

**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): **November 9, 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:

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 November 9, 2022, Cue Health Inc. ("Cue Health" or the "Company"), issued a press release announcing the Company's financial results for the third quarter ended September 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 November 9, 2022.

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

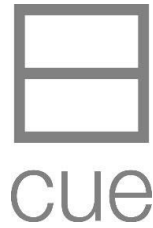
SIGNATURES

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: November 9, 2022

Cue Health Inc.

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



Cue Health Reports Third Quarter 2022 Results

SAN DIEGO, CA – November 9, 2022 – Cue Health Inc. ("Cue") (Nasdaq: HLTH), a healthcare technology company, today reported financial results for the third quarter of 2022.

Recent Highlights

- Revenue of \$69.6 million in the third quarter of 2022, exceeding guidance
- Flu A/B molecular 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 A/B + COVID multiplex molecular test submission to the FDA for emergency use authorization (EUA) for at-home and point-of-care use
- RSV molecular test clinical studies began in the third quarter of 2022 as planned
- Strep Throat molecular test development completed and expect to begin clinical studies during the current respiratory season
- Chlamydia + Gonorrhea multiplex molecular test clinical studies on track to begin in the fourth quarter of 2022
- Monkeypox molecular test developed with analytical and clinical studies planned to support an EUA submission in the first quarter of 2023
- Cue Care™ launched, offering nationwide test-to-treat solution for patients who test positive on any COVID-19 test
- Cash and cash equivalents of \$304.7 million while the \$100 million secured revolving credit facility remains undrawn at quarter end and company continues to operate with no debt obligations

"We continue to make significant progress advancing our pipeline of future tests, having completed U.S. regulatory submissions for both our Flu A/B + COVID and Flu A/B molecular tests, started our RSV clinical study, and completed development in other respiratory and sexual health programs," said Ayub Khattak, Chairman and CEO of Cue Health. "I am pleased with the rapid pace of development, which we believe will enable early detection and early treatment for a variety of common health concerns, leading to better outcomes for patients and furthering our mission of empowering people to live their healthiest lives."

Third Quarter 2022 Financial Results

Revenue in the third quarter of 2022 was \$69.6 million, driven by stronger than anticipated COVID-19 testing orders from existing customers.

Private sector revenue was \$65.9 million, or 94.7% of total revenue. Public sector revenue was 5.3% of total revenue or \$3.7 million. Disposable test cartridge revenue was \$61.4 million in the third quarter of 2022.

GAAP product gross profit margin was 24.1% in the third quarter of 2022. Adjusted product gross profit margin was 28.0% after excluding one-time inventory charges of \$2.6 million.

Operating expenses in the third quarter of 2022 were \$86.4 million, excluding cost of revenues, reflecting product development, software technology, and menu expansion investments.

GAAP net income in the third quarter of 2022 was a loss of \$66.3 million and earnings per diluted share was a loss of \$0.45. Cue's Adjusted net income was a loss of \$63.6 million and Adjusted earnings per diluted share was a loss of \$0.43. Adjusted EBITDA was a loss of \$37.2 million.

Cash and cash equivalents were \$304.7 million as of September 30, 2022.

Guidance

Cue Health expects fourth quarter 2022 revenues in the range of \$45 to \$50 million, excluding any adjustment to the deferred revenue balance of \$92.4 million related to our agreement with the U.S. Department of Defense.

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 fourth 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 A/B standalone, flu A/B + Covid multiplex, RSV test, Strep Throat test, Monkeypox test 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, Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 and Quarterly Report on Form 10-Q for the quarter ended September 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, 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue				
Product revenue	\$ 66,660	\$ 222,594	\$ 328,465	\$ 424,516
Grant and other revenue	2,929	1,085	8,234	1,085
Total revenue	69,589	223,679	336,699	425,601
Operating costs and expenses:				
Cost of product revenue	50,595	88,569	239,190	173,746
Sales and marketing	18,129	5,572	69,268	7,531
Research and development	42,516	9,079	115,303	21,150
General and administrative	25,625	33,084	77,946	56,336
Restructuring expense	137	—	2,020	—
Total operating costs and expenses	137,002	136,304	503,727	258,763
Income (loss) from operations	(67,413)	87,375	(167,028)	166,838
Interest expense	(346)	(1,786)	(413)	(9,752)
Change in fair value of redeemable convertible preferred stock warrants	—	243	—	53
Change in fair value of convertible notes	—	(36,306)	—	(59,560)
Loss on extinguishment of debt	—	—	—	(1,998)
Other income, net	409	(80)	458	(19)
Net income (loss) before income taxes	(67,350)	49,446	(166,983)	95,562
Income tax expense (benefit)	(1,047)	30,098	(4,433)	43,374
Net income (loss)	\$ (66,303)	\$ 19,348	\$ (162,550)	\$ 52,188
Net income (loss) per share attributable to common stockholders – basic	\$ (0.45)	\$ 0.14	\$ (1.10)	\$ 0.37
Weighted-average number of shares used in computation of net income (loss) per share attributable to common stockholders – basic	148,285,721	31,554,720	147,443,196	22,997,311
Net income (loss) per share attributable to common stockholders – diluted	\$ (0.45)	\$ 0.13	\$ (1.10)	\$ 0.35
Weighted-average number of shares used in computation of net income (loss) per share attributable to common stockholders – diluted	148,285,721	39,304,978	147,443,196	30,747,569

