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): **March 3, 2020**

CHEMBIO DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

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

3661 Horseblock Road, Medford, New York 11763
(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))

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 Events.

On February 21, 2020, we received a “not approvable” letter from the U.S. Food and Drug Administration, or FDA, with respect to our pre-market approval, or PMA, submission on our DPP HIV-Syphilis multiplex test for commercial use in the United States. Our DPP HIV-Syphilis System is a single-use, 15-minute screening test for the simultaneous detection of antibodies to HIV types 1 and 2 and *Treponema pallidum*, the bacteria that causes syphilis. The FDA’s letter indicates that the PMA submission was not approvable in its current form because of reproducibility issues at one of three test sites used in the submission.

In a separate communication, the FDA confirmed to us that the syphilis portion of the PMA submission was acceptable, as was data relating to the inclusion of the pregnant women.

On March 3, 2020, we issued a press release titled “Chembio Diagnostics Provides Update on Regulatory Status of DPP HIV-Syphilis System,” which describes our current actions and plans with respect to the FDA’s letter. A copy of the press release is included as Exhibit 99.1 to this report and is incorporated in this report by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press release of Chembio Diagnostics, Inc. dated March 3, 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: March 3, 2020

By: /s/ NEIL A. GOLDMAN
Neil A. Goldman
Executive Vice President and Chief Financial Officer

Exhibit 99.1

Chembio Diagnostics Provides Update on Regulatory Status of DPP HIV-Syphilis System

Medford, NY – March 3, 2020 - Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, is providing an update on the FDA Premarket Approval (PMA) application for Chembio's DPP HIV-Syphilis Assay System. The FDA has confirmed that, of the items that had been open for the PMA review, the Syphilis arm of the study was acceptable, as were the results as they relate to the inclusion of pregnant women. As indicated by the FDA on February 21, 2020, the only remaining item requested of the company is to repeat the reproducibility study, as one of the sites in the trial reported greater variability compared to the other sites. Chembio has both addressed and discussed with the FDA what it deems to be the underlying cause of the variance, and it has already initiated the reproducibility study required by the FDA. In parallel, the company has accelerated the studies for a CLIA waiver, which can be submitted upon FDA approval of the PMA application. These efforts reflect the company's continuing focus on both the achievement of the PMA milestone and the timing of ultimate approval with the CLIA waiver.

"We are continuing to work collaboratively with the FDA on a path toward PMA approval," said Gail Page, Chembio's Interim Chief Executive Officer. "We are pleased to report that the Syphilis data and the pregnant women data were accepted. We remain confident in our test, and in our team's ability to both satisfy the FDA's reproducibility study requirements and accelerate the CLIA approval, which is key to our target market."

Chembio's DPP HIV-Syphilis System is a single-use, 15-minute screening test for the simultaneous detection of antibodies to HIV types 1 and 2 and *Treponema pallidum*, the bacteria that causes syphilis. It uses a 10-microliter sample of fingerstick of whole blood, venous whole blood or plasma. The test is highly sensitive and specific, has a built-in procedural control, can be stored at room temperature, and has a shelf life of up to 24 months.

About Chembio Diagnostics
Chembio is a leading point-of-care diagnostics company focused on detecting and diagnosing infectious diseases. 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, a number of which applications are under active development with collaboration partners. 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 Statement
The statement contained in the first two paragraphs of this release with respect to the receipt of FDA approval of the PMA application for the DPP HIV-Syphilis test and of a CLIA waiver, and the anticipated timing of receipt of such approval and waiver, are not historical facts and constitute forward-looking statements within the meaning of the Securities Act of 1933, as amended. Such statements, which are estimates only, reflect management's current views, are based on certain assumptions, and involve risks and uncertainties. Actual results, events, or performance may differ materially from the above forward-looking statements due to a number of important factors, and there can be no assurance that FDA approval of the PMA application for the DPP HIV-Syphilis test or the CLIA waiver will be received by the company when anticipated or at all. Chembio undertakes no obligation to publicly update these forward-looking statements to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to these forward-looking statements or the occurrence of unanticipated events. Factors that may impact Chembio's success are more fully disclosed in Chembio's most recent public filings with the U.S. Securities and Exchange Commission.

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.

Investor contact:
Lynn Pieper Lewis
Gilmartin Group
(415) 937-5402
investor@chembio.com