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): **March 13, 2024**

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 Capital 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 March 13, 2024, Cue Health Inc. ("Cue Health" or the "Company"), issued a press release announcing the Company's financial results for the fourth quarter and full year ended December 31, 2023. 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 March 13, 2024.
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: March 13, 2024

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

Cue Health Reports Fourth Quarter 2023 Financial Results

SAN DIEGO, CA – March 13, 2024 – Cue Health Inc. ("Cue" or the "Company") (Nasdaq: HLTH), a healthcare technology company, today reported financial results for the fourth quarter and full-year 2023.

Recent Highlights

- Reported fourth quarter total revenue of $18.8 million. Full-year 2023 total revenue was $70.9 million
- Submitted additional clinical samples and stability data for RSV to the FDA in support of de novo submission
- Submitted additional clinical samples and gathering additional stability data for Flu A/B to the FDA in support of de novo submission
- In late stage development of Herpes + Mpox Multiplex Molecular Test with plan to submit for EUA in 2Q24
- Executed cost reduction plans, resulting in cash savings of approximately $200 million on an annualized basis, while prioritizing near-term revenue generating opportunities
- Reported cash and cash equivalents of $80.9 million as of December 31, 2023

"We made progress executing on our strategic priorities in 2023. We obtained two FDA authorizations including a de novo approval for our COVID-19 Molecular Test and an EUA for our Mpox Molecular Test, and made two de novo submissions for our RSV and Flu standalone molecular tests. We also drove significant development progress on our all-in-one Flu + COVID-19 + RSV test, our Herpes + Mpox multiplex test, and we expanded our Integrated Care Platform with a new suite of at-home diagnostics tests and treatments, all while streamlining our cost structure," said Ayub Khattak, Chairman and CEO of Cue. "We believe that these successes have positioned us well for 2024."

Fourth Quarter 2023 Financial Results

Revenue was $18.8 million for the fourth quarter of 2023. Private sector revenue was $17.0 million or 91% of total revenue with strong ordering from existing customers. Public sector revenue was $1.8 million and disposable test cartridge revenue was $15.5 million.

GAAP product gross profit was a loss of $18.4 million in the fourth quarter of 2023. Adjusted product gross profit was a loss of $2.7 million after excluding one-time $15.7 million inventory charges.

GAAP operating costs and expenses in the fourth quarter of 2023 were $132.0 million, excluding cost of product revenue. GAAP operating costs and expenses includes $83.6 million of impairment of long-lived assets. Adjusted operating costs and expenses were $48.3 million in the fourth quarter of 2023, a 49% decrease from $94.6 million in the fourth quarter of 2022.

GAAP net loss in the fourth quarter of 2023 was $148.4 million and earnings per diluted share was a loss of $0.96. Cue's adjusted net loss, which excludes the one-time inventory and impairment charges, was $49.1 million and adjusted earnings per diluted share was a loss of $0.32. Adjusted EBITDA was a loss of $24.4 million.

Full-Year 2023 Financial Results

Revenue was $70.9 million for the full year of 2023. Private sector revenue was $63.0 million, or 89% of total revenue. Public sector revenue was 11% of total revenue or $7.9 million. Disposable test cartridge revenue was $58.5 million for the full year 2023.

GAAP product gross profit was a loss of $62.9 million for the full year 2023. Adjusted product gross profit was a loss of $35.2 million after excluding a $12.0 million disputed vendor payment and the one-time inventory charges of $15.7 million.

GAAP operating costs and expenses for the full year 2023 were $338.7 million, excluding cost of product revenue. GAAP operating costs and expenses includes $83.6 million of impairment of long-lived assets and $14.5 million of restructuring expense. Adjusted operating costs and expenses for the full year 2023 were $240.6 million.

GAAP net loss for the full year 2023 was $373.5 million and earnings per diluted share was a loss of $2.44. Cue's Adjusted net loss was $267.2 million and adjusted earnings per diluted share was a loss of $1.75. Adjusted EBITDA was a loss of $163.8 million.

