
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 7, 2017 (December 5, 2017)



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))
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ITEM 7.01.**REGULATION FD DISCLOSURE.**

On December 5, 2017, the Company issued a press release entitled "Chembio Receives \$8.5 Million Commitment from Bio-Manguinhos to Purchase Components for Production of DPP® Assays in Brazil during 2018". A copy of the press release is furnished herewith as Exhibit 99.1.

ITEM 9.01.**FINANCIAL STATEMENTS AND EXHIBITS**

Exhibits.

- 99.1 Press Release entitled "Chembio Receives \$8.5 Million Commitment from Bio-Manguinhos to Purchase Components for Production of DPP® Assays in Brazil during 2018" dated December 5, 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.

December 7, 2017

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 entitled "Chembio Receives \$8.5 Million Commitment from Bio-Manguinhos to Purchase Components for Production of DPP® Assays in Brazil during 2018" dated December 5, 2017.



ChemBio Receives \$8.5 Million Commitment from Bio-Manguinhos to Purchase Components for Production of DPP® Assays in Brazil during 2018

ChemBio Receives \$4.2 Million in Accounts Receivable Payments from Bio-Manguinhos

MEDFORD, N.Y., December 5, 2017 -- ChemBio Diagnostics, Inc. (Nasdaq: CEMI), a leader in point-of-care (POC) diagnostic tests for infectious diseases, today announced that it has received an \$8.5 million commitment from Bio-Manguinhos, to purchase from ChemBio test components and intermediate product for production of DPP® HIV Assays and DPP® Leishmania Assays in Brazil, and for the purpose of subsequent supply to Brazil's Ministry of Health. The Company expects these sales to occur during 2018.

ChemBio also announced that subsequent to the end of the third quarter of 2017, it received payments of \$4.2 million of accounts receivable balances from Bio-Manguinhos, including payments for sales during the fourth quarter of 2017, for ChemBio products previously sold and delivered to Bio-Manguinhos.

Bio-Manguinhos is a subsidiary of the Oswaldo Cruz Foundation (Fiocruz), which is responsible for the development and production of vaccines, diagnostics and biopharmaceuticals, primarily to meet the demands of Brazil's national public health system. ChemBio has had a long-standing relationship with Bio-Manguinhos, supplying multiple products for the POC detection of HIV and other infectious diseases.

John Sperzel, ChemBio's CEO, commented, "We are appreciative that Brazil's Ministry of Health is continuing to purchase the high-quality DPP® HIV Assays and DPP® Leishmania Assays from Bio-Manguinhos, for the country's testing programs. The use of rapid POC diagnostic tests, along with prevention and treatment, are essential elements of Brazil's response to HIV and Leishmaniasis incidence, and we are pleased to play an important role in the country's effort to reduce infection rates."

ChemBio DPP® HIV 1/2 Assay detects antibodies to HIV-1 and HIV-2 in oral fluid, fingerstick whole blood, venous whole blood, serum or plasma samples, and provides results in as little as 15 minutes. Using fingerstick whole blood samples, the diagnostic sensitivity of the assay to detect HIV infection is 99.8%, and the diagnostic specificity is 100%. The DPP® HIV 1/2 Assay is FDA-approved, WHO pre-qualified, CE-marked, and ANVISA-approved.

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®, SURE CHECK®, and STAT-VIEW®.

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 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.

Contact:

Vida Strategic Partners (investor relations)
Stephanie C. Diaz
(415) 675-7401

