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 15, 2023

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's telephone number, including area code: (858) 412-8151
Former nam	e or address, if changed since last report: N	ot Applicable.
Check the appropriate box below if the Form 8-K filing following provisions (see General Instruction A.2. belo	5 5	iling obligation of the registrant under any of the
\square Written communications pursuant to Rule 425 under	r the Securities Act (17 CFR 230.425)	
\square Soliciting material pursuant to Rule 14a-12 under th	e Exchange Act (17 CFR 240.14a-12)	
\square Pre-commencement communications pursuant to Ru	ule 14d-2(b) under the Exchange Act (17 Cl	FR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Ru	ule 13e-4(c) under the Exchange Act (17 CI	FR 240.13e-4(c))
Securities registered pursuant to Section 12(b) of the A	.ct:	
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 em chapter) or Rule 12b-2 of the Securities Exchange Act		405 of the Securities Act of 1933 (§230.405 of this
Emerging growth company ⊠		
If an emerging growth company, indicate by check man or revised financial accounting standards provided pure		extended transition period for complying with any new $\hfill\Box$

Item 2.02 Results of Operations and Financial Condition.

On March 15, 2023, 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, 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 March 15, 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.

Date: March 15, 2023

Cue Health Inc.

By: /s/ Ayub Khattak

Name: Ayub Khattak

Title: Chief Executive Officer



Cue Health Reports Fourth Quarter and Full-Year 2022 Financial Results

SAN DIEGO, CA – March 15, 2023 – <u>Cue Health Inc.</u> ("Cue") (Nasdaq: HLTH), a healthcare technology company, today reported financial results for the fourth guarter and full-year 2022.

Recent and Full-Year 2022 Highlights

- Reported fourth quarter revenue of \$146.8 million, including \$92.4 million in deferred revenue related to our agreement with the U.S. Department of Defense. Full-year 2022 revenue was \$483.5 million.
- Achieved all test menu expansion milestones for 2022 including four molecular diagnostic tests submissions to the U.S.
 Food and Drug Administration (FDA):
 - COVID-19 de novo submission for full clearance in the second quarter of 2022
 - Flu A/B de novo submission in the third quarter of 2022
 - Flu A/B + COVID multiplex submission for emergency use authorization (EUA) in the third quarter of 2022
 - Mpox, formerly known as monkeypox, submission for EUA for point-of-care use in the first quarter of 2023
 - RSV molecular test clinical studies completed in the first quarter of 2023
 - Chlamydia + Gonorrhea molecular clinical studies began in the fourth quarter of 2022
 - Strep Throat molecular clinical studies began in the fourth guarter of 2022
- Launched Cue Care™ our foundational diagnostic-to-treatment solution, enabling individuals to consult with a healthcare professional and get treatment delivered to their home within hours, if medically indicated.
- Introduced a new collection of at-home diagnostic test kits for a variety of health conditions, including sexually
 transmitted infections, heart health, and food sensitivities, providing personalized care from the convenience and privacy
 of home. Individuals order tests online, collect samples, mail to a CLIA-certified laboratory partner, and get results
 delivered to their Cue Health App, with the option to access Cue Care for clinical consultation and prescriptions, if
 medically indicated.
- Executed a cost reduction plan, which is expected to result in cash savings of approximately \$100 million on an annualized basis, while prioritizing near-term revenue generating opportunities.
- Cash and cash equivalents of \$241.5 million as of December 31, 2022, while the \$100 million secured revolving credit facility remains undrawn and company continues to operate with no debt obligations.

"Our full year 2022 results reflect the success we've seen with our first product and the investments we've made to execute on all of our strategic priorities, which position us well to become the category leader in diagnostic testing both in the home and at the point of care," said Ayub Khattak, Chairman and CEO of Cue Health. "From diagnostic testing to virtual care to the procurement of treatment for a range of infectious diseases as well as a growing menu of general health and wellness concerns, Cue has strengthened its integrated care platform to empower people to live their healthiest lives."

Fourth Quarter 2022 Financial Results

Revenue was \$146.8 million for the fourth quarter of 2022, including \$92.4 million of deferred revenue recognized in the quarter from our agreement with the U.S. Department of Defense.

Excluding deferred revenue, fourth quarter of 2022 revenue was \$54.4 million from ongoing operations, driven by stronger than anticipated COVID-19 testing orders from existing customers.

