
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) **December 1, 2005**



CHEMBIO DIAGNOSTIC, INC.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction
of Incorporation)

0-30379
(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))
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ITEM 7.01. Regulation FD Disclosures.

99.1 On December 1, 2005 the Registrant issued the press release titled "On World Aids Day Chembio Updates Its Progress In Serving Global Need For Rapid HIV Testing" included herein as Exhibit 99.1.

ITEM 9.01. Financial Statements and Exhibits

(c) Exhibits.

99.2 [Press Release titled "On World Aids Day Chembio Updates Its Progress In Serving Global Need For Rapid HIV Testing" issued November 7, 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: December 1, 2005

Chembio Diagnostics, Inc.

By: /s/ Lawrence A. Siebert

Lawrence A. Siebert

Chief Executive Officer



PRESS RELEASE

ON WORLD AIDS DAY CHEMBIO UPDATES ITS PROGRESS IN SERVING GLOBAL NEED FOR RAPID HIV TESTING

MEDFORD, N.Y.--(Market Wire)--December 1, 2005--With today marking the 18th annual World AIDS Day, Chembio Diagnostics, Inc. (OTCBB: CEMI) is updating its investors on its role in the growing global demand for affordable rapid HIV tests.

A member of the Global Business Coalition ("GBC") on HIV/AIDS (www.businessfightaids.org), Chembio supports the position taken by GBC's Chairman, Richard Holbrooke, in yesterday's Washington Post regarding the need for a more aggressive scale-up in rapid testing for HIV/AIDS.

Chembio will participate in today's World AIDS Day 2005 Commemoration, hosted by UNAIDS, in partnership with the African Services Committee and the New York City Department of Health.

Furthering its efforts to engage local stakeholders in the geographic locations where these tests are most urgently needed, Chembio will likewise participate in the 14th International Conference on AIDS and sexually transmitted diseases (ICASA) in Africa scheduled for next week in Abuja, Nigeria.

US APPROVAL

Clinical data for two of Chembio's three rapid HIV tests, HIV 1/2 STAT-PAK™ and SURE CHECK® HIV 1/2 are in final review by the United States Food and Drug Administration ("FDA"). The FDA has already completed the inspection of Chembio's facility. Chembio is in discussions with potential US marketing partners.

INTERNATIONAL APPROVALS

Chembio's rapid HIV tests, qualified by the World Health Organization ("WHO"), are already approved for purchase internationally. These tests have also been approved for international procurement by the United States Agency for International Development (USAID) and the United States Centers for Disease Control. These are the agencies responsible for implementing President Bush's five-year, \$15 Billion Emergency Plan for AIDS Relief (PEPFAR) program.

Chembio is the only rapid HIV test manufacturer approved by these government agencies that offers three rapid HIV test formats, and the only US-based company with products priced to meet the massive need for these tests worldwide.

Chembio also has new patent-pending rapid HIV test technologies in development.

LATIN AMERICA

As previously reported, Chembio expects that 2005 orders will total 700,000 units, an increase from 450,000 units in 2004, from its Brazilian customer, The Oswaldo Cruz Institute, affiliated with the Brazilian Ministry of Health.

Chembio's SURE CHECK® HIV 1/2 is also approved for sale in Mexico. The Company is actively pursuing sales opportunities in Mexico as well as in several other markets in South America.

AFRICA

Over the last six months, Chembio has established regional offices in East and West Africa. The Company is now finalizing agreements with distributors in Uganda, Kenya, Mozambique, Ethiopia, Tanzania and Zambia. In Uganda, a world-wide leader in prevention and treatment efforts, Chembio's HIV 1/2 STAT-PAK™ test is in the national testing protocol. One or more of Chembio's three rapid HIV tests are also under evaluation for inclusion in the national protocols of other African nations. Local assembly is being considered.

OTHER MARKETS

Chembio is seeking to extend its global reach in other markets through local, governmental and non-governmental partnerships that recognize the urgent need for rapid HIV testing.

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.
