

# 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) **July 28, 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))

#### ITEM 7.01. Regulation FD Disclosures.

- (a) On July 25, 2006 the Registrant issued the press release titled "Chembio To Feature Dual Path Platform at American Association for Clinical Chemistry Expo" included herein as Exhibit 99.1.
- (b) On July 27, 2006 the Registrant issued the press release titled "Chembio Applies for CLIA Waiver for SURE CHECK(R) HIV 1/2" included herein as Exhibit 99.2.

#### ITEM 9.01. Financial Statements and Exhibits

- (c) Exhibits.

99.1 Press Release titled "[Chembio To Feature Dual Path Platform at American Association for Clinical Chemistry Expo](#)" issued July 25, 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: July 28, 2006

Chembio Diagnostics, Inc.

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

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## **ChemBio To Feature Dual Path Platform at American Association for Clinical Chemistry Expo**

MEDFORD, N.Y. — July 25, 2006 — ChemBio Diagnostics, Inc. (OTCBB: CEMI) is featuring its Dual Path Platform (DPP(TM)) at this year's American Association for Clinical Chemistry (AACC) Annual Meeting and Clinical Lab Exposition, being held July 25 through July 27 at the McCormick Place Convention Center in Chicago.

DPP is a new and innovative rapid chromatographic immunoassay platform that ChemBio believes improves sensitivity in single and multiple parameter tests as compared to standard single-path lateral flow assays. The improved sensitivity results from increased efficiency of antibody binding to the immobilized test antigen, enabled by the use of an independent sample flow path for the delivery of all sample types, including oral fluid samples.

ChemBio has already employed DPP to develop a next generation rapid HIV test that, based upon internal studies completed at ChemBio, will provide high sensitivity levels with early sero-conversion samples as well as oral fluid samples. DPP's independent sample delivery path also improves performance in multiple analyte tests. Based upon its internal studies, ChemBio believes this feature will enable development of an HIV confirmatory test that could replace current Western blot assays, as well as lead to the development of a rapid Tuberculosis test using blood and sputum samples that incorporate multiple antigens.

The AACC exposition will allow ChemBio to develop other possible product development and licensing opportunities for DPP outside these core areas. Prototype DPP devices and an informative video will be on display at ChemBio's AACC booth number 343.

In March 2005, ChemBio announced that it had filed a patent application for DPP with the United States Patent and Trademark Office (USPTO). The Company subsequently filed in several other jurisdictions worldwide. DPP was first presented this past spring at a conference in Brazil hosted by the Oswaldo Cruz Foundation's Bio-Manguinhos unit, the Brazilian health ministry affiliate that has been ChemBio's contract partner since 2004.

"We believe that DPP is a valuable technology not only for ChemBio's development of new infectious disease tests, but also for potential out-licensing to new partner companies with expertise in a wide range of other diagnostic applications," said Javan Esfandiari, ChemBio Vice President of Research & Development.

For further information about the AACC Annual Meeting, please visit the event Web site at [www.aacc.or/AACC/events/ann\\_meet/annual2006/ConferenceInfo/](http://www.aacc.or/AACC/events/ann_meet/annual2006/ConferenceInfo/).

For further information about DPP(TM) please visit the ChemBio Web site at [www.chembio.com/newtechnologies.html](http://www.chembio.com/newtechnologies.html).

### **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(R) HIV 1/2 and HIV 1/2 STAT-PAK(TM) rapid tests. The Company also manufactures rapid tests for veterinary Tuberculosis and Chagas Disease, and has developed a patent-pending technology, the Dual Path Platform (DPP(TM)), for its next generation HIV and other rapid tests. For additional information please visit [www.chembio.com](http://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:*

The Investor Relations Group  
Investors: James Carbonara/Andrea Raetzer  
Media: Susan Morgenbesser  
212-825-3210



## **Chembio Applies for CLIA Waiver for SURE CHECK(R) HIV 1/2**

### *CLIA Waiver Would Expand Chembio's Domestic Marketing Opportunity*

MEDFORD, N.Y. — July 27, 2006 — Chembio Diagnostics, Inc. (OTCBB: CEMI) has submitted a CLIA waiver application to the United States Food & Drug Administration for the Company's SURE CHECK(R) HIV 1/2 rapid diagnostic test. With this application, Chembio has submitted two rapid HIV tests applications for CLIA Waiver during the last few weeks, which, if granted, would expand the Company's domestic marketing opportunity.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) law established provisions for categorizing a test as waived. Waived tests under CLIA include tests that employ methodologies that are so simple and accurate 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.

There are 189,000 laboratory entities across the United States, including doctors' offices and clinics, that would be able to use the tests upon receipt of a CLIA waiver. The United States Centers for Disease Control is recommending HIV tests become part of the routine medical care of most Americans, and the CLIA-waiver would allow Chembio to provide its products to the entities most likely to conduct the tests.

"Having two tests that are CLIA-waived would provide flexibility for pricing and user preferences in public health clinics, laboratories, hospitals and physicians offices," said Larry Siebert, Chief Executive Officer of Chembio. "SURE CHECK(R) HIV 1/2 is a device format that may be preferred by some users due to its simple procedure on finger-stick whole blood samples, while the flexibility of our HIV 1/2 STAT PAK(TM) which uses the same procedure across all blood sample types (serum, plasma, finger-stick whole blood and venous whole blood) will be preferred by certain other users."

On May 25, 2006, Chembio's SURE CHECK(R) HIV 1/2 and HIV 1/2 STAT-PAK(TM) rapid tests received marketing approval from the United States Food and Drug Administration's (FDA) Center for Biologics and Research (CBER) — a prerequisite to submitting the CLIA Waiver Application.

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