

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): September 27, 2007 (September 25, 2007)



(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 September 25, 2007, the Company issued the press release titled “Chembio Diagnostics Receives ISO 13.485 Certification” included herein as Exhibit 99.1.

ITEM 9.01. Financial Statements and Exhibits

Exhibits.

99.1 Press Release titled “[Chembio Diagnostics Receives ISO 13.485 Certification](#)” issued September 25, 2007.

In accordance with General Instruction B.2 of Form 8-K, the information disclosed in Item 7.01 of, and Exhibit 99.1 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: September 27, 2007

Chembio Diagnostics, Inc.

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



Chembio Diagnostics Receives ISO 13.485 Certification

MEDFORD, N.Y. (September 25, 2007)– Chembio Diagnostics, Inc. (OTCBB: CEMI)—has received certification under ISO 13.485: 2003. ISO (International Organization for Standardization) is the world's largest developer and publisher of International Standards. It is comprised of a network of the national standards institutes of 155 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system. The primary objective of ISO 13485:2003 is to facilitate harmonized medical device regulatory requirements; in particular, it specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services. ISO 13.485 is the quality system that is most recognized throughout the European Community for products seeking a CE marking. Chembio has engaged a European Notified Body in connection with its plans to obtain a CE marking for its products.

Lawrence Siebert, Chembio's President and CEO commented, "We are proud to add this ISO certification to our other regulatory achievements which include two U.S. Food and Drug Administration approved Premarket Approval Device Applications ("PMAs"), and a product and facility license from the U.S. Department of Agriculture for our veterinary tuberculosis tests. As manufacturing is one of Chembio's core competencies, this global certification underscores the quality of our systems and demonstrates our ability to produce our point-of-care diagnostics for the global markets. We are very appreciative and proud of the work of our regulatory, quality assurance and operations teams that have enabled us to achieve ISO certification."

About Chembio Diagnostics

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 U.S. by Inverness Medical Innovations. Chembio also manufactures rapid tests for veterinary tuberculosis and chagas disease. In March 2007 Chembio was issued a U.S. 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. 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 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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