

**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 3, 2023**

CUE HEALTH INC.

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

Delaware

(State or other jurisdiction of incorporation)

001-40590

(Commission File Number)

27-1562193

(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 7.01 Regulation FD Disclosure

On August 3, 2023, Cue Health Inc. (the "Company") issued a press release announcing that it has been awarded a new contract for approximately \$28 million by the Biomedical Advanced Research and Development Authority, part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services ("BARDA"), to develop an Influenza A/B, Respiratory Syncytial Virus ("RSV"), and COVID-19 molecular multiplex test for both over-the-counter ("OTC") and point-of-care ("POC") use.

A copy of the Company's press release dated August 3, 2023 announcing the Company's award from BARDA to develop an Influenza A/B, RSV, and COVID-19 molecular multiplex test is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 7.01.

The information contained in Item 7.01 of this Current Report on Form 8-K, including the information contained in Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of such section, and such information shall not be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended.

8.01 Other Events

On August 3, 2023, the Company was awarded a new contract for approximately \$28 million by BARDA to develop an Influenza A/B, RSV, and COVID-19 molecular multiplex test for both OTC and POC use.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release issued by Cue Health Inc. dated August 3, 2023
	104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

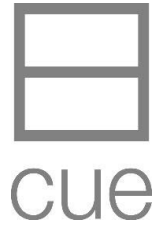
SIGNATURES

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: August 3, 2023

Cue Health Inc.

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



Cue Health Awarded New \$28 Million Federal Contract to Develop Flu A/B, RSV, COVID-19 Molecular Multiplex Test for Both Over-the-Counter and Point-of-Care Use

The test will be designed to detect and differentiate between the four viruses and deliver results in approximately 25 minutes

SAN DIEGO, CA, August 3, 2023 – Cue Health (Nasdaq: HLTH), a healthcare technology company, today announced that it has been awarded a new approximately \$28 million contract by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services (HHS), to develop a Flu A/B, RSV, and COVID-19 molecular multiplex test for both over-the-counter (OTC) and point-of-care (POC) use. Cue's test would detect and differentiate between influenza A, influenza B, respiratory syncytial virus (RSV), and COVID-19 simultaneously, with results delivered in approximately 25 minutes to connected smart devices.

The company has also applied with the U.S. FDA for Emergency Use Authorization (EUA) for its Cue Flu + COVID-19 Molecular Test for at-home and point-of-care (POC) use. Cue also requested De Novo classification from the FDA for the Cue RSV Molecular Test for at-home and point-of-care use. In March, the company received an EUA from the FDA for the Cue Mpox (Monkeypox) Molecular Test, which can be performed at the point-of-care at any CLIA-waived facility.

Influenza, RSV, and COVID-19 are common respiratory viruses that can be serious, especially for older adults, those with weakened immune systems, and infants. Combined, these viruses are responsible for hundreds of thousands of hospitalizations each year. RSV is the leading cause of hospitalization among children less than one year of age in the U.S. The flu alone caused between 27 million and 54 million illnesses last respiratory season (2022-2023), according to the Centers for Disease Control and Prevention (CDC). And approximately 7,000 people are still admitted to the hospital per week due to COVID-19 in the U.S, per CDC data as of July 15, 2023.

“By expanding our successful partnership with BARDA, we’re able to meet a critical health need by utilizing Cue’s diagnostic platform to detect and differentiate between some of the most common respiratory viruses that have similar symptoms but distinct treatment options,” said Ayub Khattak, Chairman and CEO of Cue Health. “We expect this test will arm individuals and their providers with actionable information that can reduce community spread, increase the efficacy of treatment, and help lead to better health outcomes. We’re honored to be called upon once again to partner with BARDA to strengthen the nation’s emergency preparedness, and in doing so, empower more people to live their healthiest lives.”

Cue was awarded a contract by BARDA in 2020 to accelerate the development, validation, and FDA clearance of its COVID-19 test, which was the first molecular test to receive FDA Emergency Use Authorization for at-home and over-the-counter use without a prescription. Cue also recently received De Novo authorization from the FDA for the same COVID-19 test (Cue COVID-19 Molecular Test), which was the first De Novo granted for any home use respiratory test available without a prescription. Cue's work with BARDA began in 2018 when the company received base funding to accelerate the development and regulatory validation of over-the-counter and professional use flu test cartridges, the Cue Health Monitoring System, and cartridge manufacturing technology.

The Cue molecular tests all run on the Cue Health Monitoring System (Reader), which has an installed base of more than a quarter million. Cue's molecular tests are manufactured at its San Diego headquarters, where production and assembly lines have the built-in capability to pivot between manufacturing different Cue diagnostic tests in near real-time.

This project is being funded in whole or in part with federal funds from the Department of Health and Human Services; Administration of Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, under contract number 75A50123C00036.

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 + 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 those regarding Cue's diagnostic platform, its partnership with BARDA, and statements made by Cue's CEO, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements". The words, without limitation, "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" 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 future diagnostic test menu 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 Cue's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 filed with the SEC on May 10, 2023. 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. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

MEDIA INQUIRIES
press@cuehealth.com