

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): May 4, 2020



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. ☐

Item 7.01 Regulation FD Disclosure.

On May 4, 2020, we issued a press release entitled “Chembio Diagnostics Attains CE Marking for DPP COVID-19 System for IgG and IgM Antibodies.” A copy of the press release is furnished as Exhibit 99.1 to this report.

The information contained in this Item 7.01 and in the press release furnished as Exhibit 99.1 to this report shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by us whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press release of Chembio Diagnostics, Inc. dated May 4, 2020

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: May 4, 2020

By: /s/ NEIL A. GOLDMAN

Neil A. Goldman

Executive Vice President and Chief Financial Officer



Chembio Diagnostics Attains CE Marking for DPP COVID-19 System for IgG and IgM Antibodies

HAUPPAUGE, NY, May 4, 2020 -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostic company focused on infectious diseases, today announced it has attained the CE Marking for its DPP COVID-19 System. The CE Marking represents the ability to commercialize the system within the member states of the European Union and the Caribbean region, except for Puerto Rico.

"The CE Marking is another significant accomplishment for Chembio and expands the market opportunity for our DPP COVID-19 rapid serological test meaningfully," stated Rick Eberly, Chembio's Chief Executive Officer. "We are pleased to begin commercializing and continuing to support the decentralization that is needed to address the ongoing demand for testing. We believe our platform will add tremendous value in determining the IgM and IgG values in a variety of settings."

The DPP COVID-19 System is a serological test and analyzer that provides numerical readings for both IgM and IgG antibody levels within 15 minutes from a simple finger stick drop of blood. Both Chembio's Micro Reader 1 and Micro Reader 2 analyzers are compatible with the test. The system is approved for use in the U.S. through the Emergency Use Authorization and in Brazil under ANVISA approval.

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. The company's patented DPP technology platform, which uses a small drop of blood from the fingertip, provides high-quality, cost-effective results in approximately 15 minutes. 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.

Forward-Looking Statements

The second paragraph of this press release contains statements concerning the intent, belief and current expectations of Chembio and its management that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements reflect management's current views based on certain assumptions, and they involve risks and uncertainties. Actual results, events, or performance may differ materially from the forward-looking statements due to a number of important factors, and will be dependent upon a variety of factors, including, but not limited to: the success of Chembio's research, development and commercialization efforts for its DPP COVID-19 System; Chembio's ability to maintain existing, and timely obtain additional, regulatory approvals with respect to the DPP COVID-19 System; the potential development of competing diagnostic tests for the DPP COVID-19 System; the unpredictability associated with the COVID-19 pandemic; Chembio's retention of key personnel; changes in U.S. trade policy; and other risks described in public reports filed by Chembio with the Securities and Exchange Commission, including under the caption "Risk Factors" in Chembio's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and subsequent filings. Chembio undertakes no obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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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