

**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): **August 10, 2022**

CUE HEALTH INC.

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

Delaware

001-40590

27-1562193

(State or other jurisdiction of incorporation)

(Commission File Number)

(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 August 10, 2022, Cue Health Inc. ("Cue Health" or the "Company"), issued a press release announcing the Company's financial results for the second quarter ended June 30, 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 August 10, 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: August 10, 2022

Cue Health Inc.

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



Cue Health Reports Second Quarter 2022 Results

SAN DIEGO, CA – August 10, 2022 – Cue Health Inc. ("Cue") (Nasdaq: HLTH), a healthcare technology company, today reported financial results for the second quarter of 2022.

Recent Highlights

- Revenue of \$87.7 million in the second quarter of 2022 exceeds guidance with stronger than anticipated ordering from existing customers
- 250,000+ Cue Readers shipped through the end of the second quarter of 2022
- Flu standalone clinical studies completed and preparations are underway for a *de novo* submission to the U.S. Food and Drug Administration (FDA) for at-home and point-of-care use
- Flu + COVID multiplex clinical studies started in the second quarter of 2022 and on track for submission for U.S. FDA emergency use authorization (EUA) in the third quarter of 2022
- RSV scheduled to begin clinical studies in the third quarter of 2022
- Chlamydia + Gonorrhea multiplex clinical studies expected to begin in the second half of 2022
- Began phased rollout of Cue Care™, closing the home-based virtual care loop from diagnostics, to telehealth, to medication delivery service
- Ended the quarter with cash and cash equivalents of \$363.1 million and further increased financial flexibility by entering a \$100 million secured revolving credit facility

"We achieved stronger-than expected revenue performance in the quarter and continued to deliver on our pipeline programs," said Ayub Khattak, Chairman and CEO of Cue Health. "We are very excited about our upcoming full launch of Cue Care, closing the virtual health care loop by allowing customers to conduct a molecular diagnostic test, consult a medical professional, and get treatment delivered, all within the Cue Health platform. With the addition of e-prescription fulfillment and delivery to our product offerings, Cue has taken another important step forward on our mission to enable personalized, proactive and informed healthcare that empower people to live their healthiest lives."

Second Quarter 2022 Financial Results

Revenue in the second quarter of 2022 was \$87.7 million which exceeded our guidance due to stronger than anticipated COVID-19 testing orders from existing customers.

Private sector revenue was \$80.5 million, or 91.8% of total revenue, an increase of \$48.1 million over last year. Public sector revenue was 8.2% of total revenue or \$7.2 million. Disposable test cartridge revenue was \$82.9 million in the second quarter of 2022.

GAAP product gross profit margin was a loss of 20.8% in the second quarter of 2022. Adjusted product gross profit margin was 30.0% after excluding one-time inventory charges of \$42.8 million.

Operating expenses in the second quarter of 2022 were \$88.3 million, excluding cost of revenues, driven by product development, software technology, and menu expansion investments. In the quarter, there was a one-time restructuring charge of \$1.9 million related to manufacturing workforce reduction.

GAAP net income in the second quarter of 2022 was a loss of \$99.1 million and earnings per diluted share was a loss of \$0.67. Cue's Adjusted net income was a loss of \$55.2 million and earnings per diluted share was a loss of \$0.37. Adjusted EBITDA was a loss of \$29.9 million.

Cash and cash equivalents were \$363.1 million as of June 30, 2022.

Guidance

Cue Health expects third quarter 2022 revenues in the range of \$55 to \$60 million, excluding any adjustment to deferred revenue held on the balance sheet.

