
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): July 10, 2017 (July 4, 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 5.02 **Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers**

(d) On July 4, 2017, Gail S. Page became a member of the Board of Directors (the "Board") of Chembio Diagnostics, Inc. (the "Company").

There were no arrangements or understandings between Ms. Page and any other persons, pursuant to which Ms. Page was selected as a director.

Ms. Page will be compensated in accordance with the Company's previously disclosed compensation arrangement for non-employee directors, which will be applied specifically to the timing of her situation as follows:

- She will be paid a \$25,000 annual fee (the "Annual Fee") in semi-annual payments, beginning on July 4, 2017 and continuing on each subsequent January 1 and July 1 on which she is still serving as a director.
- She will receive a \$1,000 fee for each Board meeting attended in person and a \$500 for each telephonic Board meeting attended.
- She will receive a \$500 fee for attendance at each meeting attended of each Board committee of which she is a member. Committee memberships have not been determined for Ms. Page at this time.
- On July 4, 2017 (the date on which she became a director), she received stock options to acquire, subject to vesting, 46,875 shares of the Company's common stock, with an exercise price equal to the market price on July 4, 2017. (Because July 4 is a holiday, this would be the market price on July 3, 2017.) Stock options to acquire 9,375 shares became exercisable on July 4, 2017, and stock options to acquire an additional 9,375 shares become exercisable on July 1 of each of the following four succeeding years if and to the extent she is still a director on such vesting date.

Ms. Page was elected by the Board to serve until the next meeting of the Company's stockholders at which directors will be elected by the shareholders, and will be eligible for nomination and election at that time.

ITEM 7.01. REGULATION FD DISCLOSURE.

On July 5, 2017, the Company issued a press release entitled "Chembio's DPP® Zika System Including the DPP® Micro Reader Approved by Brazil's Health Regulatory Agency". A copy of the press release is furnished herewith as Exhibit 99.1.

On July 6, 2017, the Company issued a press release entitled "Gail S. Page Joins Chembio Diagnostics Board of Directors". A copy of the press release is furnished herewith as Exhibit 99.1.

The information in this Item 7.01 of this Form 8-K is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that section. The information in this Item 7.01 of this Form 8-K also shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, except to the extent that the Company specifically incorporates it by reference.

Exhibits.

- 99.1 Press Release entitled "Chembio's DPP® Zika System Including the DPP® Micro Reader Approved by Brazil's Health Regulatory Agency", dated July 5, 2017.
 - 99.2 Press Release entitled "Gail S. Page Joins Chembio Diagnostics Board of Directors", dated July 6, 2017.
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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 hereunto duly authorized.

Date: July 10, 2017

Chembio Diagnostics, Inc.

By: /s/Richard J. Larkin
Richard J. Larkin
Chief Financial Officer

EXHIBIT INDEX

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|---|
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| 99.2 | Press Release entitled " Gail S. Page Joins Chembio Diagnostics Board of Directors", dated July 6, 2017. |



Chembio's DPP® Zika System Including the DPP® Micro Reader Approved by Brazil's Health Regulatory Agency

MEDFORD, N.Y., July 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 approval for commercial use in Brazil of its DPP® Micro Reader by the Brazilian health regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA), in collaboration with Bio-Manguinhos/Fiocruz.

With this latest ANVISA approval, Chembio's DPP® Zika System, which includes the DPP® Zika IgM/IgG Assay and DPP® Micro Reader, is now approved for commercial use in Brazil.

The DPP® Zika IgM/IgG Assay detects antibodies using a tiny (10uL) drop of blood from the fingertip and provides quantitative results in 15 minutes, when used with the handheld, battery-operated DPP® Micro Reader.

Sharon Klugewicz, Chembio's acting CEO, commented, "We are pleased to receive ANVISA approval for commercial use of the DPP® Micro Reader and look forward to commercializing our DPP® Zika System in Brazil. In recent months, we have achieved several important pre-commercial milestones. Previously, we received approval of the DPP® Zika IgM/IgG Assay by ANVISA, as well as a successful evaluation of the DPP® Zika System by Brazil's National Institute for Quality Control in Health (INCQS); and we now have received approval of the DPP® Micro Reader by ANVISA. In collaboration with Bio-Manguinhos, we can now shift our focus to commercial activities."

