

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) **February 11, 2005**

CHEMBIO DIAGNOSTIC, INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction
of Incorporation)

333-85787

(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))

ITEM 8.01. Other Events.

- a. On February 11, 2005, the Registrant issued the press release titled "New England Journal of Medicine Cites Cost-effectiveness of HIV Screening Chembio Diagnostics' Rapid Test Provides Solution" included herein as Exhibit 99.1.
- b. On February 22, 2005, the Registrant issued the press release titled "Chembio Submits Two HIV Rapid Tests to the FDA for Pre-Market Approval" included herein as Exhibit 99.2.
- c. On March 10, 2005, the Registrant issued the press release titled "Chembio Submits Veterinary Tuberculosis Test to USDA" included herein as Exhibit 99.3.

ITEM 9.01. Financial Statements and Exhibits

(c) Exhibits.

- 99.1 Press Release titled "New England Journal of Medicine Cites Cost-effectiveness of HIV Screening Chembio Diagnostics' Rapid Test Provides Solution" issued February 11, 2005.
- 99.2 Press Release titled "Chembio Submits Two HIV Rapid Tests to the FDA for Pre-Market

Approval” issued February 22, 2005.

99.3

Press Release titled “Chembio Submits Veterinary Tuberculosis Test to USDA” issued

March 10, 2005.

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.

Date: March 11, 2005

Chembio Diagnostics, Inc.

By: _ /s/ Lawrence A. Siebert

Lawrence A. Siebert
Chief Executive Officer

205851

Press Release

Source Chembio Diagnostic, Inc

New England Journal of Medicine Cites Cost-effectiveness of HIV Screening Chembio Diagnostics' Rapid Test Provides Solution

Friday February 11, 9:00 am ET

MEDFORD, N.Y.--(BUSINESS WIRE)--Feb. 11, 2005--Chembio Diagnostics, Inc. (OTCBB: [CEMI](#) - [News](#)), a leading developer, manufacturer and marketer of HIV rapid test products, announced today that The New England Journal of Medicine published an article titled "Cost Effectiveness of Screening for HIV in the Era of Highly Active Antiretroviral Therapy." The article, published in the February 10th issue of the prestigious publication, noted that "the cost effectiveness in routine HIV screening, even in relatively low-prevalence populations, is similar to commonly accepted interventions, and such programs should be expanded."

Chembio offers a unique suite of three rapid HIV tests for use in HIV testing programs in international settings. Recently, the Company launched the HIV Stat-Pak Dipstick test, which will be sold to international relief programs for approximately \$1.00 per test. Based upon growing demand for rapid testing programs, the company believes that it will be able to attract significant interest for its cost-effective HIV testing solutions.

"We believe that the demand for HIV testing continues to grow dramatically," said Lawrence A. Siebert, President of Chembio. "The New England Journal of Medicine article highlights the opportunity for our products, as cost-effective early testing of HIV as part of regular screening programs could provide a solution to the growing epidemic of HIV and AIDS."

David Miller, a member of the NYC HIV Planning Council Advisory Group and the Co-Chairman of the Cornell/ Columbia Adult AIDS Clinical Trial Group said, "This study will promote the necessity to support increased access to rapid HIV testing throughout the country in order to stem the increase of HIV infection in vulnerable populations."

ABOUT CHEMBIO

Chembio Diagnostics, Inc. (Chembio) possesses expertise in the development and manufacturing of rapid test products for various indications, including HIV, Tuberculosis and BSE (a.k.a. Mad Cow Disease). References to Chembio Diagnostics, Inc may actually refer to Chembio Diagnostic Systems, Inc., the 100%-owned subsidiary of Chembio Diagnostics, Inc. Chembio is located at 3661 Horseblock Road, Medford, NY 11763. Chembio's telephone number is 631-924-1135. Email can be directed to info@chembio.com. Additional information can be found at www.chembio.com.

