

# 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) **November 8, 2004**

### **CHEMBIO DIAGNOSTIC, 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))
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**ITEM 8.01. Other Events.**

On November 8, 2004, the Registrant issued the press release included herein as Exhibit 99.1.

**ITEM 9.01. Financial Statements and Exhibits**

(c) Exhibits.

99.1 Press Release issued November 8, 2004.

**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: November 8, 2004

**Chembio Diagnostics, Inc.**

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

**PRESS RELEASE**

**FOR RELEASE: Monday, November 8, 2004**

**CHEMBIO DIAGNOSTICS, INC.'S REGISTRATION  
STATEMENT BECOMES EFFECTIVE**

MEDFORD, New York - (November 8, 2004) Chembio Diagnostics, Inc. (OTCBB:CEMI) announced today that its registration statement on Form SB-2 became effective with the Securities and Exchange Commission at 4:00 p.m. on November 4, 2004.

Lawrence Siebert, CEO of Chembio stated, "We are extremely pleased that our registration statement has become effective. I look forward to introducing Chembio to the public marketplace and keeping our shareholders and the investment community apprised of our team's efforts in building Chembio into a leading diagnostics company."

About Chembio Diagnostics, Inc.

Chembio Diagnostics, Inc. possesses expertise in the development and manufacturing of rapid test products for various indications, including infectious diseases including HIV, Tuberculosis and Mad Cow Disease. As part of Chembio's strategy to provide its HIV rapid tests to millions of people worldwide through governmental and non-governmental agencies and through selected distributors and strategic partners, Chembio Diagnostics, Inc. (through its subsidiary Chembio Diagnostic Systems Inc.) has recently participated in numerous evaluations of its HIV rapid tests with leading agencies and companies around the world. Chembio is currently completing clinical trials in the United States for two of its HIV rapid tests, Sure Check and HIV Stat Pak, in support of a planned submission to the FDA for US regulatory approval which is anticipated in 2005. Chembio signed a technology transfer agreement with the Oswaldo Cruz Institute in February 2004 for one of its HIV tests and is a supplier to Prionics AG for a new rapid test for Mad Cow Disease that has been developed and is awaiting regulatory clearance in Europe. Chembio's headquarters are located at 3661 Horseblock Road, Medford, NY 11763. Chembio's telephone number is 631-924-1135. Email can be directed to [info@chembio.com](mailto:info@chembio.com). Additional information can be found at <http://www.chembio.com>.

Forward Looking Statements

This release contains forward-looking statements regarding Chembio's future plans and expected performance that are based on assumptions and expectations that Chembio believes are reasonable. A number of risks, uncertainties and other factors could cause any of the assumptions and expectations to be incorrect and could cause actual results to differ materially from those reflected in the forward-looking statements. Some of these risks, uncertainties and other factors include, but are not limited to, the demand for our products, our ability to obtain our products from our suppliers, our ability to maintain commercially feasible margins given significant competition, and other factors. Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date hereof. Chembio undertakes no obligation to publicly revise these forward-looking statements to reflect events or circumstances that arise after the date hereof. Readers should carefully review the risks described in other documents that Chembio files from time to time with the Securities and Exchange Commission, including its Registration Statement on Form SB-2, a copy of which is located at [www.sec.gov](http://www.sec.gov).

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