

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): **May 11, 2022**

CUE HEALTH INC.

(Exact name of Registrant, as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-40590

(Commission File Number)

27-1562193

(I.R.S. Employer Identification Number)

Mailing address:

4980 Carroll Canyon Rd.

Suite 100

San Diego, CA 92121

(Address of principal executive
offices)

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

Former name or address, if changed since last report: **Not Applicable.**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

Item 2.02 Results of Operations and Financial Condition.

On May 11, 2022, Cue Health Inc. ("Cue Health" or the "Company"), issued a press release announcing the Company's financial results for the first quarter ended March 31, 2022. A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated by reference herein.

The information contained this Current Report on Form 8-K and in the accompanying exhibit are "furnished" and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

[99.1](#) Press Release issued by Cue Health dated May 11, 2022.

104 Cover Page Interactive Data File (embedded within the Inline XBRL Document).

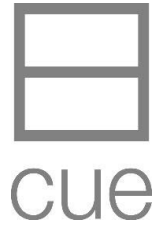
SIGNATURES

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 hereunto duly authorized.

Date: May 11, 2022

Cue Health Inc.

By: /s/ John Gallagher
Name: John Gallagher
Title: Chief Financial Officer



Cue Health Reports First Quarter 2022 Results

SAN DIEGO, CA – May 11, 2022 – [Cue Health Inc.](#) (Nasdaq: HLTH), a healthcare technology company, (“Cue”) today reported financial results for the first quarter of 2022.

Recent Highlights

- Revenue of \$179.4 million in the first quarter of 2022, compared to \$64.5 million in the first quarter of 2021
- 235,000+ Cue Readers shipped through the end of the first quarter of 2022, including 72,000+ in the quarter
- Cue Covid-19 Test *de novo* submission to the U.S. Food and Drug Administration (FDA) for full clearance for at-home and point-of-care use
- Flu clinical studies nearing completion, with full submission to the FDA expected in the third quarter of 2022
- Flu + COVID multiplex starting clinical studies this quarter, ahead of schedule
- RSV expected to begin clinical studies in the third quarter of 2022 and Chlamydia + Gonorrhea multiplex in the second half of 2022, as planned
- Generated cash of \$16.6 million in the first quarter 2022, ending with cash and cash equivalents of \$426.5 million

“I am pleased with our first quarter 2022 financial results, including \$179 million in revenue, which reflects year-over-year growth of 178%. We made excellent progress on our menu expansion activities, with all of our programs on track or ahead of schedule,” said Ayub Khattak, Co-Founder, Chairman and Chief Executive Officer of Cue Health. “Our recent COVID-19 test *de novo* submission to the FDA marked a major milestone for the company and we believe it will be the first of many submissions as we seek to address a range of diseases and conditions with our menu of molecular diagnostic tests and future care offerings.”

First Quarter 2022 Financial Results

Revenue was \$179.4 million in the first quarter 2022, an increase from \$64.5 million in the first quarter 2021. The growth was primarily driven by the continued expansion of our customer base and increases in production capacity.

Private Sector revenue grew to 98.0%, or \$175.8 million, in the first quarter 2022.

Public Sector revenue was 2.0%, or \$3.6 million, in the first quarter 2022, as we completed shipment of our contract with the U.S. Department of Defense in the fourth quarter 2021.

Disposable test cartridge revenue was \$163.2 million in the first quarter 2022.

Product gross margin was 51.1% in the first quarter 2022, compared to 53.4% in the first quarter 2021.

Operating expenses in the first quarter 2022 were \$89.9 million, excluding cost of revenues, compared to \$19.7 million in the first quarter 2021. The increase was driven by growth in our overall organization, digital marketing spend, and spend related to product development.

Net income was \$2.8 million in the first quarter 2022, compared to \$13.0 million in the first quarter 2021. Earnings per diluted share was \$0.02 in the first quarter 2022, compared to \$0.08 in the first quarter 2021.

Cash and cash equivalents were \$426.5 million as of March 31, 2022.

Guidance

Cue Health expects second quarter 2022 revenues in the range of \$50 million to \$55 million.

About Cue Health

Cue Health (Nasdaq: HLTH) is a healthcare technology company that makes it easy for individuals to access health information and places diagnostic information at the center of care. Cue Health enables people to manage their health through real-time, actionable, and connected health information, offering individuals and their healthcare providers easy access to lab-quality diagnostics anywhere, anytime, in a device that fits in the palm of the hand. Cue Health's first-of-its-kind COVID-19 test was the first FDA-authorized molecular diagnostic test for at-home and over-the-counter use without a prescription and physician supervision. Outside the United States, Cue Health has received the CE mark in the European Union, Interim Order authorization from Health Canada, regulatory approval from India's Central Drugs Standard Control Organisation, and PSAR authorization from Singapore's Health Sciences Authority. Cue Health was founded in 2010 and is headquartered in San Diego. For more information, please visit www.cuehealth.com.

Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, including statements related to the submission of any FDA applications and expectations around receiving clearance, growth in our customer base, expectations regarding production capacity, potential technology enhancements and future performance and our guidance, including first quarter 2022 guidance, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements". The words, without limitation, "continue," "estimate," "expect," "intend," "may," "plan," "potential," "would," "develop," "pave," "seek," "offer," "grow", "expand" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these or similar identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including those related to the expected capabilities of the new Omicron-specific genotyping Cue test, our ability to maintain customer growth rates, our ability to increase private sector revenue, our ability maintain or replace the revenue historically generated from our government contracts, our ability to effectively scale our manufacturing capacity to meet contractual obligations with our customers and market demand, and the factors discussed in the "Risk Factors" section of Cue's

Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 to be filed with the SEC. Any forward-looking statements contained in this press release are based on the current expectations of Cue's management team and speak only as of the date hereof, and Cue specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

This product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization, or EUA. This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Contact Us

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CONDENSED STATEMENTS OF OPERATIONS
(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 (loss) from operations	2,848	14,755
Interest expense	(51)	(535)
Other income (expense), net	6	37
Net income (loss) before income taxes	2,803	14,257
Income tax expense (benefit)	—	1,226
Net income (loss)	\$ 2,803	\$ 13,031
Net income (loss) per share attributable to common stockholders – basic	\$ 0.02	\$ 0.09
Weighted-average number of shares used in computation of net income (loss) per share attributable to common stockholders – basic	146,526,370	18,378,777
Net income (loss) per share attributable to common stockholders – diluted	\$ 0.02	\$ 0.08
Weighted-average number of shares used in computation of net income (loss) per share attributable to common stockholders – diluted	153,036,804	25,904,338

CONDENSED BALANCE SHEETS
(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	75,830	104,589
Inventory	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, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
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 16)		

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)	<u>725,138</u>	<u>706,750</u>
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 983,770</u>	<u>\$ 940,060</u>