Private sector revenue was \$52.4 million, 36% of total revenue or 96% of revenue from ongoing operations. Public sector revenue was \$94.4 million or \$1.9 million excluding deferred revenue. Disposable test cartridge revenue was \$50.5 million.

GAAP product gross profit margin was 38% in the fourth quarter of 2022. Adjusted product gross profit margin was 18% excluding the impact of deferred revenue and one-time adjustments to inventory reserves related to excess readers and reader components.

Operating expenses in the fourth quarter of 2022 were \$94.6 million, excluding cost of revenues, reflecting an increase in research and development spend to support product development, software technology, and menu expansion investments.

GAAP net income in the fourth quarter of 2022 was a loss of \$31.5 million and earnings per diluted share was a loss of \$0.21. Cue's adjusted net income was a loss of \$74.4 million and adjusted earnings per diluted share was a loss of \$0.50. Adjusted EBITDA was a loss of \$54.0 million.

Full-Year 2022 Financial Results

Revenue was \$483.5 million for the full year of 2022 or \$391.1 million when excluding deferred revenue.

Private sector revenue was \$374.7 million, or 77% of total revenue. Public sector revenue was 23% of total revenue or \$108.8 million. Disposable test cartridge revenue was \$358.1 million for the full year 2022.

GAAP product gross profit margin was 30% for the full year 2022. Adjusted product gross profit margin was 38% after excluding one-time inventory charges of \$92.8 million and the impact from deferred revenue.

Operating expenses for the full year 2022 were \$359.2 million including \$2.0 million of restructuring expenses taken during the fiscal year.

GAAP net income for the full year 2022 was a loss of \$194.1 million and earnings per diluted share was a loss of \$1.31. Cue's Adjusted net income was a loss of \$191.8 million and Adjusted earnings per diluted share was a loss of \$1.29. Adjusted EBITDA was a loss of \$91.5 million.

Cash and cash equivalents were \$241.5 million as of December 31, 2022. In addition, Cue Health's \$100 million secured revolving credit facility remains undrawn and Cue Health operates with no debt obligations.

Guidance

Cue Health expects first quarter 2023 revenues in the range of \$20 million to \$25 million.

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 first guarter 2023 quidance, 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, 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 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, DoD deferred revenue release, banking and finance-related items including fair value adjustments - convertible notes.

Adjusted product gross profit is defined as product gross profit, before DoD deferred revenue release and inventory charges – inventory reserves / warranty reserves.

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

Adjusted diluted EPS is defined as Diluted EPS before Inventory charges – inventory reserves / warranty reserves, DoD deferred revenue release, 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 (In thousands, except share data)

Three	Months	Ended
Do		21

	December 31,			Year Ended December 31,				
		2022		2021		2022		2021
Revenue								
Product revenue	\$	145,701	\$	191,280	\$	474,166	\$	615,796
Grant and other revenue		1,076		1,226		9,310		2,311
Total revenue		146,777		192,506		483,476		618,107
Operating costs and expenses:								
Cost of product revenue		90,783		102,796		329,973		276,542
Sales and marketing		19,312		21,198		88,580		28,729
Research and development		56,149		21,679		171,452		42,829
General and administrative		19,157		23,452		97,103		79,788
Restructuring Expense		_		_		2,020		_
Total operating costs and expenses		185,401		169,125		689,128		427,888
Income (loss) from operations		(38,624)		23,381		(205,652)		190,219
Interest expense		(232)		(57)		(645)		(9,809)
Change in fair value of redeemable convertible preferred stock warrants		_		_		_		53
Change in fair value of convertible notes		_		_		_		(59,560)
Loss on extinguishment of debt		_		_		_		(1,998)
Other income (expense), net		2,035		291		2,493		272
Net income (loss) before income taxes		(36,821)		23,615		(203,804)		119,177
Income tax expense (benefit)		(5,315)		(10,615)		(9,748)		32,759
Net income (loss)	\$	(31,506)	\$	34,230	\$	(194,056)	\$	86,418
Net income (loss) per share attributable to common stockholders – basic	\$	(0.21)	\$	0.23	\$	(1.31)	\$	0.63
Weighted-average number of shares used in computation of net income (loss) per share attributable to common stockholders – basic		149,711,419		146,367,756		148,024,749		52,815,449
Net income (loss) per share attributable to common stockholders – diluted	\$	(0.21)	\$	0.22	\$	(1.31)	\$	0.59
Weighted-average number of shares used in computation of net income (loss) per share attributable to common stockholders – diluted		149,711,419		152,531,173		148,024,749		59,635,384
			-		_		_	

