

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): August 17, 2007 (August 14, 2007)



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 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.

On August 14, 2007, the Company issued the press release titled “Chembio Submits CLIA Waiver Data for HIV Barrel Test to FDA” included herein as Exhibit 99.1.

On August 13, 2007, the Company issued the press release titled “Chembio Diagnostics, Inc. to Present at The RedChip Small-Cap Investor Conference” included herein as Exhibit 99.2.

ITEM 9.01. Financial Statements and Exhibits

Exhibits.

99.1 Press Release titled “[Chembio Submits CLIA Waiver Data for HIV Barrel Test to FDA](#)” issued August 14, 2007.

99.2 Press Release titled “[Chembio Diagnostics, Inc. to Present at The RedChip Small-Cap Investor Conference](#)” issued August 13, 2007.

In accordance with General Instruction B.2 of Form 8-K, the information disclosed in Item 7.01 of, and Exhibits 99.1 and 99.2 attached to, this Current Report on Form 8-K 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. This Current Report on Form 8-K does not constitute a determination of whether any information included herein is material.

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: August 17, 2007

Chembio Diagnostics, Inc.

By: /s/ Lawrence A. Siebert
Lawrence A. Siebert
Chief Executive Officer



Chembio Submits CLIA Waiver Data for HIV Barrel Test to FDA

Waiver Would Greatly Expand U.S. Market Potential of FDA-Approved Test

Medford, New York, August 14, 2007 -- Chembio Diagnostics, Inc. (OTC BB:[CEML.OB](#) - [News](#)) has completed the studies required as part of a Clinical Laboratory Improvement Amendment (CLIA) waiver application for its "HIV barrel format" rapid test. Chembio has submitted this data and associated information in an amendment to its 2006 submission to the Center for Devices and Radiological Health division of the United States Food & Drug Administration (FDA). If the CLIA waiver is granted, it would expand the available market for Chembio's HIV barrel format test to include doctors' offices and clinics, as well as other hospitals and reference laboratories. This unique, self-contained rapid HIV test is FDA approved and exclusively marketed worldwide by Inverness Medical Innovations, Inc. as Clearview® COMPLETE HIV 1/2.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) established that some tests could be waived from certain laboratory requirements. Waived products include tests that employ methodologies that are so simple to use as to render the likelihood of erroneous results negligible; or that pose no reasonable risk of harm to the patient if the test is performed incorrectly. Rapid HIV antibody tests were only added to the list of tests that could be waived within the last few years, and this development is what created the main U.S. market opportunity for these products.

A CLIA waiver greatly expands the available potential U.S. market opportunity for a product from sites that require much greater certification and oversight (i.e. reference laboratories and hospitals) to additional venues where point of care testing is particularly beneficial (i.e. emergency rooms, doctors offices and public health clinics). There are approximately 189,000 testing sites across the United States that can use tests that are CLIA-waived. The United States Centers for Disease Control has issued recommendations that HIV testing become part of the routine medical care provided to all Americans between the ages of 13 and 64. Chembio's HIV barrel product was approved in 2006 by the FDA, initially as a moderately complex product. This approval was a prerequisite to submitting the CLIA Waiver Application.

According to Larry Siebert, CEO of Chembio, "Obtaining a CLIA-waiver for our HIV barrel test, combined with our HIV STAT PAK® cassette product which is already CLIA-waived, should significantly enhance the point-of-care rapid HIV product offering of our US marketing partner."

ABOUT CHEMBIO

Chembio Diagnostics, Inc., a developer and manufacturer of rapid diagnostic tests for infectious diseases, is on the frontlines of the global battle against the AIDS pandemic. The Company has received marketing approval from the FDA for its SURE CHECK® HIV 1/2 and HIV 1/2 STAT-PAK™ rapid tests, marketed under the brand name Clearview® in the United States by Inverness Medical Innovations. The Company also manufactures rapid tests for veterinary Tuberculosis and Chagas Disease. In March 2007 Chembio was issued a United States patent for the Dual Path Platform (DPP™), a next generation lateral flow platform. DPP has demonstrated significant advantages over currently available lateral flow methods, including increased sensitivity, sample flexibility, and multiplexing capabilities.

Further 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 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 for its products 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.

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**CHEMBIO DIAGNOSTICS, INC. TO PRESENT AT THE REDCHIP
SMALL-CAP INVESTOR CONFERENCE**

MEDFORD, NY, August 13, 2007– Chembio Diagnostics Inc.'s (OTCBB: CEMI) Chief Executive Officer, Lawrence Siebert, will present at the RedChip Small-Cap Investor Conference on August 16th at 2:15 p.m. Eastern Time at the Waldorf-Astoria Hotel in New York City.

Mr. Siebert will speak about the market opportunities for the Company's HIV and other rapid diagnostic tests including the FDA-approved products being marketed by Inverness Medical Innovations, Inc. as well as Chembio's newly patented Dual Path Platform (DPP(TM)), for which the Company is generating a significant amount of interest.

Individuals may listen to a live webcast of the presentation by logging on to the Investors section of Chembio's web site, www.chembio.com, a few minutes prior to start time. The presentation will be archived for 90 days. Additional information regarding the conference can be found at www.redchip.com.

ABOUT CHEMBIO

ChemBio Diagnostics, Inc., a developer and manufacturer of rapid diagnostic tests for infectious diseases, is on the frontlines of the global battle against the AIDS pandemic. The Company has received marketing approval from the FDA for two of its rapid HIV tests and these are marketed in the United States by Inverness Medical Innovations under their Clearview® brand. The Company also manufactures rapid tests for veterinary Tuberculosis and Chagas Disease. In March 2007 Chembio was issued a United States patent for the Dual Path Platform (DPP(TM)), a next generation lateral flow platform. DPP has demonstrated significant advantages over currently available lateral flow methods, including increased sensitivity, sample flexibility, and multiplexing capabilities. Further information please visit www.chembio.com

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