Cash and cash equivalents were $80.9 million as of December 31, 2023 and Cue continues to operate with no debt obligations.

Guidance

Cue expects first quarter 2024 revenues in the range of $9 million to $11 million.

Webcast and Conference Call Information

Cue will host a conference call to discuss the fourth quarter and full year 2023 financial results, after market close on Wednesday, March 13, 2024, at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time.

To access the live call via telephone, please register in advance using the link here. Upon registering, each participant will receive an email confirmation with dial-in numbers and a unique personal PIN that can be used to join the call.

The live webinar may be accessed by visiting the "Events" section of the Company's website at investors.cuehealth.com. A replay of the webinar will be available on the Company's website shortly after the conclusion of the call.

About Cue

Cue Health Inc. (Nasdaq: HLTH) is a healthcare technology company that uses diagnostic-enabled care to empower people to live their healthiest lives. Cue's 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 received De Novo authorization from the U.S. Food and Drug Administration (FDA) for its COVID-19 test, which became the first home use respiratory test to receive this FDA approval. Cue also received Emergency Use Authorization from the FDA for its molecular Mpox test at the point-of-care and, to expand its test menu, Cue 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 and authorization and timing of such clearance, authorization and submissions, growth in our customer base, expectations regarding production capacity and product launches, potential technology enhancements, expectations related to availability of our programs and testing volumes, the ability to achieve growth in the future, and future results of operations and performance and our guidance, including first quarter 2024 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," "design" 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 expectations around FDA submissions, applications, authorizations and timing, 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, 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 (Loss) Margin, Adjusted Operating Expenses, Adjusted Net Loss, 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 income, interest expense, income tax expense (benefit), depreciation and amortization, stock-based compensation, impairment of long-lived assets, restructuring expense, tax credits, disputed vendor payment, inventory charges, U.S. Department of Defense (the "DoD") deferred revenue release.

Adjusted product gross profit (loss) is defined as product gross profit (loss), before DoD deferred revenue release, disputed vendor payment, inventory charges.

Adjusted operating costs and expenses is defined as operating costs and expenses before cost of product revenue, impairment of long-lived assets, restructuring expense.

Adjusted net loss is defined as Net loss, before impairment of long-lived assets, restructuring expense, tax credits, disputed vendor payment, inventory charges and tax effects.

Adjusted diluted EPS is defined as Diluted EPS before impairment of long-lived assets, restructuring expense, tax credits, disputed vendor payment, inventory charges 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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CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Revenue				
Product revenue	$ 17,381	$ 145,701	$ 64,223	$ 474,166
Grant and other revenue	1,417	1,076	6,713	9,310
Total revenue	18,798	146,777	70,936	483,476
Operating costs and expenses:				
Cost of product revenue	35,742	90,783	127,091	329,973
Sales and marketing	6,226	19,312	32,584	88,580
Research and development	32,248	56,149	150,620	171,452
General and administrative	9,866	19,157	57,355	97,103
Impairment of long-lived assets	83,639	—	83,639	—
Restructuring expense	(18)	—	14,500	2,020
Total operating costs and expenses	167,703	185,401	465,789	689,128
Loss from operations	(148,905)	(38,624)	(394,853)	(205,652)
Interest income	1,084	1,988	6,240	3,328
Interest expense	(344)	(232)	(1,159)	(645)
Tax credits	—	—	20,939	—
Other income (expense), net	(207)	46	162	(835)
Net loss before income taxes	(148,372)	(36,821)	(368,671)	(203,804)
Income tax expense (benefit)	60	(5,315)	4,793	(9,748)
Net loss	$ (148,432)	$ (31,506)	$ (373,464)	$ (194,056)
Net loss per share – basic & diluted	$ (0.96)	$ (0.21)	$ (2.44)	$ (1.31)
Weighted-average number of shares used in computation of net loss per share – basic & diluted	154,807,021	149,711,419	152,877,306	148,024,749

