
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 3, 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 2.02. Results of Operations and Financial Condition.

- (a) On October 3, 2005, the Registrant issued the press release titled "Chembio Quarter Net Sales Up By 93% Over 2004" included herein as Exhibit 99.1.

ITEM 9.01. Financial Statements and Exhibits

- (c) Exhibits.

99.1 [Press Release titled "Chembio Quarter Net Sales Up By 93% Over 2004" issued October 3, 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 3, 2005

Chembio Diagnostics, Inc.

By: /s/ Lawrence A. Siebert

Lawrence A. Siebert
Chief Executive Officer

Chembio Third Quarter Net Sales Up By 93% Over 2004

MEDFORD, N.Y.--(Market Wire)—Oct. 3, 2005: Chembio Diagnostics, Inc. (CEMI: OTCBB) announced today that third quarter shipments of 220,000 HIV 1/2 Stat Pak™ test kits to Bio-Manguinhos, an affiliate of the Brazilian Ministry of Health (MOH), one of the largest manufacturers of vaccines in the world and a growing diagnostic producer, when taken together with other third quarter sales, by company estimates will increase net sales for the three-month period ended Sept. 30, 2005 to an estimated \$850,000, a 93% increase over net sales of \$440,371 for the same period in 2004. 150,000 units were shipped during the second quarter.

Chembio and Bio-Manguinhos have a three year technology transfer agreement to supply HIV tests to combat Brazil's burgeoning AIDS problem. This agreement dictates that over a three-year period starting 2004, Chembio will transfer its proprietary technology to Bio-Manguinhos in exchange for test kit purchase commitments during this transfer period. Chembio will receive royalties for ten years once Bio-Manguinhos starts production of these rapid tests using Chembio's proprietary technology. More news on this collaboration can be accessed at

www.chembio.com/images/Chembio_AIDSLink_Brazil.pdf

Chembio's rapid HIV tests include the HIV 1/2 Stat-Pak™, HIV 1/2 Stat-Pak™ Dipstick and the Sure Check HIV™. All three tests are simple, safe, cost-effective and operator-friendly requiring less than five micro-liters of blood from a finger-stick. The HIV 1/2 Stat-Pak and the Sure Check HIV™ tests are currently under review by the FDA for U.S. marketing.

Chembio also reported today that it had received a court memorandum and order dated September 27, 2005 responding to motions for claim construction and for summary judgment in the case it brought in 2004 against Saliva Diagnostic Systems, Inc. ("SDS") in the U.S. District Court Eastern District of New York. Chembio is seeking a declaratory judgment that Chembio's Sure Check™ HIV barrel device does not infringe SDS' US Patent #5,935,864, or in the alternative, that the '864 patent is invalid or unenforceable. The motions for summary judgment made by both parties were denied, opening the way to fact discovery in the case. In responding to the motion for claim construction, the order interpreted the patent in a way such that only the sampling part of the device is to exclude absorbent material, a narrower finding than what Chembio's motion had requested. The case is in a preliminary stage and this order does not address issues of patent infringement, validity or enforceability.

Chembio is seeking FDA approval for its Sure Check™ HIV as well as its HIV 1/2 Stat Pak™ product, making it the only company that would have multiple rapid test formats in the US market. Although Sure Check™ HIV's higher cost and limited flexibility as to sample type compared with the Stat Pak™ formats make Sure Check™ HIV less desirable in donor-funded developing country programs, it may be a desirable format in certain user and market segments in the US and other developed countries that have greater financial resources .

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.
