quarter of 2020 and a Chief Financial Officer in the first quarter of 2021, the hiring of a Vice President and Treasurer in the second quarter of 2021, the hiring of an Interim Controller, an Assistant Controller and a Director of Tax in the fourth quarter of 2021. During the first quarter of 2022, we recruited a Chief Accounting Officer and a Vice President of Internal Audit who joined the Company in the second quarter of 2022. We have dedicated resources to capturing and documenting current state processes while identifying opportunities for process improvement. In addition, we continue to engage external advisors to evaluate and document the design and operating effectiveness of our internal controls and assist with the remediation and implementation of our internal controls as required. We have evaluated the longer-term resource needs of our various financial functions and plan to significantly expand the size of the financial organization to help address these material weaknesses, while utilizing external advisor in the short term to bridge this gap. The weaknesses will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

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

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

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

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

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

Furthermore, in the last twelve months we have experienced significant growth and have hired a large number of employees to support such growth. Rapid expansion in personnel could mean that less experienced people are performing important functions within our company, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. If our new hires perform poorly, if we are unsuccessful in hiring, training, managing and integrating these new employees or if we are not successful in retaining our existing employees, we may not be able to maintain the quality of our products or satisfy customer demand and our business may otherwise be materially harmed.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds

On September 28, 2021, we completed our IPO, in which we sold 14,375,000 shares of our common stock at an offering price of $16.00 per share, including 1,875,000 shares pursuant to the exercise in full of the underwriters' option to purchase additional shares. We received net proceeds of $206.0 million after deducting underwriting commissions and legal, accounting, and consulting fees related to the IPO. All of the shares of common stock issued and sold in our IPO were registered under the Securities Act of 1933, as amended pursuant to a registration statement on Form S-1 (File No. 333259250), which was declared effective by the SEC on September 23, 2021. The representatives of the underwriters of our IPO were Goldman Sachs & Co. LLC, Morgan Stanley & Co. LLC and Cowen and Company, LLC.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates. As of March 31, 2022, we have paid approximately $24.0 million of expenses incurred in connection with our IPO and no further expenses in connection with our IPO are expected.

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

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date
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 11, 2022

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

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

Exhibit 31.1

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

I, Ayub Khattak, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 11, 2022

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

Exhibit 31.2

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

I, John Gallagher, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 11, 2022

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2022 of Cue Health Inc. (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned hereby certifies in his capacity as the specified officer of the Company, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

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

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

Date: May 11, 2022

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

Date: May 11, 2022

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

This certification accompanies the Quarterly Report on Form 10-Q to which it relates and shall not be deemed filed with the Securities and Exchange Commission or incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.