CONDENSED BALANCE SHEETS

(In thousands, except share amounts and share data)

		ecember 31, 2022	C	December 31, 2021
Assets				
Current assets:				
Cash and cash equivalents	\$	241,530	\$	409,873
Restricted cash		800		13,837
Accounts receivable		18,751		104,589
Inventories		82,210		88,388
Prepaid expenses		15,728		45,889
Other current assets		12,134		7,446
Total current assets		371,153		670,022
Non-current inventories		25,436		_
Property and equipment, net		189,275		177,456
Operating lease right-of-use assets		85,321		79,474
Intangible assets, net		16,867		7,673
Other non-current assets		6,528		5,435
Total assets	\$	694,580	\$	940,060
Liabilities and Stockholders' Equity (Deficit)				
Current liabilities:				
Accounts payable	\$	7,150	\$	37,208
Accrued liabilities and other current liabilities		52,378		29,498
Income taxes payable		_		8,297
Deferred revenue, current		1,566		82,165
Operating lease liabilities, current		7,739		7,147
Finance lease liabilities, current		2,362		2,621
Total current liabilities		71,195		166,936
Deferred revenue, net of current portion		_		10,283
Operating leases liabilities, net of current portion		44,045		46,464
Finance lease liabilities, net of current portion		849		3,271
Other non-current liabilities		1,997		6,356
Total liabilities		118,086		233,310
Stockholders' Equity (Deficit)				
Common stock, \$0.0001 par value; 500,000,000 and 500,000,000 shares authorized, 150,406,014 and 146,402,991 issued and outstanding at December 31, 2022 and December 31, 2021, respectively		1		1
Additional paid-in-capital		794,567		730,767
Accumulated deficit		(218,074)		(24,018)
Total stockholders' equity (deficit)		576,494		706,750
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$	694,580	\$	940,060

Non-GAAP Net Income (Loss) (In thousands, except share data)

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

	Three Months Ended December 31,					Year Ended December 31,			
		2022		2021		2022		2021	
Net (loss) income	\$	(31,506)	\$	34,230	\$	(194,056)	\$	86,418	
Interest expense		232		57		645		9,809	
Income tax expense (benefit)		(5,315)		(10,615)		(9,748)		32,759	
Depreciation and amortization		11,953		6,430		44,942		32,509	
Stock-based compensation		15,776		17,421		64,291		42,979	
Restructuring expense		_		_		2,020		_	
Inventory charges - inventory reserves / warranty reserves		47,352		_		92,806		_	
DoD deferred revenue release		(92,448)		_		(92,448)		_	
Fair value adjustment - convertible notes		_		_		_		59,560	
Forgiveness of promissory notes		_		_		_		12,880	
Banking and finance-related items		_		_		_		7,998	
Adjusted EBITDA	\$	(53,956)	\$	47,523	\$	(91,548)	\$	284,912	

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

	Th	ree Months En	ded [December 31,		Year Ended	Dece	December 31,		
		2022	2021			2022		2021		
Product revenue	\$	145,701	\$	191,280	\$	474,166	\$	615,796		
Cost of product revenue		90,783		102,796		329,973		276,542		
Product gross profit		54,918		88,484		144,193		339,254		
Product gross profit margin		38 %	46 %			30 %)	55 %		
DoD deferred revenue release		(92,448)		_		(92,448)		_		
Adjusted product revenue		53,253		191,280		381,718		615,796		
Inventory charges - inventory reserves / warranty reserves		47,352		_		92,806		_		
Adjusted product gross profit	\$	9,822	\$	88,484	\$	144,551	\$	339,254		
Adjusted product gross profit margin		18 %		46 %		38 %		55 %		

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 December 31,					Year Ended December 31,			
	2022				2022				
	Dol	lar Amount		Per Diluted Share	D	ollar Amount	Pe	r Diluted Share	
Net (loss) income / diluted EPS	\$	(31,506)	\$	(0.21)	\$	(194,056)	\$	(1.31)	
Inventory charges - inventory reserves / warranty reserves		47,352		0.32		92,806		0.63	
DoD deferred revenue release		(92,448)		(0.62)		(92,448)		(0.62)	
Restructuring expense		_		_		2,020		0.01	
Tax effects		2,165		0.01		(114)		_	
Adjusted net (loss) income / diluted EPS	\$	(74,437)	\$	(0.50)	\$	(191,792)	\$	(1.29)	