Cue Health Reports First Quarter 2023 Financial Results

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SAN DIEGO--(BUSINESS WIRE)--May 10, 2023-- Cue Health Inc. ("Cue") (Nasdaq: HLTH), a healthcare technology company, today reported financial results for the first quarter 2023.

Recent Highlights

- Reported first quarter revenue of $24.8 million
- Granted U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for Cue Mpox (Monkeypox) Molecular Test for point-of-care use
- Submitted the Cue RSV Molecular Test as a De Novo submission to the FDA for home and point-of-care use during the second quarter, as planned
- Launched Cue Pharmacy, a new Cue Integrated Care Platform expansion to enable individuals to connect with a healthcare provider and be prescribed common medications as a subscription
- Launched Cue Lab, a collection of at-home test kits for a wide variety of diagnostic panels and standalone tests providing personalized care from the convenience and privacy of home
- Cue Strep Molecular Test is on track with clinical studies ongoing and a submission to the FDA expected in the second half of 2023
- Cue Chlamydia + Gonorrhea Molecular Test is on track with clinical studies ongoing and a submission to the FDA expected in the second half of 2023
- Achieved our previously announced cost reduction goal of $100 million of annualized run rate cost savings in the first quarter, earlier than anticipated
- Initiated additional cost reduction efforts expected to contribute an additional $50 million of annualized savings, bringing the total goal to $150 million of annualized cost savings
- Ended the first quarter with cash and cash equivalents of $178.2 million and no debt obligations

“We reached several significant milestones including launching Cue Pharmacy, Cue Lab, and receiving authorization for the Cue Mpox test, our second FDA authorization,” said Ayub Khattak, Chairman and CEO of Cue Health. “We have four Cue tests submitted to the FDA, including for RSV and a Flu + COVID combo test. We are executing our strategic plan including expanding the menu on the Cue Health Monitoring System as well as expanding the offering for the Cue Integrated Care Platform. We have cut our annualized costs by an expected $150 million to weather the macroeconomic climate as we make significant progress on our plan.”

First Quarter 2023 Financial Results

Revenue was $24.8 million for the first quarter of 2023. Private sector revenue was $24.2 million or 98% of total revenue with strong ordering from existing customers. Public sector revenue was $0.6 million and disposable test cartridge revenue was $22.4 million.

GAAP product gross profit margin was a loss of 63% in the first quarter of 2023. Adjusted product gross profit margin was a loss of 14% excluding a disputed payment charge impacting cost of product revenue.

GAAP operating expenses in the first quarter of 2023 were $80.8 million, excluding cost of revenue, including $7.9 million of restructuring expense related to the implementation of the cost reduction plan. On an adjusted basis, excluding the impact of the restructuring expense, operating expenses were $72.9 million or a 23% decrease compared to $94.6 million in the fourth quarter of 2022.

GAAP net loss in the first quarter of 2023 was $94.2 million and earnings per diluted share was a loss of $0.62. Cue's adjusted net loss was $74.3 million and adjusted earnings per diluted share was a loss of $0.48. Adjusted EBITDA was a loss of $47.6 million.

Cash and cash equivalents were $178.2 million as of March 31, 2023 and the company continues to operate with no debt obligations.

Guidance

Cue Health expects second quarter 2023 revenues in the range of $8 million to $10 million reflecting an expected shift to a seasonal respiratory pattern for COVID testing volumes.

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 and future performance and our guidance, including second 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 March 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 COVID-19 Molecular Test 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.

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 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, disputed vendor payment.

Adjusted product gross profit (loss) is defined as product gross profit (loss), before disputed vendor payment.

Adjusted net (loss) income is defined as Net (loss) income, 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.

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

	Three Months Ended March 31,	
	2023	**2022**
Revenue		
Product revenue	$ 24,494	$ 177,454
Grant and other revenue	271	1,956
Total revenue	24,765	179,410
Operating costs and expenses:		
Cost of product revenue	39,823	86,697
Sales and marketing	11,248	34,168
Research and development	44,733	28,787
General and administrative	16,938	26,910
Restructuring expense	7,873	—
Total operating costs and expenses	120,615	176,562
(Loss) income from operations	(95,850)	2,848
Interest expense	(220)	(51)
Other income, net	1,872	6
Net (loss) income before income taxes	(94,198)	2,803
Income tax (benefit) expense	—	—

Net (loss) income	$ (94,198)	$ 2,803
Net (loss) income per share – basic	$ (0.62)	$ 0.02
Weighted-average number of shares used in computation of net (loss) income per share – basic	151,083,716	146,526,370
Net (loss) income per share – diluted	$ (0.62)	$ 0.02
Weighted-average number of shares used in computation of net (loss) income per share – diluted	151,083,716	153,036,804

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 178,201	$ 241,530
Restricted cash	800	800
Accounts receivable, net	9,799	18,751
Inventories, current	82,006	82,210
Prepaid expenses	11,617	15,728
Other current assets	4,574	12,134
Total current assets	286,997	371,153
Non-current inventories	27,718	25,436
Property and equipment, net	184,197	189,275
Operating lease right-of-use assets	84,542	85,321
Intangible assets, net	19,774	16,867
Other non-current assets	5,333	6,528
Total assets	$ 608,561	$ 694,580
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 16,644	$ 7,150
Accrued liabilities and other current liabilities	40,173	52,378
Deferred revenue, current	754	1,566
Operating lease liabilities, current	7,739	7,739
Finance lease liabilities, current	2,148	2,362
Total current liabilities	67,458	71,195
Operating leases liabilities, net of current portion	42,826	44,045
Finance lease liabilities, net of current portion	417	849
Other non-current liabilities	1,997	1,997
Total liabilities	112,698	118,086
Stockholders' Equity		
Common stock, $0.00001 par value; 500,000,000 and 500,000,000 shares authorized, 151,567,650 and 150,406,014 issued and outstanding at March 31, 2023 and December 31, 2022, respectively	2	1
Additional paid-in-capital	808,133	794,567
Accumulated deficit	(312,272)	(218,074)
Total stockholders' equity	495,863	576,494
Total liabilities and stockholders' equity	$ 608,561	$ 694,580

Non-GAAP Measures
(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 March 31,	
	2023	2022
Net (loss) income	$ (94,198)	$ 2,803
Interest expense	220	51
Depreciation and amortization	12,064	10,606
Stock-based compensation	14,407	16,035
Restructuring expense	7,873	—
Disputed vendor payment	12,000	—
Adjusted EBITDA	$ (47,634)	$ 29,495

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 March 31,	
	2023	2022

Product revenue	$ 24,494	$ 177,454
Cost of product revenue	39,823	86,697
Product gross profit (loss)	(15,329)	90,757
Product gross profit (loss) margin	(63)%	51%
Disputed vendor payment	12,000	—
Adjusted product gross profit (loss)	$ (3,329)	$ 90,757
Adjusted product gross profit (loss) margin	(14)%	51%

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 March 31, 2023	
	Dollar Amount	Per Diluted Share
Net (loss) income / diluted EPS	$ (94,198)	$ (0.62)
Disputed vendor payment	12,000	0.08
Restructuring expense	7,873	0.06
Tax effects	—	—
Adjusted net (loss) income / diluted EPS	$ (74,325)	$ (0.48)

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