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): **December 21, 2021**

(Exact name of registrant as specified in its charter)

CHEMBIO DIAGNOSTICS, INC.

Nevada	**0-30379**	**88-0425691**
(State or Other Jurisdiction of Incorporation or Organization)	*(Commission File Number)*	*(I.R.S. Employer Identification No.)*

555 Wireless Blvd.
Hauppauge, NY 11788
(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: **(631) 924-1135**

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:

☐ 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	Name of each exchange on which registered
Common Stock, $0.01 par value	CEMI	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 8.01 Other Matters.

On December 21, 2021, the U.S. Food and Drug Administration, or FDA, notified us that it was declining to review our application for an emergency use authorization, or EUA, for the DPP Respiratory Antigen Panel. The DPP Respiratory Antigen Panel is a test system designed, when used in combination with the DPP Micro Reader optical analyzer, to provide simultaneous, discrete and differential detection of SARS-CoV-2, Influenza A and Influenza B antigens from a single patient respiratory specimen, such as a nasal swab, in approximately 20 minutes.

As we disclosed previously, during the clinical trials for the DPP Respiratory Antigen Panel we encountered delays resulting principally from the near absence of influenza in the United States. As a result, we had incorporated in our clinical data for the DPP Respiratory Antigen Panel foreign-sourced influenza-positive samples preserved in viral transport media, which we intended to mitigate the impact of the extremely low incidence of influenza in the United States.

The FDA notice informed us that, in order to proceed, we will need to prospectively collect Influenza A and Influenza B samples and then submit a new EUA application for the DPP Respiratory Antigen Panel. We cannot assure you that we will be able to compile the additional specimens requested by the FDA in a timely manner or at all, and therefore we cannot assure you that we will be able to submit a new EUA application for the DPP Respiratory Antigen Panel at any specific time in the future or at all.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be filed on its behalf by the undersigned hereunto duly authorized.

CHEMBIO DIAGNOSTICS, INC.

Dated: December 28, 2021

By: /s/ Richard L. Eberly
Chief Executive Officer and President