

# 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) **January 3, 2005**

#### **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.**

- (a) On December 21, 2004, the Registrant issued the press release titled “Chembio completes U.S. clinical trials for two HIV rapid tests” included herein as Exhibit 99.1.
- (b) On December 21, 2004, the Registrant issued the press release titled “Chembio supports CSF leak research at SUNY-Stony Brook” included herein as Exhibit 99.2.
- (c) On January 3, 2005, the Registrant issued the press release titled “Chembio Diagnostics, Inc. Receives Exclusive License to Develop, Manufacture & Market Rapid Tuberculosis Test” included herein as Exhibit 99.3.

#### **ITEM 9.01. Financial Statements and Exhibits**

(c) Exhibits.

99.1 Press Release titled “Chembio completes U.S. clinical trials for two HIV rapid tests” issued December 21, 2004.

99.2 Press Release titled “Chembio supports CSF leak research at SUNY-Stony Brook” issued December 21, 2004.

99.3 Press Release titled “Chembio Sees Fourth Quarter Revenue and Margin Gains” issued January 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: January 3, 2005

Chembio Diagnostics, Inc.

By: /s/ Lawrence A. Siebert

Lawrence A. Siebert  
Chief Executive Officer

# **Chembio Completes US Clinical Trials for Two HIV Rapid Tests**

Tuesday December 21, 8:30 am ET

## **Nears Pre-Marketing Approval Submission to the FDA**

MEDFORD, NY--(BUSINESS WIRE)--Dec. 21, 2004--Chembio Diagnostics, Inc. (OTCBB:[CEMI](#) - [News](#)) today announced that it has completed clinical trials on two HIV rapid tests, HIV Stat Pak and Sure Check(TM) HIV, with results which meet current FDA expectations for specificity and sensitivity.. The completion of these clinical trials enables the company to submit a completed Pre-Marketing Approval ("PMA") to the FDA which Chembio expects to do very soon.

Each of these rapid tests provide test results within 15 minutes, thereby allowing individuals who are tested to learn their HIV status at the time the test is taken. This allows prevention and treatment strategies in the US and globally to be implemented more effectively and efficiently.

The clinical trial protocol was conducted pursuant to an Investigational Device Exemption ("IDE") granted the Company by the United States Food & Drug Administration (FDA) to conduct these trials at five different approved clinical settings across the United States. A total of 2,700 patients were tested from low risk and high risk populations and individuals known to be HIV-positive, all as prescribed in the protocol. Samples of finger-stick whole blood, venous whole blood, serum and plasma were collected from the 2,700 participants in sufficient quantities to run on each of Chembio's tests and to then confirm such test results against a sequence of laboratory reference tests. In addition to the high correlation with the reference methods, it is also noteworthy that there were no discrepancies either between sample types (whole blood, serum, etc) or between the two tests.

The data have not been reviewed by the FDA nor have the products been approved for sale in the United States, which will only be possible after satisfaction of all PMA requirements and conditions which include a complete review of all manufacturing facilities and related documentation. The products however may be exported internationally pursuant to FDA export regulations.

"We are very pleased with the results of these clinical trials and look forward to working with FDA in the months ahead on satisfying the remaining requirements for approval of our PMA and providing the public health community committed to fighting this epidemic with an essential and cost-effective tool for slowing the spread of this epidemic " commented Lawrence Siebert, President of Chembio. Mr. Siebert further stated, "This is an important milestone for our company and I am most appreciative of the fine job that our professional development and regulatory team has done in bringing us to this point"

## **ABOUT CHEMBIO**

Chembio Diagnostics, Inc. possesses expertise in the development and manufacturing of rapid test products for various indications, 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, 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 [www.chembio.com](http://www.chembio.com)

## **FORWARD-LOOKING STATEMENTS**

Statements contained herein that are not historical facts are forward-looking statements within the meaning of the Securities Act of 1933, as amended. Those 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, the Company's ability to obtain additional financing and access funds from its existing financing arrangements that will allow it to continue its current and future operations and whether demand for its test products in domestic and international markets will continue to expand. The Company 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 the Company's expectations with regard to these forward-looking statements or the occurrence of unanticipated events. Factors that may impact the Company's success are more fully disclosed in the Company's most recent public filings with the U.S. Securities and Exchange Commission ("SEC").

*Contact:*  
CEOcast, Inc. for Chembio  
Ed Lewis, 212-732-4300x 225

# **Chembio Supports CSF Leak Research at SUNY-Stony Brook**

Tuesday December 21, 9:00 am ET

## **Acquires Exclusive Option to License Technology**

MEDFORD, N.Y.--(BUSINESS WIRE)--Dec. 21, 2004--Chembio Diagnostics, Inc. (OTCBB: [CEMI](#) - [News](#)) announced today that it has entered into an agreement with The Research Foundation of State University of New York ("SUNY"), acting on behalf of the Center for Biotechnology at Stony Brook University, to support a project entitled "Rapid Identification of Cerebrospinal Fluid in Biological Fluids," commonly known as CSF Leak. Chembio has been granted an ex clusive option to negotiate a license with SUNY to the patent and/or all other proprietary technology coming out of this research project.

