

UNITED STATES
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 24, 2005 (March 18, 2005)

Chembio Diagnostics, 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 No.)

3661 Horseblock Road, Medford, NY

(Address of principal executive offices)

11763

(Zip Code)

Registrant's telephone number, including area code (631) 924-1135

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 (see General Instruction A.2. below):

- ☐ 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 1.01. Entry into a Material Definitive Agreement.

On March 18, 2005, Chembio Diagnostics, Inc. (the "Company") granted to each of the Company's two new non-employee directors, Dr. Gary Meller and Gerald A. Eppner, an option to purchase 36,000 shares of the Company's common stock at an exercise price of \$0.80, as a part of their compensation for their service on the Company's Board of Directors. One-third of the options granted vest immediately, one-third of the options vest one year after the date of grant, and one-third of the options vest two years after the date of grant. Each of these options expire on March 18, 2010.

On March 18, 2005, the Company's Board of Directors agreed to amend the exercise price of warrants to purchase 425,000 shares of the Company's common stock owned by Mark L. Baum from \$0.90 per share to \$0.75 per share. Mr. Baum has been a member of the Company's Board of Directors since December 11, 2003, during which time he has not received compensation for his time or efforts as a member of the Company's Board of Directors.

Item 2.02.

Results of Operations and Financial Condition.

On March 23, 2005, the Company issued a press release containing financial results for the year and quarter ended December 31, 2004. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instructions B.2 of Form 8-K, the information in this Item 2.02 of this report shall not be deemed “filed” for the purpose of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing.

Item 9.01.

Financial Statements and Exhibits.

(c) Exhibits

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
99.1	Press Release, dated March 23, 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 hereunto duly authorized.

Chembio Diagnostics, Inc.

Date: March 24, 2005

By: /s/ Lawrence A. Siebert

Lawrence A. Siebert
Chief Executive Officer

Chembio Diagnostics Reports Fourth Quarter and Year-end Results

Strong Sales of HIV Products Contribute to 99.3% Fourth Quarter Revenue Growth

MEDFORD, N.Y.--(BUSINESS WIRE)-- --Chembio Diagnostics, Inc. (OTCBB:CEMI) announced fourth quarter and year-end results for the period ended December 31, 2004. For the fourth quarter of 2004 the Company reported net sales of \$1,067,552, a 99.3% increase versus \$535,534 during the same period in fiscal 2003. Chembio generated gross profit of \$439,128, a 101.4% increase versus \$218,015 generated in the fourth quarter of fiscal 2003. The Company reported a net loss of \$893,273, compared to a loss of \$261,819 during the fiscal 2003 fourth quarter. The increased loss was primarily as a result of (1) a \$465,000 increase in research and development activities related to the clinical trials for two of the Company's HIV rapid tests that were recently submitted to the Food and Drug Administration (FDA) for Pre-Market Approval (PMA) and (2) a \$400,000 increase in selling, general and administrative expenses associated with increased sales commissions, marketing costs, legal and accounting costs. Chembio reported a net loss for the fourth quarter available to common shareholders which reflected the accretion of and declaration of dividends on Preferred stock, of \$2,687,842, or \$0.41 per diluted share, versus a net loss available to common shareholders of \$261,819, or \$0.05 per diluted share, for the year earlier period.

For the full year ended December 31, 2004, Chembio reported net sales of \$2,749,143, an 8.1% increase versus \$2,542,621 in fiscal 2003. The increase in net sales is primarily attributable to increased sales of the Company's HIV products of \$730,844, which more than offset reduced pregnancy test kit sales, which declined \$383,313. The Company generated gross profit of \$820,339, a 23.4% increase, versus \$664,897 in fiscal 2003. The Company reported a net loss, of 3,098,891 versus a net loss in 2003 of 1,059,704. The increased operating loss was a result of an increase in research and development expenses of \$1,119,512 and an increase of \$1,288,113 in selling, general and administrative expenses. The higher R&D expenses were a result of costs associated with regulatory approvals, clinical studies, product evaluations and registrations. The Company reported a net loss available to common shareholders which reflected the accretion of and declaration of dividends on Preferred stock of \$5,041,964, or \$0.85 per diluted share, compared to a net loss available to common shareholders, of \$1,059,704, or \$0.22 per diluted share in fiscal 2003.

Some of the highlights of fiscal 2004 include:

- Completion of clinical trials for the Company's HIV rapid tests in the United States and submission of this data with its Pre-Marketing Approval application to the United States Food and Drug Administration.
- Achieving "waiver" status with the United States Agency for International Development for procurements being made under the Presidential Emergency Plan for AIDS Relief which enables Chembio's products to be procured pending FDA approval.
- Achieving inclusion on the World Health Organization Bulk Procurement Scheme for two of the Company's HIV rapid tests. This provides United Nations funded programs the ability to purchase Chembio's products and should enhance the Company's marketing initiatives in many countries.

"2004 was a strong year for Chembio," said Lawrence A. Siebert, Chembio's President. "We were able to dramatically increase sales of our HIV products. In addition, we recently completed a \$5 million private placement which we believe will allow us to achieve wider distribution of our products in the global market and prepare for FDA approval this year of our Sure Check™ and HIV Stat Pak products. We also are working on completing the development of the mad cow, dental bacteria and tuberculosis rapid tests that are under product development agreements and/or research grants. We believe that these products can begin to generate revenue this year. Our recent accomplishments and greatly improved balance sheet put Chembio in an excellent position to pursue activities that will support further growth."

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 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 U.S. Securities and Exchange Commission ("SEC")

Contact:

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