

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) **September 21, 2005**



CHEMBIO DIAGNOSTICS, 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 7.01. Regulation FD Disclosures.

- (a) On Sept, 2005, the Registrant issued the press release titled "ChemBio's Hiv 1/2 Test Now The Confirmatory Test In Uganda" included herein as Exhibit 99.1.

ITEM 9.01. Financial Statements and Exhibits

- (c) Exhibits.

99.1 [Press Release titled "ChemBio's Hiv 1/2 Test Now The Confirmatory Test In Uganda" issued September 21, 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: September 21, 2005

Chembio Diagnostics, Inc.

By: /s/ Lawrence A. Siebert
Lawrence A. Siebert
Chief Executive Officer

CHEMBIO's HIV 1/2 TEST NOW THE CONFIRMATORY TEST IN UGANDA

MEDFORD, N.Y.--(MarketWire)—Sept. 21, 2005 Chembio Diagnostics Inc., announced today that Uganda's Ministry of Health has officially designated Chembio's rapid HIV 1/2 Stat Pak test to be the confirmatory test in its national testing algorithm. The national testing algorithm is the sequential protocol of tests typically recommended by the ministries of public health to diagnose HIV/AIDS infected persons, in conjunction with the VCT (Voluntary Counseling and Testing) and PMTCT (Prevention of Mother to Child Transmission) programs. Once a patient has tested positive, the protocol in Uganda requires a second confirmatory rapid test to follow the initial screening test at the point of care, since many patients would otherwise fail to return for their confirmatory lab results.

The market for rapid tests is expected to increase exponentially in Uganda as public health officials are encouraging the use of rapid testing devices to diagnose HIV/AIDS infected individuals. Uganda is one of the largest recipients of PEPFAR (President's Emergency Program for AIDS Relief) in Africa. While the screening test is used on 100% of the people tested, the confirmatory test is used only on those who test positive, a number which varies with the prevalence of the disease in the groups screened. Uganda's demand for rapid HIV tests exceeded 400,000 in 2004, with the number expected to exceed 1.5 - 2.0 million tests for 2005.

Chembio also announced that Quality Chemicals Limited (QCL) will be its distributor in Uganda. QCL, a leading importer and distributor in the sales of medical devices and drugs, is the largest supplier of antiretroviral drugs (ARVs) to the Ugandan government. Incorporated in 1997 as a result of the Ugandan government's liberalization and privatization policies, QCL has played a significant role in helping this HIV ravaged region acquire much-needed testing devices and drugs. QCL recent agreement with Cipla of India to build an ARV facility in Kampala will be the first of its kind, allowing Uganda to scale up the manufacture of ARVs to treat infected individuals.

"We are very pleased to be Chembio's partner, in light of the StatPak test now being the confirmatory test in Uganda" said Emmanuel Katangole, Managing Director of QCL. "Testing being the gateway to treatment, this collaboration fits in very well with QCL's mission to help Uganda control the HIV pandemic."

ABOUT CHEMBIO

Chembio Diagnostics, Inc. (Chembio) possesses expertise in the development and manufacturing of rapid test products for various infectious diseases, including HIV, Tuberculosis and Chagas 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 Investor Relations contact is Maya Wagle at 631-924-1135/ ext.125. Email can be directed to mwagle@chembio.com. Additional information can be found at 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 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 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.