CSF leak occurs when there is a tear in the dura (the membrane that surrounds the brain and spinal cord in which the CSF is found). CSF leaks may occur spontaneously or by invasive procedures, either traumatic or non-traumatic. CSF leaks can occur as result of the placement of a needle/catheter for anesthesia and analgesia, as a result of trauma, skull fractures, intracranial surgical procedures, infection, and other reasons. CSF leaks are one of the more persistent problems encountered in neurosurgical practice.

Dr. Srinivas Pentiyala, an Assistant Professor of Anesthesiology/Urology/Physiology & Biophysics at the School of Medicine, Stony Brook University, Stony Brook, New York will lead this project on behalf of the University. The initial one year agreement is for a total project cost of \$80,000, which will be shared by the Center for Biotechnology and Chembio. Additional state and federal grant support is anticipated if the project proceeds through its milestones.

Dr. Peter Glass, Chairman of the Anesthesiology Department at the School of Medicine at Stony Brook University commented: "CSF Leak is an area where I believe a rapid diagnostic test could be of tremendous value to enhance patient safety and the tools available to Physicians, EMTs, RNs, and PA's. Dr. Pentiyala has done a tremendous amount of work in his laboratory in establishing the feasibility of this project and we look forward to continued developments so that Chembio can take this technology and commercialize it to serve these needs."

Lawrence A. Siebert, President of Chembio commented: "We are proud to be in on the development of another product with SUNY-Stony Brook. We were involved in the development of the only rapid test for Lyme Disease combining technology developed at SUNY-Stony Brook with our rapid test platform. SUNY-Stony Brook is an important partner and we look forward to future collaborations."

With the ability to rapidly identify CSF in body fluids, health care providers might be able to avoid associated complications in invasive procedures. Such a test could serve as a tool to rapidly decide on optimal patient management as well as help assess the efficacy of treatment. It could also be used as a routine test for anyone undergoing epidural anesthesia, suffering base of skull fracture, skull based surgery or other procedures where it is important to detect the presence of CSF.

In connection with this work, a patent was filed with the US Patent and Trademarks Office.

## **ABOUT THE RESEARCH FOUNDATION**

The Research Foundation of SUNY administers sponsored research and public service projects that are funded by a wide range of sponsoring entities including governments, corporations, and foundations. New technologies and knowledge generated through these activities have led to the creation of new industries such as biotechnology and photonics and have helped existing industries such as wood products, ceramics and agriculture remain competitive in today's global economy.

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## ABOUT THE CENTER FOR BIOTECHNOLOGY

The Center for Biotechnology is a New York State Center for Advanced Technology supported by the New York State Office of Science, Technology and Academic Research (NYSTAR). The Center for Biotechnology focuses its resources on the translation of academic research into commercial products both alone, and in partnership with New York State bioscience companies. The Center has contributed to the development of such products as ReoPro(TM), PerioStat® and V3D Colon(TM) virtual colonoscopy, and catalyzed the creation of six new companies over the last five years. The Center also invests considerable resources in the creation of infrastructure to support industry growth, and participated as a founder of the Long Island High Technology Incubator, the New York Biotechnology Association, and the Long Island Life Sciences Initiative. Total economic impact related to the Center's activities for the five year period 1998-2003 was \$499 million.

## ABOUT CHEMBIO

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## 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 <http://www.sec.gov>.

## Contact:

CEOcast, Inc. for Chembio Diagnostics  
Ed Lewis, 212-732-4300x225

# **Chembio Sees Fourth Quarter Revenue and Margin Gains**

Monday January 3, 9:00 am ET

## **Strategy to Focus on Core Products Results in 140% Increase in HIV Product Sales**

MEDFORD, N.Y.--(BUSINESS WIRE)--Jan. 3, 2005--Chembio Diagnostics, Inc., (OTCBB: [CEMI](#) - [News](#)), a leading company in the development and manufacture of rapid tests for HIV and other infectious diseases, today announced that it expects 2004 fourth quarter net revenue and gross margins to be substantially improved. The Company expects fourth quarter net revenue will exceed \$1.1 million and that gross margins will exceed 40%. As a result, the Company expects total net revenues increasing in 2004 over 2003 by at least 15%, despite significantly reduced revenue from non-core and discontinued products of about \$700,000.

Lawrence A. Siebert, Chembio's President commented, "These results demonstrate that our shift from several non-core products to focusing on the market for our growing line of HIV rapid test kits is working. Our 2004 HIV product sales will be approximately \$1.2 million as compared with slightly over \$500,000 in 2003, which represents a significant increase."

During 2004, Chembio streamlined its product offerings in order to focus its business in HIV and TB rapid testing and in developing products through strategic collaborations with world-class organizations. As a result, several small product lines were discontinued and the Company also transferred its pregnancy test business to a third party.

### **ABOUT CHEMBIO**

Chembio Diagnostics, Inc. (CDI) possesses expertise in the development and manufacturing of rapid test products for various indications, including HIV, Tuberculosis and BSE (a.k.a. Mad Cow Disease). Chembio Diagnostic Systems, Inc. is a wholly-owned subsidiary of Chembio Diagnostics, Inc. References to Chembio Diagnostics, Inc may actually refer to Chembio Diagnostic Systems, Inc., the 100%-owned subsidiary of CDI. Chembio is 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 [www.chembio.com](http://www.chembio.com).

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