
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): December 1, 2006 (November 27, 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))
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ITEM 7.01. Regulation FD Disclosures.

On November 27, 2006 the Registrant issued the press release titled “Chembio and CDC to Develop Rapid Syphilis Test Using Dual Path Platform (DPPTM) Technology” included herein as Exhibit 99.1.

On November 28, 2006 the Registrant issued the press release titled “Chembio Receives CLIA Waiver for HIV 1/2 STAT-PAKTM” included herein as Exhibit 99.2.

On December 1, 2006 the Registrant issued the press release titled “Chembio Diagnostics Undertakes HIV/AIDS Media Education Initiative 19th Annual World AIDS Day Today” included herein as Exhibit 99.3.

ITEM 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1 Press Release titled “[Chembio and CDC to Develop Rapid Syphilis Test Using Dual Path Platform \(DPPTM\) Technology](#)” issued November 27, 2006.

99.2 Press Release titled “[Chembio Receives CLIA Waiver for HIV 1/2 STAT-PAKTM](#)” issued November 28, 2006.

99.3 Press Release titled “[Chembio Diagnostics Undertakes HIV/AIDS Media Education Initiative 19th Annual World AIDS Day Today](#)” issued December 1, 2006.

In accordance with General Instruction B.2 of Form 8-K, the information in 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: December 1, 2006

ChemBio Diagnostics, Inc.

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



ChemBio and CDC to Develop Rapid Syphilis Test Using Dual Path Platform (DPP™) Technology

Cooperative Research and Development Agreement Signed to Leverage Respective Technologies and Create New Rapid Test

MEDFORD, NEW YORK - November 27, 2006 - ChemBio Diagnostics, Inc. (OTCBB:CEMI) has signed a Cooperative Research and Development Agreement (CRADA) with the United States Centers for Disease Control and Prevention (CDC) to develop a rapid combination test for syphilis utilizing ChemBio's Dual Path Platform (DPP™) technology and the CDC's patented Syphilis antigens. The test is being designed to detect both treponemal and nontreponemal antibodies in the same device and therefore could potentially be both a screening and confirmatory test in a point of care setting.

A team of scientists from ChemBio and CDC will work together to develop the test. After successful completion of device design and analyses of experimental data, initiation of field studies and data collection would proceed in accordance with the Food and Drug Administration (FDA) and the World Health Organization (WHO) requirements. At that time, CDC will be responsible, among other matters, for undertaking testing procedures and clinical trials. ChemBio's responsibilities will include, among other matters, providing manufacturing capacity for producing prototype devices and submitting certain regulatory documents to the FDA.

Lawrence Siebert, President and CEO of ChemBio commented, "The CRADA with CDC illustrates how valuable the DPP technology is to ChemBio. This agreement enables us to simultaneously broaden our rapid test products beyond our core areas of HIV, Chagas Disease and Tuberculosis, capitalize on our DPP intellectual property, and collaborate with the leading public health organization in the U.S. that has expertise in sexually transmitted diseases such as Syphilis".

The DPP technology is a point of care test platform, which, based on internal tests, can overcome the sensitivity and specificity issues related to conventional lateral flow technology. ChemBio believes DPP will be an excellent platform for a serology test for Syphilis due to the separate delivery path for sample and simultaneous binding of antibodies in the samples to several antigens in the test area. ChemBio has posted on its web site at <http://www.chembio.com/newtechnologies.html> a video animation of the basic DPP system, which will soon be updated to include a prototype of an oral fluid (HIV) DPP system under development.

Syphilis is a sexually transmitted disease (STD) caused by the bacterium *Treponema pallidum*. Worldwide 12 million individuals are diagnosed with syphilis each year and are at increased risk of becoming infected with and transmitting HIV. In addition, syphilis can be transmitted from infected women to their unborn child during pregnancy. Early and appropriate diagnosis and treatment prevents infection of the child and development of severe complications.

The difficulty in following up patients who have undergone syphilis testing in a variety of settings and testing for syphilis in many prenatal settings are major obstacles to effective syphilis control. The development of a rapid, point of care test that combines the sensitivity of a screening test with the specificity of a confirmatory test will assist clinicians in providing appropriate treatment during an initial clinic visit.

