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 20, 2021**

CHEMBIO DIAGNOSTICS, INC.

Nevada	**0-30379**	**88-0425691**
(State or Other Jurisdiction of Incorporation or Organization)	*(Commission File Number)*	*(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 20, 2021, we issued a press release titled “Chembio Diagnostics Receives $28.3 Million Purchase Order from Bio-Manguinhos for DPP SARS-CoV-2 Antigen Tests in Brazil.” 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 20, 2021
104	Cover page interactive date 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 20, 2021

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

Exhibit 99.1

Chembio Diagnostics Receives $28.3 Million Purchase Order from Bio-Manguinhos for DPP SARS-CoV-2 Antigen Tests in Brazil

HAUPPAUGE, N.Y., July 20, 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 $28.3 million purchase order from Bio-Manguinhos for the purchase of Chembio's DPP SARS-CoV-2 Antigen tests for delivery during 2021 to support the urgent needs of Brazil's Ministry of Health in addressing the COVID-19 pandemic. The DPP SARS-CoV-2 Antigen test is designed to detect the SARS-CoV-2 antigen, which indicates an active COVID-19 infection, in only 20 minutes using a minimally invasive nasal swab. 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.

Bio-Manguinhos, a subsidiary of the Oswaldo Cruz Foundation (Fiocruz), is responsible for the development and production of vaccines, diagnostics, and biopharmaceuticals, primarily to meet demands of Brazil's national public health system. Chembio has a long-standing relationship with Bio-Manguinhos, having supplied multiple products for point-of-care detection of COVID-19 antibodies, HIV, and other infectious diseases. Bio-Manguinhos received regulatory approval from Agência Nacional de Vigilância Sanitária (ANVISA) in March 2021, following ANVISA approval of the test for Chembio's Brazilian subsidiary in November 2020.

"We are pleased to significantly expand our customer relationship with Bio-Manguinhos to address the testing needs surrounding COVID-19," said Javan Esfandiari, Chembio's Executive VP, Chief Science & Technology Officer. "Enabling providers to test patients at the point-of-care and determine their infection status in only 20 minutes can be one of the most effective methods for controlling the spread of COVID-19 and improving patient outcomes. We believe the purchase order validates the investments we made earlier this year in inventory for the DPP SARS-CoV-2 Antigen test and look forward to ramping up production. We are very proud to provide this test in Brazil and assist in efforts to manage the global pandemic."

About the DPP Rapid Test Platform

Chembio's proprietary DPP technology platform provides high-quality, rapid diagnostic results in 15 to 20 minutes using a small drop of blood from the fingertip or alternative samples. Through advanced multiplexing, the DPP platform can detect up to eight, distinct test results from a single patient sample, delivering greater clinical value than other rapid tests. For certain applications, Chembio's easy-to-use, highly portable, battery-operated DPP Micro Reader optical analyzer then reports accurate results in approximately 15 seconds, making it well-suited for decentralized testing where real-time results enable patients to be clinically assessed while they are still on-site. Objective results produced by the DPP Micro Reader reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many rapid tests.

Chembio's portfolio of DPP-based point-of-care tests with FDA regulatory approvals include the DPP HIV-Syphilis System (PMA approved), DPP HIV 1/2 Assay (PMA approved and CLIA waived), DPP Zika IgM System (510(k)), and DPP Ebola Antigen System (EUA). Additionally, DPP-based tests have received regulatory approvals from the World Health Organization, CE-Mark, ANVISA, and other global organizations, where they aid in the detection and diagnosis of several other critical diseases and conditions.

All DPP tests are developed and manufactured in the United States and are the subject of a range of domestic and global patents and patents pending.

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 DPP SARS-CoV-2 Antigen test pursuant to the purchase order from Bio-Manguinhos. 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, Brazil, 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 Bio-Manguinhos; 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 and Bio-Manguinhos to maintain existing, and timely obtain additional, regulatory approvals for its COVID-19 diagnostic tests, which approvals are subject to processes that can change recurringly without notice; Chembio's dependence upon, and limited experience with, COVID-19 diagnostic tests; and, the highly competitive and rapidly developing market for testing solutions for COVID-19, 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 is Chembio's registered trademark. For convenience, this trademark appears 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 trademark.

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