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 9, 2023**

CUE HEALTH INC.

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

Delaware	**001-40824**	**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 August 9, 2023, 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, 2023. A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated by reference herein.

The information contained in 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 9, 2023.
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.

Cue Health Inc.

Date: August 9, 2023

By:	/s/ Aasim Javed
Name:	Aasim Javed
Title:	Chief Financial Officer

Cue Health Reports Second Quarter 2023 Financial Results

SAN DIEGO, CA – August 9, 2023 – Cue Health Inc. ("Cue") (Nasdaq: HLTH), a healthcare technology company, today reported financial results for the second quarter 2023.

Recent Highlights

- Reported second quarter total revenue of $10 million at the top-end of our guidance.
- Received landmark first, over-the-counter De Novo authorization from the FDA for the Cue COVID-19 Molecular Test.
- Awarded a new $28.3 million contract from BARDA, the U.S. Biomedical Advanced Research and Development Authority, to accelerate the development, validation, and regulatory authorization of a Flu A/B + RSV + COVID-19 molecular multiplex test for both at-home and point-of-care setting.
- Submitted the Cue RSV Molecular Test as a De Novo submission to the FDA for at-home and point-of-care use during the second quarter.
- Flu + COVID combo test under review at FDA.
- Chlamydia + Gonorrhea molecular test is on track for a submission to the FDA planned for the fourth quarter of 2023.
- Achieved our previously announced cost reduction goal of $150 million of annualized run rate cost savings during the second quarter ahead of our original plan.
- Ended the second quarter with cash and cash equivalents of $128.6 million and no debt obligations.

“We achieved the top-end of our guidance in the quarter, and expect to return to growth in the second half of the year. We achieved the industry-first FDA De Novo authorization for over-the-counter use of our COVID-19 test, a positive signal for our menu expansion objectives. These include our combination Flu + COVID molecular test and our standalone RSV test, both of which are now under FDA review,” said Ayub Khattak, Chairman and CEO of Cue Health. “Another recent achievement driving our momentum is our new contract with BARDA to develop a Flu + COVID + RSV multiplex test for over-the-counter and point-of-care use. We continue to make good progress on our sexual health menu, with the EUA for our mpox test and our chlamydia & gonorrhea molecular test, which is on-track to submit to the FDA in the fourth quarter. These milestones, together with the early positive signs we’re seeing from Cue Lab and Cue Pharmacy, gives us optimism and confidence in the future of the Cue Health platform.”

Second Quarter 2023 Financial Results

Revenue was $9.9 million for the second quarter of 2023. Private sector revenue was $7.6 million or 76% of total revenue with strong ordering from existing customers. Public sector revenue was $2.3 million and disposable test cartridge revenue was $7.3 million.

GAAP product gross profit was a loss of $21.8 million in the second quarter of 2023 impacted by lower manufacturing volumes and a $11.7 million write-down of excess inventory.

GAAP operating expenses in the second quarter of 2023 were $65.9 million, excluding cost of revenue, including $6.6 million of restructuring expense related to the cost reduction plan. On an adjusted basis, excluding the impact of the restructuring expense, operating expenses were $59.3 million, a sequential decrease of 19% compared to the first quarter and a 37% decrease from $94.6 million in the fourth quarter of 2022. As of the end of the second quarter, the company has achieved the full amount of the previously announced cost reduction goal of $150 million annualized run rate cost savings.

GAAP net loss in second quarter of 2023 was $83.9 million and earnings per diluted share was a loss of $0.55 or an improvement of $0.12 from the second quarter of 2022. Cue's adjusted net loss was $77.2 million and adjusted earnings per diluted share was a loss of $0.51. Adjusted EBITDA was a loss of $53.1 million.

Cash and cash equivalents were $128.6 million as of June 30, 2023 and the company continues to operate with no debt obligations.

Guidance

Cue Health expects third quarter 2023 revenues in the range of $11 million to $13 million.

About Cue Health
Cue Health Inc. (Nasdaq: HLTH) is a healthcare technology company that uses diagnostic-enabled care to empower people to live their healthiest lives. The Cue Health platform offers individuals and healthcare providers convenient and personalized access to lab-quality diagnostic tests at home and at the point of care, as well as on-demand telehealth consultations and treatment options for a wide range of health and wellness needs. Cue's customers include federal and state public sector agencies and the private sector, which includes healthcare providers, enterprises, and individual consumers. Cue's COVID-19 test was the first FDA-authorized molecular diagnostic test for at-home and over-the-counter use without a prescription. Cue has since received Emergency Use Authorization from the FDA for its molecular mpox test at the point of care and, to expand its test menu, the company has a number of other submissions under review by the FDA. Cue, founded in 2010, owns over 100 patents 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, expectations related to testing volumes, the ability to achieve growth in the future, our contract with BARDA, and future results of operations and performance and our guidance, including third quarter 2023 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”, “look forward”, “believe” 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, mpox test and Chlamydia + Gonorrhea multiplex test, the expansion 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, our ability to realize operating expense annualized savings as a result of the previously announced cost reduction program, and the factors discussed in the "Risk Factors" section of Cue’s Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 16, 2023 and of Cue’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 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.