The Federal Technology Transfer Act of 1986 (15 U.S.C. 3710a) authorizes federal agencies to permit Directors of government-operated federal laboratories to enter into a Cooperative Research and Development Agreement (CRADA) with a federal or non-federal entity, including a state or local government, college and university, corporation, sole proprietorship, and trade association, for the purpose of broadening the U.S. technological base by disseminating and making available new knowledge from a Government research laboratory for the development of new products and technologies

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® HIV 1/2 and HIV 1/2 STAT-PAK™ 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™), for its next generation HIV and other rapid tests. 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 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 212-825-3210

Investors: James Carbonara

Media: Susan Morgenhesser



ChemBio Receives CLIA Waiver for HIV 1/2 STAT-PAK™

Potential Customers: 189,000 Doctor's Offices and Clinics

MEDFORD, N.Y. November 28, 2006 -ChemBio Diagnostics Inc. (OTCBB: CEMI) has received CLIA Waiver for one of its two FDA-approved rapid HIV tests, HIV 1/2 STAT-PAK™. The CLIA (Clinical Laboratory Improvement Act) waiver allows ChemBio to market these HIV tests to a potential market of approximately 189,000 laboratory entities across the United States, including doctors' offices and clinics.

Larry Siebert, Chief Executive Officer of ChemBio said, "CLIA Waiver is an important milestone, as this now allows us to submit final labeling changes to the FDA for marketing by Inverness Medical Innovations (AMEX: IMA), our U.S. marketing partner for this product. These changes will be submitted during December which should permit sales to begin in the first quarter of 2007. We are glad that as we approach World AIDS Day this Friday to be entering a US market that we believe is expanding as a result of the recent CDC recommendations for routine HIV testing in the United States. We believe therefore that Inverness has an excellent opportunity to be successful with this product and our other FDA approved product, SURE CHECK HIV® 1/2. A CLIA Waiver application for that product was submitted, and is currently under review by the FDA.

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ChemBio Diagnostics Undertakes HIV/AIDS Media Education Initiative

19th Annual World AIDS Day Today

Rapid HIV Tests Critical to Treatment and Prevention

New York, December 1, 2006--- ChemBio Diagnostics, Inc.'s (OTCBB:CEMI) Lawrence Siebert, President and Chief Executive Officer, was interviewed by television and radio stations covering various regions of the country this week to discuss the state of HIV/AIDS, new routine HIV testing recommendations recently issued by the United States Centers for Disease Control, and how critical rapid HIV testing is for both treatment and prevention efforts. The interviews were part of an education initiative by ChemBio on what is being done to fight AIDS in the US and globally. Today marks the 19th Annual World AIDS Day.

Stations that interviewed Mr. Siebert include affiliate stations of Fox, NBC, CBS as well as other stations including Voice of America.

During the interviews, Mr. Siebert discussed that most of the 40 million individuals living with AIDS worldwide do not know their status. Even in the United States, where there are an estimated one million people living with HIV/AIDS, the percentage not aware of their status is estimated to be 30%. Studies show that infected individuals who are aware of their status take measures to prevent spreading the disease and treatment is becoming increasingly available at an affordable cost. Until recently, the lack of availability of rapid diagnosis has been a stumbling block to AIDS treatment and prevention.

Mr. Siebert said, "Often times, those who have been tested never return to get their results, but with a rapid HIV test, individuals can learn their status at the point of care. ChemBio manufactures three rapid HIV tests, two of which have marketing approval from the FDA. Our HIV 1/2 STAT-PAK™ is CLIA waived, and our SURE CHECK® HIV 1/2 CLIA waiver application is currently being reviewed. Both tests offer results within 15 minutes. We are proud to be part of the worldwide battle to test for and prevent the spread of HIV/AIDS."

Anyone interested in receiving a copy of aired interviews (for personal use) may submit a request to marce@chembio.com, 631-924-1135 ext 123.

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Contact:

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