About Cue Health

Cue 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 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'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 has received the CE mark in the European Union, Interim Order authorization from Health Canada, regulatory approval from India's Central Drugs Standard Control Organization, and PSAR authorization from Singapore's Health Sciences Authority. Cue 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 third 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 flu standalone, flu + Covid multiplex, RSV and Chlamydia + Gonorrhea multiplex test, the rollout of Cue Care, 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 Annual Report on Form 10-K for the year ended December 31, 2021 and Quarterly Report on Form 10-Q for the quarter ended June 30, 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.*

Use of Non-GAAP Financial Measures

To supplement our financial information presented in accordance with GAAP, we consider certain financial measures that are not prepared in accordance with GAAP, including Adjusted Product Gross Profit Margin, Adjusted Net (loss) Income, Adjusted Diluted EPS and Adjusted EBITDA (loss). We use these financial measures in conjunction with GAAP measures as part of our overall assessment of our performance, including the preparation of our annual operating budget and quarterly forecasts, to evaluate the effectiveness of our business strategies and to communicate with our board of directors concerning our business and financial performance. We believe that these non-GAAP financial measures provide useful information to investors about our business and financial performance, enhance their overall understanding of our past performance and future prospects, and allow for greater transparency with respect to metrics used by our management in their financial and operational decision making. We are presenting these non-GAAP financial measures to assist investors in seeing our business and financial performance through the eyes of management, and because we believe that these non-GAAP financial measures provide an additional tool for investors to use in comparing results of operations of our business over multiple periods with other companies in our industry.

Adjusted EBITDA is defined as net income before interest expense, income tax expense (benefit), depreciation and amortization, stock-based compensation, restructuring expense, inventory charges – inventory reserves/warranty reserves, banking and finance-related items including fair value adjustments - convertible notes.

Adjusted product gross profit is defined as product gross profit (loss), before inventory charges – inventory reserves / warranty reserves.

Adjusted net (loss) income is defined as Net (loss) income, before Inventory charges – inventory reserves / warranty reserves, restructuring expense and tax effects.

Adjusted diluted EPS is defined as Diluted EPS before Inventory charges – inventory reserves / warranty reserves, restructuring expense and tax effects.

Our definitions may differ from the definitions used by other companies and therefore comparability may be limited. In addition, other companies may not publish these or similar metrics. Further, these metrics have certain limitations in that they do not include the impact of certain expenses that are reflected in our consolidated statements of operations. Thus, these non-GAAP metrics should be considered in addition to, not as substitutes for, or in isolation from, measures prepared in accordance with GAAP. For reconciliations of these non-GAAP financial measures to their most directly comparable GAAP financial measures see the financial tables below.

Contact Us

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue				
Product revenue	\$ 84,351	\$ 137,423	\$ 261,805	\$ 201,922
Grant and other revenue	3,349	—	5,305	—
Total revenue	87,700	137,423	267,110	201,922
Operating costs and expenses:				
Cost of product revenue	101,898	55,142	188,595	85,177
Sales and marketing	16,971	1,529	51,139	1,959
Research and development	44,000	4,662	72,787	12,071
General and administrative	25,411	11,382	52,321	23,252
Restructuring expense	1,883	—	1,883	—
Total operating costs and expenses	190,163	72,715	366,725	122,459
Income (loss) from operations	(102,463)	64,708	(99,615)	79,463
Interest expense	(16)	(9,429)	(67)	(9,964)
Change in fair value of redeemable convertible preferred stock warrants	—	(190)	—	(190)
Change in fair value of convertible notes	—	(23,254)	—	(23,254)
Other income, net	43	24	49	61
Net income (loss) before income taxes	(102,436)	31,859	(99,633)	46,116
Income tax expense (benefit)	(3,386)	12,050	(3,386)	13,276
Net income (loss)	\$ (99,050)	\$ 19,809	\$ (96,247)	\$ 32,840
Net income (loss) per share attributable to common stockholders – basic	\$ (0.67)	\$ 0.14	\$ (0.65)	\$ 0.23
Weighted-average number of shares used in computation of net income (loss) per share attributable to common stockholders – basic	147,498,162	18,822,474	147,014,951	18,617,247
Net income (loss) per share attributable to common stockholders – diluted	\$ (0.67)	\$ 0.14	\$ (0.65)	\$ 0.22
Weighted-average number of shares used in computation of net income (loss) per share attributable to common stockholders – diluted	147,498,162	26,241,564	147,014,951	26,036,337

