
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) **March 13, 2006**



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.

- (a) On March 13, 2006 the Registrant issued the press release titled “Chembio Supports Regulatory Path Recommended By FDA Committee for Approval of Over the Counter Rapid HIV Tests” included herein as Exhibit 99.1.
- (b) On March 14, 2006 the Registrant issued the press release titled “Chembio Diagnostics Appoints Dr. Mariano Levin, An Expert in Chagas and Other Neglected Diseases, to Advisory Board” included herein as Exhibit 99.2.

ITEM 9.01. Financial Statements and Exhibits

- (c) Exhibits.

99.1 Press Release titled [“Chembio Supports Regulatory Path Recommended By FDA Committee for Approval of Over the Counter Rapid HIV Tests”](#) issued March 13, 2006.

99.2 Press Release titled [“Chembio Diagnostics Appoints Dr. Mariano Levin, An Expert in Chagas and Other Neglected Diseases, to Advisory Board”](#) issued March 14, 2006.

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 15, 2006

Chembio Diagnostics, Inc.

By: /s/ Lawrence A. Siebert

Lawrence A. Siebert

Chief Executive Officer



Chembio Supports Regulatory Path Recommended By FDA Committee for Approval of Over the Counter Rapid HIV Tests

MEDFORD, N.Y. - March 13, 2006 - Chembio is pleased by the recommendation that was given to the Food & Drug Administration (FDA) by FDA's Blood Products Advisory Committee (BPAC) on Friday, March 10 concerning proposed regulatory requirements for the approval of over the counter (OTC) distribution of rapid HIV tests.

The BPAC was unanimous in its recommendation that products that are or become approved by the FDA for professional use would automatically meet the analytical sensitivity and specificity requirements that are part of the first of three phases of requirements that BPAC recommended for OTC distribution. Chembio is expecting professional market approval of two of its three rapid HIV tests, HIV 1/2 STAT-PAK™ and SURE CHECK® HIV during the first half of this year. The main additional recommended requirements will be for studies to ensure that untrained users, in both controlled and intended use settings, will be able to properly perform the tests, interpret results, and fully understand the informational materials that will be required to accompany each test kit, which will include information regarding access to counseling and treatment.

Chembio's CEO Lawrence Siebert, who attended the hearing with Avi Pelossof, Chembio's VP Sales, Marketing and Business Development, said: "Possible U.S. OTC approval opens up a new potential market for our products, one that should help identify those HIV-positive individuals in the U.S. who are unaware of their status."

Avi Pelossof said: "Our goal is to make HIV rapid tests more accessible. The OTC market will provide more options for those wishing to learn their HIV status. Chembio's ability to produce high quality, multi-platform products that are also competitively priced and have a 24 month shelf-life should be a significant advantage in the OTC market."

ABOUT CHEMBIO

Chembio Diagnostics, Inc. (OTCBB: CEMI) possesses expertise in the development and manufacturing of rapid diagnostic tests for various infectious diseases. Chembio is participating in the frontlines of the global battle against the devastating AIDS pandemic. This battle, to which the United States alone has pledged \$15 billion in international aid, is the impetus behind Chembio's rapid HIV tests. Because rapid tests can detect HIV antibodies within minutes, the massive prevention and treatment programs that are now scaling up can be much more effective. Chembio is one of four global rapid HIV test suppliers under the Clinton HIV/AIDS Initiative (www.clintonfoundation.org). The Company also manufactures additional rapid tests that it has developed for other deadly diseases, including human and veterinary Tuberculosis and Chagas Disease. References to Chembio Diagnostics, Inc. may actually refer to Chembio Diagnostic Systems, Inc.; the wholly owned subsidiary of Chembio Diagnostics, Inc. Chembio is located at 3661 Horseblock Road, Medford, NY 11763. For additional information please visit 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 are estimates only, as the Company has not completed the preparation of its financial statements for those periods, nor has its auditor completed the audit of those results. Actual revenue may differ materially from those anticipated in this press release. 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, to obtain regulatory approvals in a timely manner, 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.

Contact: IR: Vince Daniels/James Carbonara

PR: Judy Katz

The Investor Relations Group 212-825-3210



**Chembio Diagnostics Appoints Dr. Mariano Levin,
An Expert in Chagas and Other Neglected Diseases, to Advisory Board**

MEDFORD, N.Y. - March 14, 2006 - Chembio Diagnostics Inc. (OTCBB: CEMI) has appointed Dr. Mariano Jorge Levin, a leading expert on Chagas Disease, to its Advisory Board.

Dr. Levin is head of the Laboratory of Molecular Biology of Chagas Disease at the Institute for Research on Genetic Engineering and Molecular Biology in Buenos Aires, Argentina. He received a Ph.D. in biochemistry in 1981 from the University of Leipzig, Germany and conducted postdoctoral work in France at INSERM, CNRS, and Institut Pasteur. He has received several prizes from the Argentine Society of Cardiology, and, in 1998 was awarded a John Simon Guggenheim Foundation fellowship. He is currently a Howard Hughes International Research Scholar. As Full Professor at the School of Science and with the support of the Howard Hughes Medical Institute and the University of Buenos Aires, he created and directs the first genomic facility of this University, CeGA (Center of Applied Genomics). He is also a member of the Board of the South South Initiative (SSI) of the World Health Organization Special Program for Research and Training in Tropical Diseases (WHO - TDR), and the coordinator in the field of Trypanosomiasis, including Chagas Disease and African Sleeping Sickness.

"We are delighted to have an individual of Dr. Levin's distinction and expertise on our Advisory Board," said Larry Siebert, Chairman and President of Chembio.

Earlier this year Chembio received a \$1.2 million order for Chagas STAT-PAK™, a rapid test for this largely neglected yet deadly infectious disease that affects some 18 million people. The test incorporates a cocktail of recombinant antigens that have been exclusively licensed to Chembio.

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