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

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 80,889	$ 241,530
Restricted cash	800	800
Accounts receivable, net	1,352	18,751
Inventories, net - current	14,039	82,210
Prepaid expenses	8,479	15,728
Other current assets	4,803	12,134
Total current assets	110,362	371,153
Non-current inventories, net	56,273	25,436
Property and equipment, net	72,096	189,275
Operating lease right-of-use assets	78,519	85,321
Intangible assets, net	19,644	16,867
Other non-current assets	2,893	6,528
Total assets	$ 339,787	$ 694,580
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,705	$ 7,150
Accrued liabilities and other current liabilities	29,300	52,378
Deferred revenue, current	162	1,566
Operating lease liabilities, current	5,142	7,739
Finance lease liabilities, current	1,157	2,362
Total current liabilities	43,466	71,195
Operating leases liabilities, net of current portion	41,640	44,045
Finance lease liabilities, net of current portion	—	849
Other non-current liabilities	4,429	1,997
Total liabilities	89,535	118,086
Stockholders' Equity		
Common stock	2	1
Additional paid-in-capital	841,788	794,567
Accumulated deficit	(591,538)	(218,074)
Total stockholders' equity	250,252	576,494
Total liabilities and stockholders' equity	$ 339,787	$ 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 December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Net loss	$ (148,432)	$ (31,506)	$ (373,464)	$ (194,056)
Interest income	(1,084)	(1,988)	(6,240)	(3,328)
Interest expense	344	232	1,159	645
Income tax expense (benefit)	60	(5,315)	4,793	(9,748)
Depreciation and amortization	15,219	14,337	56,278	48,972
Stock-based compensation	10,138	15,776	48,735	64,291
Impairment of long-lived assets	83,639	—	83,639	—
Restructuring expense	(18)	—	14,500	2,020
Tax credits	—	—	(20,939)	—
Disputed vendor payment	—	—	12,000	—
Inventory charges	15,705	47,352	15,705	92,806
DoD deferred revenue release	—	(92,448)	—	(92,448)
Adjusted EBITDA	$ (24,429)	$ (53,560)	$ (163,834)	$ (90,846)

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 December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Product revenue	$ 17,381	$ 145,701	$ 64,223	$ 474,166
Cost of product revenue	35,742	90,783	127,091	329,973
Product gross profit (loss)	$ (18,361)	$ 54,918	$ (62,868)	$ 144,193
Product gross profit (loss) margin	(106)%	38 %	(98)%	30 %
DoD deferred revenue release	—	(92,448)	—	(92,448)
Adjusted product revenue	17,381	53,253	64,223	381,718
Disputed vendor payment	—	—	12,000	—
Inventory charges	15,705	47,352	15,705	92,806
Adjusted product gross profit (loss)	$ (2,656)	$ 9,822	$ (35,163)	$ 144,551
Adjusted product gross profit (loss) margin	(15)%	18 %	(55)%	38 %

The following table presents the reconciliation of Operating costs and expenses to Adjusted operating costs and expenses, for the periods presented:

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Operating costs and expenses	$ 167,703	$ 185,401	$ 465,789	$ 689,128
Cost of product revenue	35,742	90,783	127,091	329,973
Operating costs and expenses excluding cost of product revenue	131,961	94,618	338,698	359,155
Impairment of long-lived assets	83,639	—	83,639	—
Restructuring expense	(18)	—	14,500	2,020
Adjusted operating costs and expenses	$ 48,340	$ 94,618	$ 240,559	$ 357,135

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

	Three Months Ended December 31, 2023		Twelve Months Ended December 31, 2023	
	Dollar Amount	Per Diluted Share	Dollar Amount	Per Diluted Share
Net loss / diluted EPS	$ (148,432)	$ (0.96)	$ (373,464)	$ (2.44)
Impairment of long-lived assets	83,639	0.54	83,639	0.55
Restructuring expense	(18)	—	14,500	0.09
Tax credits	—	—	(20,939)	(0.14)
Disputed vendor payment	—	—	12,000	0.08
Inventory charges	15,705	0.10	15,705	0.10
Tax effects	40	—	1,364	0.01
Adjusted net loss / diluted EPS	$ (49,066)	$ (0.32)	$ (267,195)	$ (1.75)