FORWARD-LOOKING STATEMENTS

Statements contained herein that are not historical facts are forward-looking statements within the meaning of the Securities Act of 1933, as amended. Those statements include statements regarding the intent, belief or current expectations of the Company and its management. Such statements 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, the Company's ability to obtain additional financing and the demand for the Company's products. The Company 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 the Company's expectations with regard to these forward-looking statements or the occurrence of unanticipated events. Factors that may impact the Company's success are more fully disclosed in the Company's most recent public filings with the

Contact:

CEOcast, Inc. for Chembio Diagnostics:
Ed Lewis, 212-732-4300 x225

Press Release

Source: Chembio Diagnostic, Inc

Chembio Submits Two HIV Rapid Tests to the FDA for Pre-Market Approval

Tuesday February 22, 9:01 am ET

Products Also Qualified for USAID and UN Global Fund Procurements

MEDFORD, NY--(BUSINESS WIRE)--Feb. 22, 2005--Chembio Diagnostics, Inc. (OTCBB:[CEMI](#) - [News](#)) today announced that it submitted an application to the U.S. Food and Drug Administration (FDA) for Pre-Market Approval of its Sure Check(TM) HIV and HIV Stat-Pak rapid HIV tests. Both Sure Check HIV and HIV Stat-Pak are rapid test devices that can detect antibodies to the HIV virus within 15 minutes using finger stick whole blood samples. The FDA submittal, which also includes claims for venous whole blood, serum and plasma samples, was made on February 17th.

Chembio also announced that it has been notified by the World Health Organization (WHO) and the United States Agency for International Development (USAID) that its HIV rapid tests have qualified for procurements pursuant to the WHO Bulk Procurement Scheme and the USAID "Waiver" List pending FDA approval. These qualifications enable Chembio to participate in procurements under the United States \$15 Billion President's Emergency Plan for AIDS Relief (PEPFAR), the UNAIDS Global Fund for HIV, TB & Malaria and other agency procurements affiliated with these major programs worldwide. These qualifications are as a result of evaluations that the United States Centers for Disease Control and Prevention and the World Health Organization performed with Chembio's HIV rapid tests during 2004.

Chembio's President, Lawrence A. Siebert said, "There is a clear and immediate health need for a high quality, cost-effective rapid HIV test both in the United States as well as globally and we are proud to have a role in serving this need. The threat of a more virulent drug resistant strain entering at-risk populations must be countered by expanded and aggressive surveillance of primary incidences of infection. Critical decisions about treatment depend on the availability of accurate and immediate HIV test results at a reasonable price and we believe our tests most effectively fulfill that need."

Chembio manufactures in Medford, New York three rapid HIV tests, Sure Check(TM) HIV, HIV Stat- Pak and HIV Stat-Pak Dipstick. These products are sold to resource-poor settings at end-user prices of between \$1.00 and \$2.00 per test. The first two, Sure Check(TM) and Stat-Pak, have completed clinical trials in the United States, and have now been submitted to the FDA; Stat-Pak and Stat-Pak Dipstick have also been evaluated by the World Health Organization (WHO). WHO is expected to evaluate Sure Check later this year. All three products have been involved in many other evaluations around the world over the last three years.

According to a recent study in the New England Journal of Medicine, health experts recommend that virtually all Americans be screened routinely for the HIV/ AIDS virus, much as they are for cancer and other conditions. In addition, the report cited recent federally funded studies which determined that the cost of routinely testing and treating nearly all adults would be outweighed by a reduction in new infections and the opportunity to start patients on antiretroviral medications early in the disease progression.

Mr. Siebert added, "This submittal to the FDA, our qualification for the WHO Bulk Procurement Scheme and our being included on the USAID Waiver List for the PEPFAR program represents the culmination of an extraordinary amount of effort on the part of our entire team. We are proud to have reached this milestone and look forward to working with the FDA, the WHO, USAID, and their collaborating partners in the months ahead."

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Press Release

Source: Chembio Diagnostic, Inc

Chembio Submits Veterinary Tuberculosis Test To USDA

Thursday March 10, 9:30 am ET

Initial Product Targeting Pharmaceutical Research Operations

MEDFORD, N.Y.--(BUSINESS WIRE)--March 10, 2005--Chembio Diagnostics, Inc. (OTCBB:[CEMI](#) - [News](#)) today announced that it submitted the Company's first application to the U.S. Department of Agriculture ("USDA") for Prima TB Stat Pak, a rapid test to detect tuberculosis (TB) in non-human primates (NHPs).

Chembio will manufacture and market the product as it has previously announced pursuant to its exclusive license agreement with Sequella Corporation. The test will be directly marketed by Chembio to a targeted group of pharmaceutical research operations. Chembio believes that this product will address a need that these operations have for a more cost-effective and reliable means of TB testing. It is estimated that several hundred thousand NHPs are actively used in biomedical research in the US and Europe, but an increasing number of public health crises have led to a shortage of NHPs and a corresponding increase in their cost. TB can devastate colonies of NHPs, has a high fatality rate, and is easily transmitted to humans. Current diagnostic methods are extremely difficult to administer, costly and unreliable. The many false positive readings often result in euthanizing these expensive NHPs unnecessarily.

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