
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) **October 20, 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 October 20, 2005, the Registrant issued the press release titled "Chembio Welcomes FDA's Consideration of OTC AIDS Tests" included herein as Exhibit 99.1.

ITEM 9.01. Financial Statements and Exhibits

- (c) Exhibits.

99.1 [Press Release titled "Chembio Welcomes FDA's Consideration of OTC AIDS Tests" issued October 20, 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: October 20, 2005

Chembio Diagnostics, Inc.

By: /s/ Lawrence A. Siebert

Lawrence A. Siebert

Chief Executive Officer

CHEMBIO WELCOMES FDA's CONSIDERATION OF OTC AIDS TESTS

MEDFORD, N.Y.--(Market Wire)—Oct. 20, 2005: Chembio Diagnostics, Inc. (CEMI: OTCBB) today welcomed news that the FDA Blood Products Advisory Committee (BPAC) will be considering whether and under what conditions it could allow rapid HIV tests to be sold over-the-counter (OTC) to consumers for at home testing. This consideration by BPAC was recently announced by OraSure Technologies, Inc. (OSUR) and reported in the New York Times. OraSure and Chembio are among a small group of companies in the US that have or are seeking FDA approval of rapid HIV tests for use in the professional market such as public health clinics and emergency rooms. These tests incorporate technologies that allow the tests to be performed quickly, accurately, and with a minimal number of procedural steps.

Chembio is seeking professional use FDA approval for its Sure Check™ and HIV Stat-Pak™ products. Chembio's management believes that its tests could be well suited for the OTC market if that market becomes available. However, there is no assurance that the FDA will decide to allow OTC marketing of rapid HIV tests. Furthermore, the specific conditions relating to any such allowance can not be known at this time.

“We are immensely pleased that the FDA is considering a process which would make AIDS testing as easy as diabetes and pregnancy testing,” said Larry Siebert, Chairman and CEO of Chembio. “Wider access to testing could help identify more positive cases and improve prevention efforts.”

Chembio's rapid HIV tests include the HIV 1/2 Stat-Pak™, HIV 1/2 Stat-Pak Dipstick™ and the HIV 1/2 Sure Check™. These tests are simple, safe, cost-effective and operator-friendly requiring less than five microliters of whole blood from a fingerstick.

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.

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.
