

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 3, 2020



CHEMBIO DIAGNOSTICS, INC.

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.

Item 8.01 Other Matters.

Contract with Biomedical Advanced Research and Development Authority (BARDA)

On December 2, 2020, we issued a press release titled “Chembio Diagnostics Awarded \$12.7 Million by BARDA for Development of Rapid DPP Respiratory Antigen Panel and 510(k) Submission of the Rapid DPP SARS-CoV-2 Antigen Test System.” A copy of the press release is included as Exhibit 99.1 to this report.

Response Letter from Food and Drug Administration (FDA)

On December 3, 2020, we received from the FDA a letter responding to the request we submitted in September 2020 for an emergency use authorization, or EUA, for the DPP SARS CoV-2 IgM/IgG with DPP Micro Reader, which we refer to as the IgM/IgG EUA, intended for use in the detection of antibodies to SARS-CoV-2. The response letter states that, given the volume of EUA requests it has received, the FDA is prioritizing review of EUA requests for tests, taking into account a variety of factors such as the public health need for the product and the availability of the product. The response letter further states that the FDA has determined that review of the IgM/IgG EUA request is not a priority because, for example, authorization of the test would have relatively limited impact on testing accessibility or testing capacity, and therefore the FDA has declined to review the IgM/IgG EUA request at this time.

We intend to work with the FDA to seek to establish priority for our IgM/IgG EUA, based on our belief that the DPP SARS CoV-2 IgM/IgG with DPP Micro Reader would increase testing accessibility. We cannot assure you, however, that we will be successful in our efforts to obtain FDA review of our IgM/IgG EUA or that FDA authorization of the IgM/IgG EUA will ever be obtained.

The response letter received with respect to our IgM/IgG EUA has no effect on our pending request, which we submitted in October 2020, for an EUA for the DPP SARS-CoV-2 Antigen test system.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibit*

Exhibit No.	Description
99.1	Press release of Chembio Diagnostics, Inc., dated December 2, 2020, titled “Chembio Diagnostics Awarded \$12.7 Million by BARDA for Development of Rapid DPP Respiratory Antigen Panel and 510(k) Submission of the Rapid DPP SARS-CoV-2 Antigen Test System.”
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 4, 2020

By: /s/ RICHARD L. EBERLY

Chief Executive Officer and President

Chembio Diagnostics Awarded \$12.7 Million by BARDA for Development of Rapid DPP Respiratory Antigen Panel and 510(k) Submission of the Rapid DPP SARS-CoV-2 Antigen Test System

HAUPPAUGE, NY, December 2, 2020 -- Chembio Diagnostics, Inc. (Nasdaq: CEMI) a leading point-of-care diagnostic company focused on infectious diseases, today announced it has been awarded a contract from the Biomedical Advanced Research and Development Authority (BARDA), which is part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response. The contract will support the development and pursuit of U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for a rapid, multiplex DPP Respiratory Antigen Panel point-of-care test system using Chembio's proprietary DPP technology for the upcoming flu season.

The contract also supports preparation of a submission in pursuit of FDA 510(k) clearance for the rapid DPP SARS-CoV-2 Antigen test system that was recently submitted to the FDA for an EUA. The award totals \$12,691,726.

The DPP Respiratory Antigen Panel test system is intended to provide simultaneous, discrete, and differential detection of Influenza A, Influenza B, and SARS-CoV-2 antigens from a single patient respiratory specimen, such as a nasal or nasopharyngeal swab. It is expected to provide results in approximately 20 minutes and be run on Chembio's DPP Micro Reader analyzer. The system is intended to enable appropriate clinical management of patients with suspected respiratory infections and assist in the containment of COVID-19 cases during the flu season.

The U.S. Centers for Disease Control and Prevention has recognized that contemporaneous testing for the three viruses will provide public health officials with information to help limit the spread of the viruses while conserving scarce resources.

A second portion of the contract will support the verification, process validation, and production of clinical validation data to be included in a submission to the FDA for 510(k) clearance and CLIA-waiver for the DPP SARS-CoV-2 Antigen test system. This system consists of a DPP SARS-CoV-2 Antigen test cartridge and a DPP Micro Reader analyzer and is designed to use a minimally invasive nasal swab to detect SARS-CoV-2 viral antigens in only 20 minutes. The system was developed by Chembio and submitted to the FDA for an EUA on October 15, 2020, with support from BARDA under contract number 75A50120C00138.

