

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 11, 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.

On January 11, 2005, the Registrant issued the press release included herein titled “Chembio Diagnostics, Inc. Receives Exclusive License to Develop, Manufacture & Market Rapid Tuberculosis Test” as Exhibit 99.1.

On January 12, 2005, the Registrant issued the press release included herein titled “Outbreak of Mad Cow Disease Generates Interest in Chembio Diagnostics' Rapid Test for BSE” as Exhibit 99.2.

On January 20, 2005, the Registrant issued the press release included herein titled “Chembio Files Patent Application for New Rapid Test Platform” as Exhibit 99.3.

On January 27, 2005, the Registrant issued the press release included herein titled “Chembio Diagnostics Launches Cost-Effective HIV Stat- Pak Dipstick” as Exhibit 99.4.

On January 31, 2005, the Registrant issued the press release included herein titled “Chembio Completes \$5 Million Private Placement” as Exhibit 99.5 the details of which were filed on Form 8-K dated January 31, 2005.

ITEM 9.01. Financial Statements and Exhibits

(c) Exhibits.

99.1 Press Release issued January 11, 2005.

99.2 Press Release issued January 12, 2005.

99.3 Press Release issued January 20, 2005.

99.4 Press Release issued January 27, 2005.

99.5 Press Release issued January 31, 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: February 8, 2005

Chembio Diagnostics, Inc.

By: /s/ Lawrence A. Siebert

Lawrence A. Siebert
Chief Executive Officer

Chembio Diagnostics, Inc. Receives Exclusive License to Develop, Manufacture & Market Rapid Tuberculosis Test

Tuesday January 11, 9:12 am ET

MEDFORD, N.Y.--(BUSINESS WIRE)--Jan. 11, 2005--Chembio Diagnostics, Inc. ("Chembio") and Sequella, Inc. ("Sequella") announced today that they have entered into a license agreement in which Sequella grants Chembio's wholly-owned subsidiary, Chembio Diagnostic Systems, Inc. ("CDS") exclusive rights to develop, manufacture, and market a rapid diagnostic test for the detection of tuberculosis (TB) in non-human primates.

Nonhuman primates (NHP) are crucial to biomedical research, but an increasing number of public health crises have led to a shortage of NHPs and a corresponding increase in cost. TB can devastate colonies of NHPs, has a high fatality rate, and is easily transmitted to humans. Current diagnostic methods are extremely difficult to administer, costly and unreliable. The many false positive readings often result in euthanizing these expensive NHPs unnecessarily.

CDS has already completed development and validation of this product, and regulatory documentation is being prepared for submission to the United States Department of Agriculture. Under the agreement with Sequella, CDS is responsible for developing, manufacturing, marketing and obtaining any intellectual property licenses required for the NHP TB test. Sequella is responsible for administering the grant from the National Institutes of Health, providing CDS with regulatory and marketing support and managing any patents relating to this product.

"We are thrilled to be working with CDS on a new diagnostic that will be so valuable to the scientific community," said Dr. Carol Nacy, CEO of Sequella, Inc. "I look forward to seeing the commercial results of a project that we have all worked so hard to bring to fruition."

Lawrence Siebert, President of Chembio said, "We believe that this product will provide a much needed diagnostic tool to the pharmaceutical research market that will save time and resources. This product, when approved, will mark the first commercialization of a number of endeavors we have undertaken with regard to veterinary applications for TB that complement the work we have done to develop and commercialize our human TB test technologies."

ABOUT CHEMBIO

Chembio Diagnostics, Inc. (Chembio) 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 Chembio Diagnostics, Inc. 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. Additional information can be found at www.chembio.com.

ABOUT SEQUELLA

Sequella, Inc. is a development stage biotechnology company designed to facilitate the translation of concepts that exist at the lab bench into commercial products that can alleviate the global burden of infectious disease. The company, headquartered in Rockville, MD, is focusing its initial research efforts on therapeutics, diagnostics and vaccines to address the growing TB problem worldwide. For company information, please visit www.sequella.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 the demand for the Company's products. 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 Diagnostics, Inc. Ed Lewis, 212-732-4300 x 225

Outbreak of Mad Cow Disease Generates Interest in Chembio Diagnostics' Rapid Test for BSE

Wednesday January 12, 8:39 am ET

MEDFORD, N.Y.--(BUSINESS WIRE)--Jan. 12, 2005--Chembio Diagnostics, Inc. (OTCBB: [CEMI](#) - [News](#)) announced today that the recent concerns surrounding Bovine Spongiform Encephalopathy (BSE), also known as "mad cow disease", could generate significant interest in the PrioSTRIP(TM) rapid test which provides a unique combination of high-speed testing and reliability with simple handling, resulting in very low total operational costs.

Recently, the Canadian Food Inspection Agency said that the brain wasting disease showed up in an Alberta cow under seven years old. While officials say no part of the animal has entered the human or animal feed system, this is the second case of BSE found in Canada this year. The PrioSTRIP(TM) provides the ability to rapidly detect BSE in cattle. The Company intends to seek approval from the United States Department of Agriculture to distribute the product prior to the end of the year. Upon approval of the product in Europe, Chembio will be a supplier of PrioSTRIP(TM) to Prionics and its distributors in Europe.

In a report dated November 16, 2004, the EFSA Working Group on TSE Testing expressed its favorable opinion on PrioSTRIP(TM) among several other new tests it evaluated and is now recommending the PrioSTRIP(TM) test for approval by the European Commission.

