
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 25, 2018 (May 24, 2018)



CHEMBIO DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of Incorporation)

0-30379

(Commission File Number)

88-0425691

(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 24, 2018, the Company issued a press release titled “Chembio Diagnostics Announces Agreement with Bio-Manguinhos to Commercialize Point-of-Care Tests for Dengue, Zika and Chikungunya in Brazil”. A copy of the press release is provided herewith as Exhibit 99.1.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

Exhibits.

- 99.1 Press Release, dated May 24, 2018, titled “Chembio Diagnostics Announces Agreement with Bio-Manguinhos to Commercialize Point-of-Care Tests for Dengue, Zika and Chikungunya in Brazil”.

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.

May 25, 2018

Chembio Diagnostics, Inc.

By: /s/ John J. Sperzel III
John J. Sperzel III
Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated May 24, 2018, titled “Chembio Diagnostics Announces Agreement with Bio-Manguinhos to Commercialize Point-of-Care Tests for Dengue, Zika and Chikungunya in Brazil”.



**Chembio Diagnostics Announces Agreement with Bio-Manguinhos to Commercialize
Point-of-Care Tests for Dengue, Zika and Chikungunya in Brazil**

MEDFORD, NY, May 24, 2018 -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leader in point-of-care ("POC") diagnostic tests for infectious diseases, today announced the signing of a long-term agreement with Bio-Manguinhos to commercialize Chembio's POC diagnostic tests for Dengue, Zika and Chikungunya in Brazil.

Bio-Manguinhos is a unit of the Oswaldo Cruz Foundation, a government agency responsible for the development and production of vaccines, diagnostics and biopharmaceuticals, primarily to meet the demands of Brazil's national public health system. Over the last 14 years, Chembio and Bio-Manguinhos have successfully collaborated to develop and commercialize a number of POC diagnostics, including tests for HIV, Syphilis, and Leishmania.

In 2016, Chembio announced a collaboration with Bio-Manguinhos to develop POC tests for Dengue, Zika and Chikungunya, as both standalone and multiplex tests. Since that time, using Chembio's patented DPP® technology platform, which detects antibodies in less than 15 minutes using a tiny (10uL) drop of blood from the fingertip, Chembio has accomplished:

- Development of new point-of-care DPP® tests for Dengue, Zika, and Chikungunya as both standalone and multiplex tests.
- Clinical testing of the new DPP® tests and DPP® Micro Reader in numerous regions, including the United States, Africa, Latin America and Southeast Asia.
- Regulatory approval for the DPP® Zika System, including Brazil Agência Nacional de Vigilância Sanitária approval, U.S. Food and Drug Administration Emergency Use Authorization, and CE mark.
- A conditional agreement from UNICEF for purchases of the Company's DPP® Zika System, which includes a purchase commitment of \$1.5 million and possible additional purchases of up to \$3.4 million.

"We are pleased to announce a long-term agreement with Bio-Manguinhos, which is an important step toward commercializing the DPP® Dengue, Zika and Chikungunya tests in Brazil," stated John Sperzel, Chembio's Chief Executive Officer. "Despite improved prevention measures to combat the viruses, the risk of incipient epidemic remains in many parts of Brazil. We believe our DPP® assays can become important tools to discriminate among the viruses and identify co-infected patients, as we battle these debilitating and often life-threatening viruses."

About Chembio Diagnostics

Chembio Diagnostics, Inc. develops, manufactures, licenses, and markets rapid diagnostic tests in the growing \$8.0 billion POC testing market. Chembio's patented DPP® technology platform offers significant advantages over traditional POC lateral-flow technologies and provides the Company with a robust pipeline of business opportunities in the areas of sexually transmitted disease, tropical and fever disease, and technology collaborations.

The Company markets its products directly and through third-party distributors under the brand names: DPP®, STAT-PAK®, SURE CHECK®, and STAT-VIEW®.

Headquartered in Medford, NY, Chembio is licensed by 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.

Investor Relations Contact

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