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

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 363,124	\$ 409,873
Restricted cash	1,334	13,837
Accounts receivable	54,008	104,589
Inventory	139,047	88,388
Prepaid expenses	50,436	45,889
Other current assets	12,186	7,446
Total current assets	620,135	670,022
Property and Equipment, Net	190,131	177,456
Operating lease right-of-use assets	85,971	79,474
Intangible assets, net	10,936	7,673
Other non-current assets	6,902	5,435
Total assets	\$ 914,075	\$ 940,060
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 38,351	\$ 37,208
Accrued liabilities and other current liabilities	75,820	29,498
Income taxes payable	—	8,297
Deferred revenue, current	85,576	82,165
Operating lease liabilities, current	7,679	7,147
Finance lease liabilities, current	2,605	2,621
Total current liabilities	210,031	166,936
Deferred revenue, net of current portion	10,283	10,283
Operating leases liabilities, net of current portion	46,455	46,464
Finance lease liabilities, net of current portion	1,990	3,271
Other non-current liabilities	4,943	6,356
Total liabilities	273,702	233,310
Stockholders' Equity (Deficit)		
Common stock, \$0.00001 par value; 500,000,000 and 500,000,000 shares authorized, 147,834,377 and 146,402,991 issued and outstanding at June 30, 2022 and December 31, 2021, respectively	1	1
Additional paid-in-capital	760,637	730,767
Accumulated deficit	(120,265)	(24,018)
Total stockholders' equity	640,373	706,750
Total liabilities and Stockholders' Equity	\$ 914,075	\$ 940,060

**Non-GAAP Reconciliation
(In thousands)**

The following table presents the reconciliation of Net (loss) income to Adjusted EBITDA, for the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net (loss) income	\$ (99,050)	\$ 19,809	\$ (96,247)	\$ 32,840
Interest expense	16	9,429	67	9,964
Income tax expense (benefit)	(3,386)	12,050	(3,386)	13,276
Depreciation and amortization	10,979	9,616	21,585	14,500
Stock-based compensation	16,792	2,569	32,826	5,591
Restructuring expense	1,883	—	1,883	—
Inventory charges - inventory reserves / warranty reserves	42,844	—	42,844	—
Fair value adjustment - convertible notes	—	23,254	—	23,254
Banking and finance-related items	—	7,998	—	7,998
Adjusted EBITDA	\$ (29,922)	\$ 84,725	\$ (428)	\$ 107,423

The following table presents the reconciliation of Product gross profit (loss) margin to Adjusted product gross profit margin, for the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Product revenue	\$ 84,351	\$ 137,423	\$ 261,805	\$ 201,922
Cost of product revenue	101,898	55,142	188,595	85,177
Product gross profit (loss)	(17,547)	82,281	73,210	116,745
Product gross profit (loss) margin	(21)%	60 %	28 %	58 %
Inventory charges - inventory reserves / warranty reserves	42,844	—	42,844	—
Adjusted product gross profit	\$ 25,297	\$ 82,281	\$ 116,054	\$ 116,745
Adjusted product gross profit margin	30 %	60 %	44 %	58 %

The following table presents the reconciliation of Net (loss) income / diluted EPS to Adjusted net (loss) income / diluted EPS, for the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022		2022	
	Dollar Amount	Per Diluted Share	Dollar Amount	Per Diluted Share
Net (loss) income / diluted EPS	\$ (99,050)	(0.67)	\$ (96,247)	(0.65)
Inventory charges - inventory reserves / warranty reserves	42,844	0.29	42,844	0.29
Restructuring expense	1,883	0.01	1,883	0.01
Tax effects	(868)	(0.01)	(868)	(0.01)
Adjusted net (loss) income / diluted EPS	\$ (55,191)	(0.37)	\$ (52,388)	(0.36)