In 2016, Chembio announced its Zika collaboration with Bio-Manguinhos, a subsidiary of the Oswaldo Cruz Foundation (Fiocruz), which is Brazil's Government unit responsible for the development and production of vaccines, diagnostics and biopharmaceuticals, primarily to meet the demands of Brazil's national public health system. Brazil has been the nation hardest hit by the Zika virus, where more than 2,300 cases of microcephaly, a devastating birth defect associated with Zika virus, have been confirmed and more than 3,000 cases are under investigation.

Zika virus is a mosquito-borne virus that was first identified in Uganda in 1947. While there are cases of sexual transmission of the Zika virus, it is believed that the virus is primarily transmitted to humans through the bite of an infected mosquito from the *Aedes* genus, mainly *Aedes aegypti*, the same mosquito that transmits dengue, chikungunya, and yellow fever. Since 2015, Zika outbreaks have been recorded in over 80 countries and territories.

About Chembio Diagnostics

Chembio Diagnostics, Inc. develops, manufactures, licenses and markets proprietary rapid diagnostic tests in the growing \$8.0 billion point-of-care testing market. Chembio markets each of its DPP® HIV 1/2 Assay, HIV 1/2 STAT-PAK® Assay, and SURE CHECK® HIV 1/2 Assay, with these Chembio brand names, in the U.S. and internationally both directly and through third-party distributors.

Chembio has developed a patented point-of-care (POC) test platform technology, the Dual Path Platform (DPP®) technology, which has significant advantages over lateral-flow technologies. This technology is providing Chembio with a significant pipeline of business opportunities for the development and manufacture of new products.

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 RVR Diagnostics Sdn Bhd, a Malaysia corporation, 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:

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Gail S. Page Joins Chembio Diagnostics Board of Directors

Adds Additional Diagnostic Industry Leadership and Healthcare Expertise

MEDFORD, N.Y., July 6, 2017 -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leader in point-of-care (POC) diagnostic tests for infectious diseases, today announced that Gail S. Page has joined the Company's Board of Directors. "Gail is an accomplished executive with extensive experience in the diagnostics industry. Her impressive record in product development, commercialization, operations, healthcare finance, and strategic transactions strengthens our Board," stated Katherine L. Davis, Chair of Chembio's Board of Directors. "Chembio is developing a range of point-of-care diagnostic tests to address a number of the world's most serious sexually transmitted and fever diseases. We are also growing our global commercial organization. This is a pivotal time for Chembio and the Board of Directors will benefit from Gail's insight, judgment and counsel."

Ms. Page has spent her entire career in health care with a focus on diagnostics and emerging technologies. In January 2013, Ms. Page founded Vineyard Investment Advisors (VIA), through which she works with entrepreneurs, businesses, and universities to transform their ideas into products and services. Prior to VIA, Ms. Page served as the President, CEO and a Director of Vermillion, Inc., a healthcare company focused on developing and commercializing novel diagnostic blood tests. As President and CEO, Ms. Page directed Vermillion's repositioning to highlight the progressive nature of its pipeline, successfully raised over \$100M in funding, developed and commercially launched the OVA1® Test, which was the first FDA-cleared blood test to help diagnose ovarian cancer, and engaged Quest Diagnostics as an equity and commercial partner.

In the years preceding Vermillion, Ms. Page served as Executive Vice President and Chief Operating Officer at Luminex, and as Sr. Vice President at Roche Biomedical / Laboratory Corporation of America (LabCorp), during which time her team launched approximately 300 innovative tests, including a suite of HIV and infectious disease assays.

Ms. Page's current board appointments include Sword Diagnostics, Inc., Consortia Health Holdings (Chair and Co-founder), and NxPrenatal, Inc., for which she serves as Executive Chair. Ms. Page earned a Bachelors of Science in Medical Technology from the University of Florida, and completed an executive management program at the Kellogg School in Chicago.

"Throughout my career, I have been privileged to work with exceptional entrepreneurs and organizations committed to the development and commercialization of cutting-edge healthcare technologies," stated Gail S. Page. "I believe that Chembio's DPP® technology is at the forefront of the next generation of rapid, point-of-care, diagnostic testing, and that Chembio's innovative products such as its DPP® HIV-Syphilis Assay and its DPP® Fever Panel, which address many of the most serious global infectious diseases, have the potential to significantly improve treatment through rapid and accurate diagnosis. I am very pleased to offer my experience to Chembio as it pursues its development and global commercialization goals."

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