

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 1, 2021**



**CHEMBIO DIAGNOSTICS, INC.**

(Exact name of registrant as specified in its charter)

**Nevada**  
(State or Other Jurisdiction of Incorporation or Organization)

**0-30379**  
(Commission File Number)

**88-0425691**  
(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. ☐

*Request for Additional Data Related to CLIA Waiver Submission for DPP HIV-Syphilis Test System*

On December 1, 2021, we received notice from the U.S. Food and Drug Administration, or FDA, that the FDA would require additional data related to our Clinical Laboratory Improvement Amendment, or CLIA, waiver submission for the DPP HIV-Syphilis test system. We are in active discussions with the FDA in connection with the FDA's review of our submission and we intend to seek to comply with the FDA's request for additional data, but the process of seeking additional data will extend, for a currently undeterminable period, our process for seeking a CLIA waiver for the DPP HIV-Syphilis test system. We cannot assure you that we will be able to compile the additional data requested by the FDA in a timely manner or at all, and therefore we cannot assure you that a CLIA waiver will be granted with respect to the DPP HIV-Syphilis test system at any specific time in the future or at all.

*Scheduled Expiration of BARDA Agreement*

Our contract, which we refer to as the BARDA Agreement, dated December 2, 2020 with the Biomedical Advanced Research and Development Authority, or BARDA (part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response), expired in accordance with its terms on December 2, 2021. Under the BARDA Agreement, up to \$12.7 million of awards were available from BARDA in order to assist us in (a) developing, and requesting an EUA from the FDA for, the DPP Respiratory Panel and (b) performing the clinical trials for and submitting the DPP SARS-CoV-2 Antigen test system to the FDA, for 510(k) clearance.

As of September 30, 2021 we had earned a total of \$9.6 million in grant income under the BARDA Agreement, and from October 1, 2021 through December 2, 2021 we earned an additional \$2.9 million of grant income under the BARDA Agreement. As a result, we earned \$12.5 million of the \$12.7 million available under the BARDA Agreement, with the remaining \$0.2 million having not been earned because it was contingent on our receiving an emergency use authorization for the DPP Respiratory Panel by December 2, 2021.

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## 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 8, 2021

By: /s/ Richard L. Eberly

Chief Executive Officer and President

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