Cue Health Reports Third Quarter 2023 Financial Results

November 8, 2023 9:01 PM EST

SAN DIEGO--(BUSINESS WIRE)--Nov. 8, 2023-- Cue Health Inc. ("Cue") (Nasdaq: HLTH), a healthcare technology company, today reported financial results for the third quarter 2023.

Recent Highlights

- Reported third quarter total revenue of $17.5 million, approximately 50% above the midpoint of our guidance range of $11 to $13 million.
- Three tests in review with the FDA:
  - Cue® Flu A/B + COVID-19 Multiplex Molecular Test Emergency Use Authorization (EUA) for at-home and point-of-care use.
  - Cue Flu A/B Molecular Tests De Novo application for at-home and point-of-care use.
  - Cue RSV Molecular Test De Novo application for at-home and point-of-care use.
- Flu A/B, RSV, and COVID Multiplex Molecular Test development program is progressing with plans for an EUA submission and an initial objective of having this multiplex available for the 2024-2025 respiratory season.
- Announced the Herpes + Mpox Multiplex Molecular Test development program with initial plans to enter the market in 2024 with an EUA regulatory pathway.
- Publication of an independent, peer-reviewed study in Microbiology Spectrum, which finds that Cue's COVID-19 test demonstrates accuracy comparable to laboratory PCR, while being fast and easy-to-use in the point-of-care setting.
- Annualized run rate cost savings of approximately $165 million, overachieving our previously stated cost reduction goal of $150 million.
- Net change in cash for the quarter was $(17.1) million.
- Ended the third quarter with cash and cash equivalents of $111.5 million.

"In the third quarter our revenue exceeded our expectations, and we continued to execute on our strategic priorities with strong financial discipline. Our cost lowering program has now achieved $165 million in annualized savings, above our $150 million target," said Ayub Khattak, Chairman and CEO of Cue Health. "We have our Flu + COVID Multiplex Molecular Test, Flu De Novo, and RSV De Novo all deep in review with the FDA. I'm proud of the Cue team for the strong execution across all fronts."

Third Quarter 2023 Financial Results

Revenue was $17.5 million for the third quarter of 2023. Private sector revenue was $14.4 million or 82% of total revenue with strong ordering from existing customers. Public sector revenue was $3.1 million and disposable test cartridge revenue was $13.2 million.

GAAP product gross profit was a loss of $7.4 million in the third quarter of 2023.

GAAP operating expenses in the third quarter of 2023 were $60.0 million, excluding cost of revenue, in line with second quarter spend and a 37% decrease from $94.6 million in the fourth quarter of 2022.

Received employee retention credit of $20.9 million during the third quarter and recognized in tax credits on the income statement.

GAAP net loss in the third quarter of 2023 was $47.0 million and earnings per diluted share was a loss of $0.31, an improvement of $0.24 from the second quarter of 2023. Cue's adjusted net loss was $63.6 million and adjusted earnings per diluted share was a loss of $0.42. Adjusted EBITDA was a loss of $36.6 million.

Cue ended the third quarter with cash of $111.5 million and the company continues to operate with no debt obligations.

Guidance

Cue Health expects fourth quarter 2023 revenues in the range of $16 million to $18 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 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. To further expand its test menu, Cue has made other submissions that are now under review by the FDA, including for the Cue® Flu A/B + COVID-19 Molecular Test and the Cue® RSV Molecular Test, both of which are designed for at-home and point-of-care use. 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, growth in our customer base, expectations regarding production capacity, 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 fourth 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," "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 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 September 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 expense (benefit), depreciation and amortization, stock-based compensation, tax credits, restructuring expense, disputed vendor payment, inventory charges – inventory reserves / warranty reserves.

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 tax credits, disputed vendor payment, restructuring expense and tax effects.

