

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 22, 2021



CHEMBIO DIAGNOSTICS, INC.

Nevada
(State or Other Jurisdiction of Incorporation or
Organization)

0-30379
(Commission File Number)

88-0425691
(I.R.S. Employer Identification No.)

555 Wireless Blvd. Hauppauge, NY 11788
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.01 par value	CEMI	The NASDAQ Stock Market LLC

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 Matters.

On July 22, 2021, we issued a press release titled “Chembio Diagnostics Receives \$4 Million HIV Test Purchase Order Supported by The Global Fund.” A copy of the press release is included as Exhibit 99.1 to this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Exhibit Description
99.1	Press release of Chembio Diagnostics, Inc. dated July 22, 2021
104	Cover page interactive data file (embedded within the XBRL document)

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: July 22, 2021

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

Chembio Diagnostics Receives \$4 Million HIV Test Purchase Order Supported by The Global Fund

HAUPPAUGE, N.Y., July 22, 2021 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostic company focused on infectious diseases, announced its receipt today of a \$4 million purchase order from the Partnership for Supply Chain Management (PFSCM), supported by The Global Fund, for the purchase of Chembio's HIV 1/2 STAT-PAK Assay for shipment to Ethiopia into early 2022. Chembio's delivery of the full number of tests covered by the purchase order may be affected by limitations of Chembio's supply chain, staffing, and liquidity, and other matters outside Chembio's control.

The HIV 1/2 STAT-PAK Assay is a World Health Organization (WHO) prequalified, rapid point-of-care assay for the detection of HIV-1 and HIV-2 antibodies in fingerstick whole blood, venous whole blood, serum, or plasma. With 99.7% sensitivity and 99.9% specificity, the HIV 1/2 STAT-PAK Assay is the only HIV test that exceeds WHO performance thresholds according to an independent, multi-site study published in the Journal of the International AIDS Society in 2017. Its innovative design can be performed in three simple steps with minimal training, requires only 5 microliters of blood, and includes a built-in biological control. A version of the HIV 1/2 STAT-PAK Assay for the U.S. market has received premarket approval (PMA) and a Clinical Laboratory Improvement Amendments (CLIA) waiver from the U.S. Food and Drug Administration.

"We are proud to continue our support of The Global Fund's pursuit of UNAIDS's '90-90-90' targets," said Richard L. Eberly, Chembio's President and Chief Executive Officer. "We look forward to working closely with PFSCM to continue the supply of our high-quality HIV tests to help the people of Ethiopia know their HIV status and obtain treatment."

Chembio was first awarded the front-line testing algorithm position in Ethiopia in 2018 to screen for HIV. With this latest purchase order, Chembio is continuing that important role, now under the contractual auspices of The Global Fund, and expanding its longstanding relationship with PFSCM, which leverages its planning and logistics resources for clients, governments, and nongovernmental organizations (NGOs) in over 85 countries.

Testing for HIV across Africa and Asia fell by 41% during the period from April to September 2020 compared to the same period in 2019, according to an April 2021 report by The Global Fund on the disruptive impact of the COVID-19 pandemic, despite The Global Fund's actions to continue essential HIV services and protect healthcare workers. The Joint United Nations Programme on HIV/AIDS (UNAIDS) has identified "90-90-90" targets under which 90% of HIV-positive people will know their status, 90% of HIV-positive people who know their status will be on HIV treatment, and 90% of people on HIV treatment will have achieved viral suppression and have undetectable levels of HIV in their bodies.

About Chembio Diagnostics

Chembio is a leading point-of-care diagnostics company focused on detecting and diagnosing infectious diseases, including COVID-19, sexually transmitted, respiratory and insect vector diseases. Coupled with Chembio's extensive scientific expertise, its novel DPP technology offers broad market applications beyond infectious disease. 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 Statements

Certain statements contained in the first and third paragraphs above are not historical facts and may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding the intent, belief or current expectations with respect to manufacturing, distribution, and sale of the HIV 1/2 STAT-PAK Assay pursuant to the purchase order from PFSCM. Such statements, which are expectations 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 forward-looking statements due to a number of important factors, and will be dependent upon a variety of factors, including, but not limited to, the following, any of which could be exacerbated even further by the continuing COVID-19 outbreak in the United States, Ethiopia, and globally: constraints on Chembio's supply chain, staffing, and other resources that could inhibit Chembio's ability to deliver the number of tests contemplated by the purchase order from PFSCM; the need for Chembio to obtain sufficient working capital to fund the procurement of raw materials, the employment and recruitment of personnel, and other costs associated with manufacturing tests, as well as Chembio's ongoing operational infrastructure; the risks of doing business with foreign governmental entities, including geopolitical, international, and other challenges; the ability of Chembio to maintain existing, and timely obtain additional, regulatory approvals for its HIV tests, which approvals are subject to processes that can change recurrently without notice; and, the highly competitive market for testing solutions for HIV, which includes a number of competing companies with strong relationships with current and potential customers, including governmental authorities, and with significantly greater financial and other resources that are available to Chembio. Chembio undertakes no obligation to publicly update forward-looking statements in this release to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to the forward-looking statements or the occurrence of unanticipated events. Factors that may impact Chembio's success are more fully disclosed in Chembio's periodic public filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and its subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, particularly under the heading "Risk Factors." Readers should interpret many of the risks identified in these reports as being heightened as a result of the ongoing and numerous adverse impacts of the COVID-19 pandemic.

DPP and STAT-PAK are Chembio's registered trademarks. For convenience, these trademarks appear 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 trademarks.

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