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): September 29, 2017 (September 28, 2017)

CHEMBIO DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**0-30379**	**88-0425691**
(State or other jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification Number)

3661 Horseblock Road
Medford, NY 11763
(Address of principal executive offices)
631-924-1135
(Registrant's Telephone Number)

N/A
(Former name or former address, if changed since last report)

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))

ITEM 8.01. OTHER EVENTS.

On September 28, 2017, the Company issued a press release entitled "Chembio Diagnostics Receives FDA Emergency Use Authorization for the First Rapid Zika IgM Test". A copy of the press release is included herewith as Exhibit 99.1 and incorporated herein by reference.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

Exhibits.

99.1 Press Release entitled "Chembio Diagnostics Receives FDA Emergency Use Authorization for the First Rapid Zika IgM Test" dated September 28, 2017.

SIGNATURES

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

September 29, 2017 Chembio Diagnostics, Inc.

By: /s/ Sharon Klugewicz
Sharon Klugewicz
Acting Chief Executive Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release entitled "Chembio Diagnostics Receives FDA Emergency Use Authorization for the First Rapid Zika IgM Test" dated September 28, 2017.

Chembio Diagnostics Receives FDA Emergency Use Authorization for the First Rapid Zika IgM Test

MEDFORD, N.Y., September 28, 2017 -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leader in point-of-care (POC) diagnostic tests for infectious diseases, today announced that it has received U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for its DPP® Zika System.

The DPP® Zika System, which provides results in 15-20 minutes from only 10µL of blood, is the first rapid Zika test to receive an FDA EUA for use in high and moderate complexity CLIA certified laboratories. The DPP® Zika System includes the DPP® Zika IgM Assay and DPP® Micro Reader, which is portable, hand-held, easy to use, and can reduce the risk of human error during test interpretation.

The test is authorized for the presumptive detection of Zika virus IgM antibodies in fingerstick whole blood, EDTA venous whole blood, EDTA plasma (each collected alongside a patient-matched serum specimen) or serum (plain or separation gel) specimens collected from individuals meeting CDC Zika virus clinical and/or epidemiological criteria, from 8 days of on-set and up to 12 weeks.

The DPP® Zika System has been authorized by FDA under an EUA for use in authorized laboratories in the United States that are certified under the Clinical Laboratory Improvement Amendment (CLIA), to perform high or moderate complexity tests, or by similarly qualified non-U.S. laboratories. The DPP® Zika System utilizes the patented technology platform used in the Company's FDA approved and CLIA waived DPP® HIV 1/2 Assay. The DPP® Zika System has not been FDA cleared or approved and has been authorized only for the diagnosis of Zika virus infection and not for any other viruses or pathogens. The DPP® Zika System is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Sharon Klugewicz, acting Chief Executive Officer, commented, "We are delighted to receive FDA Emergency Use Authorization for our DPP® Zika System and we appreciate the close interaction with the FDA throughout the EUA process. We believe the deployment of a rapid test for the presumptive detection of human IgM antibodies to Zika virus will be a critical tool in dealing with the ongoing spread of Zika virus, and we plan to make the DPP® Zika System immediately available in the U.S., Puerto Rico, and the U.S. Virgin Islands."

This project has been funded in part with federal funds from the U.S. Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA). Chembio has been awarded a contract for $5.9 million to develop the product and obtain FDA EUA authorization and FDA 510(k) clearance with the potential of $13.2 million in total funding from BARDA if all options are exercised, to advance clinical development of its DPP® Zika System and its DPP® Zika / Dengue / Chikungunya System.

About Chembio Diagnostics

Chembio Diagnostics, Inc. develops, manufactures, licenses and markets rapid diagnostic tests in the growing $8.0 billion POC testing market. The Company markets its products directly and through third-party distributors under the brand names: DPP®, STAT-PAK® and SURE CHECK®.

Chembio has developed and patented the DPP® technology platform, which offers significant advantages over traditional POC lateral-flow technologies and provides the Company with a significant pipeline of business opportunities in the area of sexually transmitted disease, tropical and fever disease, and technology collaborations.

Headquartered in Medford, NY, Chembio is registered with the U.S. Food and Drug Administration (FDA) as well as the U.S. Department of Agriculture (USDA), and is certified for the global market under the International Standards Organization (ISO) directive 13485. Each of Chembio Diagnostic Systems, Inc. and Chembio Diagnostics Malaysia Sdn. Bhd is a wholly-owned subsidiary of Chembio Diagnostics, Inc. For more information, please visit: www.chembio.com.

Forward-Looking Statements

Statements contained herein 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 the Company and its management. 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 will be dependent upon a variety of factors, including, but not limited to Chembio's ability to obtain additional financing and to obtain regulatory approvals in a timely manner, as well as the demand for Chembio's products. 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.

Contacts:

Vida Strategic Partners
Stephanie C. Diaz (investor relations)
(415) 675-7401
sdiaz@vidasp.com

Tim Brons (media)
(415) 675-7402
tbrons@vidasp.com