"We are honored to again partner with BARDA and appreciate their support as we endeavor on the shared mission to expand and decentralize COVID-19 testing," stated Richard Eberly, Chembio's President and Chief Executive Officer. "The DPP technology is highly versatile, and these new product and regulatory objectives illustrate our commitment to offering virus detection for diagnosis at the point-of-care. We believe rapid, point-of-care tests can improve clinical outcomes and play a major role in combating this ongoing pandemic, especially during the upcoming flu season."

About the DPP Rapid Test Platform

Chembio's proprietary DPP technology platform provides high-quality, rapid diagnostic results in 15 to 20 minutes using a small drop of blood from the fingertip or alternative samples. Through advanced multiplexing, the DPP platform can detect up to eight, distinct test results from a single patient sample, delivering greater clinical value than other rapid tests. For certain applications, Chembio's easy-to-use, highly portable, battery-operated DPP Micro Reader optical analyzer then reports accurate results in approximately 15 seconds, making it well-suited for decentralized testing where real-time results enable patients to be clinically assessed while they are still on-site. Objective results produced by the DPP Micro Reader reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many rapid tests.

Chembio's portfolio of DPP-based point-of-care tests with FDA regulatory approvals include the DPP HIV-Syphilis System (PMA approved), DPP HIV 1/2 Assay (PMA approved and CLIA waived), DPP Zika IgM System (510(k)), and DPP Ebola Antigen System (EUA). Additionally, DPP-based tests have received regulatory approvals from the World Health Organization, CE-Mark, Agência Nacional de Vigilância Sanitária (ANVISA), and other global organizations, where they aid in the detection and diagnosis of several other critical diseases and conditions.

All DPP tests are developed and manufactured in the United States and are the subject of a range of domestic and global patents and patents pending.

About Chembio Diagnostics

Chembio is a leading point-of-care diagnostics company focused on detecting and diagnosing infectious diseases, including COVID-19, sexually transmitted disease, and fever and tropical disease. Coupled with Chembio's extensive scientific expertise, its novel DPP technology offers broad market applications beyond infectious disease. Chembio's products are sold globally, directly and through distributors, to hospitals and clinics, physician offices, clinical laboratories, public health organizations, government agencies, and consumers. Learn more at www.chembio.com.

About the Project

Chembio will use the federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50121P00012.

Forward-Looking Statements

Statements contained in this release that are not historical facts may be forward-looking statements within the meaning of the Securities Act of 1933, as amended. Forward-looking statements include statements regarding the intent, belief or current expectations of Chembio and its management with respect to the development of, and obtaining an EUA for, a COVID-19 point-of-care antigen system. Such statements reflect management's current views, are based on certain assumptions, and involve risks and uncertainties. Actual results, events, or performance may differ materially from forward-looking statements due to a number of important factors, and will be dependent upon a variety of factors, including, but not limited to: Chembio's research, development and commercialization efforts may not result in its successfully and timely developing and commercializing the DPP Respiratory Antigen Panel point-of-care test system or the DPP SARS-CoV-2 Antigen test system; Chembio may be unable to anticipate or respond to changes in FDA regulatory requirements with respect to its proposed DPP Respiratory Antigen Panel point-of-care test system or DPP SARS-CoV-2 Antigen test system, or otherwise may be unable to obtain or maintain an EUA or other necessary regulatory approvals; potential customers may not adopt point-of-care antigen systems to the extent expected by Chembio; and Chembio may not be able to compete successfully with other companies that have developed, or develop in the future, COVID-19 antigen detection systems, some of which companies have substantially greater resources than Chembio. Chembio undertakes no obligation to publicly update forward-looking statements in this release to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to the forward-looking statements or the occurrence of unanticipated events. Factors that may impact Chembio's success are more fully disclosed in Chembio's public filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and its subsequent Quarterly Reports on Form 10-Q, particularly under the heading "Risk Factors." Readers should interpret many of the risks identified in these reports as being heightened as a result of the ongoing and numerous adverse impacts of the COVID-19 pandemic.

DPP is Chembio's registered trademark. For convenience, this trademark appears in this release without ® symbols, but that practice does not mean that Chembio will not assert, to the fullest extent under applicable law, its rights to the trademark.

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