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

Chembio Files Patent Application for New Rapid Test Platform

Thursday January 20, 8:30 am ET

Innovative Lateral Flow Technology Drives Improved Performance

MEDFORD, N.Y.--(BUSINESS WIRE)--Jan. 20, 2005--Chembio Diagnostics, Inc. (OTCBB: [CEMI](#) - [News](#)) announced today that it has filed a new patent application with the United States Patent and Trademark Office for a novel method and device incorporating lateral flow technology, which the company believes provides it with a proprietary platform upon which it will be able to develop several new rapid tests.

The company believes that by having its own proprietary platform, and one which represents a significant departure from existing lateral flow technology, it will facilitate plans for developing new cost-effective rapid tests that have improved performance features.

"We are committed to the continued development of innovative rapid diagnostic test solutions," said Lawrence A. Siebert, President of Chembio. "The product development, manufacturing, and technology transfer agreements that we have in place today with leading organizations such as Bio-Manguinhos and Prionics are a result of our experience and know-how in the area of lateral flow technology. This patent application represents the ingenuity of our development team as well as their knowledge of the limitations of current technologies. We will be working hard during 2005 to complete our initial product offerings utilizing these as well as other innovations."

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Contact:

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

Chembio Diagnostics Launches Cost-Effective HIV Stat- Pak Dipstick

Thursday January 27, 8:38 am ET

Low Cost Rapid Test Anticipated to be Qualified for Inclusion in President's \$15 Billion AIDS Relief Plan

MEDFORD, N.Y.--(BUSINESS WIRE)--Jan. 27, 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 has launched its third HIV rapid test, HIV Stat-Pak Dipstick, to complete its unique suite of three rapid HIV tests for use in HIV testing programs in international settings. This latest format, HIV Stat-Pak Dipstick, is the most cost effective of the three; the product will be sold to international relief programs for approximately \$1.00 per test. As such, the Company believes that this product will be an attractive option for international rapid testing programs where cost is the major factor in procurement decisions.

HIV Stat-Pak Dipstick is based upon the same test strip as Chembio's two other HIV rapid tests but does not have the plastic housings they use to facilitate sample collection and other features. This reduces material, labor and shipping costs as compared with Chembio's and other companies' products. Chembio's two other products, Sure Check(TM) (integrated sample collection in test device), and Stat-Pak (standard cassette format), sold to resource-poor countries for \$1.50 to \$2.00, are the products for which the company recently completed U.S. clinical trials for submission to the US FDA. HIV Stat- Pak cassette and the new Dipstick have recently been evaluated by the World Health Organization for inclusion in its Bulk Procurement list, which the Company anticipates to be confirmed soon. The company also anticipates that all three of these tests will be eligible for procurement under the US government's five year, fifteen billion dollar program known as PEPFAR (President's Emergency Plan for AIDS Relief).

Lawrence A. Siebert, Chembio's President commented, "We are committed to providing PEPFAR and other international programs with a menu of rapid test options that will enable them to achieve their prevention and treatment goals in the most cost effective way, while at the same time providing them with products of the highest quality that are manufactured in accordance with US regulatory and other requirements. Products procured from Chembio with US taxpayer funds will provide essential jobs to New Yorkers and others in the United States. The announcement this week that PEPFAR funds may be used to purchase generic drugs manufactured in South Africa underscores the importance of our having cost competitive products in order to provide an opportunity for US manufacturers such as Chembio to participate in PEPFAR procurements."

About Chembio Diagnostics

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. Additional information can be found at www.chembio.com.

Forward-Looking Statements

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Contact:

CEOcast, Inc. for Chembio Diagnostics
Ed Lewis, 212-732-4300, ext. 225

Chembio Completes \$5 Million Private Placement

Monday January 31, 8:30 am ET

MEDFORD, N.Y.--(BUSINESS WIRE)--Jan. 31, 2005--Chembio Diagnostics, Inc., (OTCBB: [CEMI - News](#)), today announced that it has completed a \$5 million private placement with institutional and other accredited investors. The Company issued Series B 9% Convertible Preferred Stock and Series B Warrants (the "Series B Transaction") to a group of investors led by Crestview Capital. Millennium 3 Opportunity Fund, LLC was also a major investor. Midtown Partners & Co., LLC acted as the lead Placement Agent in this transaction.

Lawrence A. Siebert, Chembio's President, who also invested in the placement, commented, "We are pleased to have completed this financing with such high quality investors. This new capital provides us with the opportunity to achieve significant growth, in part because of our products and platforms, but also because of our dedicated and creative management team."

Mr. Siebert added, "In evaluating financing alternatives and deal size, we always consider the balance of dilution and financial security. We believe that a prudent balance has been achieved with this round of financing. Proceeds from the placement will be used primarily for sales and marketing, research and development, manufacturing, intellectual property and working capital, all so that we can monetize our portfolio of rapid tests as quickly as possible."

The shares of common stock into which the Series B 9% Convertible Preferred Stock is convertible and the Series B Warrants have not been registered under the Securities Act of 1933, as amended, and cannot be offered or sold absent registration or an applicable exemption from registration. In connection with the Series B Transaction, the Company is required to file a registration statement for all of the shares and warrants associated with this financing by March 28, 2005. Other material terms of the Series B Transaction will be described in a Form 8-K to be filed on or before February 1, 2005.

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ABOUT CRESTVIEW CAPITAL AND MILLENNIUM 3 OPPORTUNITY FUND, LLC

Crestview Capital invests in small-cap public companies that are undercapitalized and are seeking capital for growth, acquisitions or other constructive uses. Crestview has completed over 70 investments since inception and has over 90 different deal sources around the US and Western Europe. Additional information can be viewed at www.crestviewcap.com. Millennium 3 Opportunity Fund LLC provides capital to high potential early stage companies and start-ups. Additional information can be viewed at www.mill3cap.com. Both Crestview and Millennium have experienced principals that are highly involved in adding strategic value to their portfolio companies.

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