The Cue Mpox (Monkeypox) Molecular Test has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA. This product has been authorized only for the detection of nucleic acid from monkeypox virus, 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 infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola Orthopoxvirus, 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 Operating Expenses, 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 loss before interest expense, income tax benefit, depreciation and amortization, stock-based compensation, restructuring expense, disputed vendor payment.

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

Adjusted operating expenses is defined as operating expenses before cost of revenue, restructuring expense.

Adjusted net loss is defined as Net loss, before disputed vendor payment, restructuring expense and tax effects.

Adjusted diluted EPS is defined as Diluted EPS before disputed vendor payment, 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue				
Product revenue	$ 7,591	$ 84,351	$ 32,085	$ 261,805
Grant and other revenue	2,305	3,349	2,576	5,305
Total revenue	9,896	87,700	34,661	267,110
Operating costs and expenses:				
Cost of product revenue	29,346	101,898	69,169	188,595
Sales and marketing	8,059	16,971	19,307	51,139
Research and development	36,536	44,000	81,269	72,787
General and administrative	14,703	25,411	31,641	52,321
Restructuring expense	6,645	1,883	14,518	1,883
Total operating costs and expenses	95,289	190,163	215,904	366,725
Loss from operations	(85,393)	(102,463)	(181,243)	(99,615)
Interest expense	(291)	(16)	(511)	(67)
Other income, net	1,820	43	3,692	49
Net loss before income taxes	(83,864)	(102,436)	(178,062)	(99,633)
Income tax benefit	—	(3,386)	—	(3,386)
Net loss	(83,864)	(99,050)	(178,062)	(96,247)
Net loss per share – basic	$ (0.55)	$ (0.67)	$ (1.18)	$ (0.65)
Weighted-average number of shares used in computation of net loss per share – basic	151,869,131	147,498,162	151,478,593	147,014,951
Net loss per share – diluted	$ (0.55)	$ (0.67)	$ (1.18)	$ (0.65)
Weighted-average number of shares used in computation of net loss per share – diluted	151,869,131	147,498,162	151,478,593	147,014,951

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

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 128,551	$ 241,530
Restricted cash	800	800
Accounts receivable, net	1,707	18,751
Inventories, current	68,373	82,210
Prepaid expenses	9,318	15,728
Other current assets	3,326	12,134
Total current assets	212,075	371,153
Non-current inventories	28,014	25,436
Property and equipment, net	175,447	189,275
Operating lease right-of-use assets	82,752	85,321
Intangible assets, net	21,769	16,867
Other non-current assets	3,802	6,528
Total assets	$ 523,859	$ 694,580
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 11,210	$ 7,150
Accrued liabilities and other current liabilities	35,924	52,378
Deferred revenue, current	468	1,566
Operating lease liabilities, current	7,672	7,739
Finance lease liabilities, current	1,756	2,362
Total current liabilities	57,030	71,195
Operating leases liabilities, net of current portion	41,655	44,045
Finance lease liabilities, net of current portion	—	849
Other non-current liabilities	1,997	1,997
Total liabilities	100,682	118,086
Stockholders' Equity		
Common stock	2	1
Additional paid-in-capital	819,311	794,567
Accumulated deficit	(396,136)	(218,074)
Total stockholders' equity	423,177	576,494
Total liabilities and stockholders' equity	$ 523,859	$ 694,580

Non-GAAP Measures
(In thousands, except share data)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	$ (83,864)	$ (99,050)	$ (178,062)	$ (96,247)
Interest expense	291	16	511	67
Income tax benefit	—	(3,386)	—	(3,386)
Depreciation and amortization	12,356	10,979	24,420	21,585
Stock-based compensation	11,502	16,792	25,910	32,826
Restructuring expense	6,645	1,883	14,518	1,883
Disputed vendor payment	—	—	12,000	—
Inventory charges	—	42,844	—	42,844
Adjusted EBITDA	$ (53,070)	$ (29,922)	$ (100,703)	$ (428)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Product revenue	$ 7,591	$ 84,351	$ 32,085	$ 261,805
Cost of product revenue	29,346	101,898	69,169	188,595
Product gross profit (loss)	(21,755)	(17,547)	(37,084)	73,210
Product gross profit (loss) margin	(287)%	(21)%	(116)%	28 %
Disputed vendor payment	—	—	12,000	—
Inventory charges - inventory reserves / warranty reserves	—	42,844	—	42,844
Adjusted product gross profit (loss)	$ (21,755)	$ 25,297	$ (25,084)	$ 116,054
Adjusted product gross profit (loss) margin	(287)%	30 %	(78)%	44 %

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023		2023	
	Dollar Amount	Per Diluted Share	Dollar Amount	Per Diluted Share
Net loss / diluted EPS	$ (83,864)	$ (0.55)	$ (178,062)	$ (1.18)
Disputed vendor payment	—	—	12,000	0.08
Restructuring expense	6,645	0.04	14,518	0.10
Tax effects	—	—	—	—
Adjusted net loss / diluted EPS	$ (77,219)	$ (0.51)	$ (151,544)	$ (1.00)