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 304,654	\$ 409,873
Restricted cash	1,334	13,837
Accounts receivable, net	24,779	104,589
Inventories	133,309	88,388
Prepaid expenses	44,355	45,889
Other current assets	13,441	7,446
Total current assets	521,872	670,022
Property and equipment, net	194,259	177,456
Operating lease right-of-use assets	85,284	79,474
Intangible assets, net	16,044	7,673
Other non-current assets	7,577	5,435
Total assets	\$ 825,036	\$ 940,060
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 32,521	\$ 37,208
Accrued liabilities and other current liabilities	47,105	29,498
Income taxes payable	—	8,297
Deferred revenue, current	84,899	82,165
Operating lease liabilities, current	8,356	7,147
Finance lease liabilities, current	2,581	2,621
Total current liabilities	175,462	166,936
Deferred revenue, net of current portion	10,283	10,283
Operating leases liabilities, net of current portion	44,235	46,464
Finance lease liabilities, net of current portion	1,268	3,271
Other non-current liabilities	3,828	6,356
Total liabilities	235,076	233,310
Stockholders' Equity (Deficit)		
Common stock, \$0.00001 par value; 500,000,000 and 500,000,000 shares authorized, 149,177,691 and 146,402,991 issued and outstanding at September 30, 2022 and December 31, 2021, respectively	1	1
Additional paid-in-capital	776,527	730,767
Accumulated deficit	(186,568)	(24,018)
Total stockholders' equity	589,960	706,750
Total liabilities and stockholders' equity	\$ 825,036	\$ 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net (loss) income	\$ (66,303)	\$ 19,348	\$ (162,550)	\$ 52,188
Interest expense	346	1,786	413	9,752
Income tax expense (benefit)	(1,047)	30,098	(4,433)	43,374
Depreciation and amortization	11,404	11,579	32,989	26,079
Stock-based compensation	15,690	19,967	48,515	25,558
Restructuring expense	137	—	2,020	—
Inventory charges - inventory reserves / warranty reserves	2,610	—	45,454	—
Fair value adjustment - convertible notes	—	36,306	—	59,560
Forgiveness of promissory notes	—	12,880	—	12,880
Banking and finance-related items	—	—	—	7,998
Adjusted EBITDA	\$ (37,163)	\$ 131,964	\$ (37,592)	\$ 237,389

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Product revenue	\$ 66,660	\$ 222,594	\$ 328,465	\$ 424,516
Cost of product revenue	50,595	88,569	239,190	173,746
Product gross profit	16,065	134,025	89,275	250,770
Product gross profit margin	24 %	60 %	27 %	59 %
Inventory charges - inventory reserves / warranty reserves	2,610	—	45,454	—
Adjusted product gross profit	\$ 18,675	\$ 134,025	\$ 134,729	\$ 250,770
Adjusted product gross profit margin	28 %	60 %	41 %	59 %

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	2022		2022	
	<u>Dollar Amount</u>	<u>Per Diluted Share</u>	<u>Dollar Amount</u>	<u>Per Diluted Share</u>
Net (loss) income / diluted EPS	\$ (66,303)	(0.45)	\$ (162,550)	(1.10)
Inventory charges - inventory reserves / warranty reserves	2,610	0.02	45,454	0.31
Restructuring expense	137	—	2,020	0.01
Tax effects	(55)	—	(954)	(0.01)
Adjusted net (loss) income / diluted EPS	<u>\$ (63,611)</u>	<u>(0.43)</u>	<u>\$ (116,030)</u>	<u>(0.79)</u>