Adjusted diluted EPS is defined as Diluted EPS before tax credits, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue				
Product revenue	$ 14,757	$ 66,660	$ 46,842	$ 328,465
Grant and other revenue	2,720	2,929	5,296	8,234
Total revenue	17,477	69,589	52,138	336,699
Operating costs and expenses:				
Cost of product revenue	22,180	50,595	91,349	239,190
Sales and marketing	7,051	18,129	26,358	69,268
Research and development	37,103	42,516	118,372	115,303
General and administrative	15,848	25,625	47,489	77,946
Restructuring expense	—	137	14,518	2,020
Total operating costs and expenses	82,182	137,002	298,086	503,727
Loss from operations	(64,705)	(67,413)	(245,948)	(167,028)
Interest expense	(304)	(346)	(815)	(413)
Tax credits	20,939	—	20,939	—
Other income, net	1,833	409	5,525	458
Net loss before income taxes	(42,237)	(67,350)	(220,299)	(166,983)
Income tax expense (benefit)	4,733	(1,047)	4,733	(4,433)
Net loss	$ (46,970)	$ (66,303)	$ (225,032)	$ (162,550)
Net loss per share – basic	$ (0.31)	$ (0.45)	$ (1.48)	$ (1.10)
Weighted-average number of shares used in computation of net loss per share – basic	153,699,408	148,285,721	152,226,999	147,443,196
Net loss per share – diluted	$ (0.31)	$ (0.45)	$ (1.48)	$ (1.10)

Weighted-average number of shares used in computation of net loss per share – diluted	153,699,408	148,285,721	152,226,999	147,443,196

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 111,454	$ 241,530
Restricted cash	800	800
Accounts receivable, net	1,320	18,751
Inventories, net - current	63,555	82,210
Prepaid expenses	9,862	15,728
Other current assets	5,248	12,134
Total current assets	192,239	371,153
Non-current inventories, net	27,640	25,436
Property and equipment, net	166,311	189,275
Operating lease right-of-use assets	80,829	85,321
Intangible assets, net	21,539	16,867
Other non-current assets	3,735	6,528
Total assets	$ 492,293	$ 694,580
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 11,109	$ 7,150
Accrued liabilities and other current liabilities	39,920	52,378
Deferred revenue, current	623	1,566
Operating lease liabilities, current	5,109	7,739
Finance lease liabilities, current	1,646	2,362
Total current liabilities	58,407	71,195
Operating leases liabilities, net of current portion	42,961	44,045
Finance lease liabilities, net of current portion	—	849
Other non-current liabilities	2,091	1,997
Total liabilities	103,459	118,086
Stockholders' Equity		
Common stock	2	1
Additional paid-in-capital	831,938	794,567
Accumulated deficit	(443,106)	(218,074)
Total stockholders' equity	388,834	576,494
Total liabilities and stockholders' equity	$ 492,293	$ 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	$ (46,970)	$ (66,303)	$ (225,032)	$ (162,550)
Interest expense	304	346	815	413
Income tax expense (benefit)	4,733	(1,047)	4,733	(4,433)
Depreciation and amortization	13,572	11,404	37,992	32,989
Stock-based compensation	12,687	15,690	38,597	48,515
Tax credits	(20,939)	—	(20,939)	—
Restructuring expense	—	137	14,518	2,020
Disputed vendor payment	—	—	12,000	—
Inventory charges - inventory reserves / warranty reserves	—	2,610	—	45,454
Adjusted EBITDA	$ (36,613)	$ (37,163)	$ (137,316)	$ (37,592)

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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Product revenue	$ 14,757	$ 66,660	$ 46,842	$ 328,465

Cost of product revenue	22,180	50,595	91,349	239,190
Product gross profit (loss)	(7,423)	16,065	(44,507)	89,275
Product gross profit (loss) margin	(50)%	24%	(95)%	27%
Disputed vendor payment	—	—	12,000	—
Inventory charges - inventory reserves / warranty reserves	—	2,610	—	45,454
Adjusted product gross profit (loss)	$ (7,423)	$ 18,675	$ (32,507)	$ 134,729
Adjusted product gross profit (loss) margin	(50)%	28%	(69)%	41%

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023		2023	
	Dollar Amount	Per Diluted Share	Dollar Amount	Per Diluted Share
Net loss / diluted EPS	$ (46,970)	$ (0.31)	$ (225,032)	$ (1.48)
Tax credits	(20,939)	(0.14)	(20,939)	(0.14)
Disputed vendor payment	—	—	12,000	0.08
Restructuring expense	—	—	14,518	0.10
Tax effects	4,325	0.03	4,325	0.03
Adjusted net loss / diluted EPS	$ (63,584)	$ (0.42)	$ (215,128)	$ (1.41)

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