
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): March 16, 2007 (March 14, 2007)



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.

On March 14, 2007 the Registrant issued the press release titled “Chembio Issued U.S. Patent for Dual Path Immunoassay Device & Method” included herein as Exhibit 99.1.

ITEM 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1 Press Release titled “[Chembio Issued U.S. Patent for Dual Path Immunoassay Device & Method](#)” issued March 14, 2007.

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: March 16, 2007

Chembio Diagnostics, Inc.

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



ChemBio Issued U.S. Patent for Dual Path Immunoassay Device & Method

'New Path' for Rapid Test Development & Partnering

Medford, New York, March 14, 2007- (OTCBB:CEMI) - ChemBio Diagnostics, Inc. has been issued United States Patent Number 7,189,522 for its "Dual Path Immunoassay Device" and is now beginning to actively seek collaborations for this exciting new technology platform. Additional patent protection is also pending both in the U.S. and worldwide.

Lawrence Siebert, President and CEO of ChemBio commented, "I am very pleased with the issuance of this new patent. The Dual Path Immunoassay system, which we will brand as the DPP™ test, gives us a great opportunity to enhance shareholder value and bring a new generation of lateral flow rapid tests to a wide variety of markets. I am most appreciative of the commitment of Javan Esfandiari, our Vice President of Research & Development, as well as the entire ChemBio R&D team, for designing this proprietary platform which has several advantages over well established conventional single path lateral flow rapid test systems."

The patent, which has an issue date of March 13, 2007, describes a device and method for detection that includes a separate, second flow path for application of the sample material to be tested versus other solutions used in developing lateral flow rapid tests. Based upon a number of studies conducted at ChemBio which have compared DPP™ test devices to conventional single path lateral flow devices, this separate, second flow path, enables the development of diagnostic tests that can (1) increase sensitivity; (2) extend the spectrum of useful sample types beyond just the more typical sources such as blood, serum and plasma (e.g., oral fluid, sputum, urine, feces, animal meat juices, etc.); (3) improve results when testing for multiple conditions and/or different parameters of one related condition, and; (4) reduce the amount of expensive reagents required, as well as other advantages. A video animation of ChemBio's oral fluid HIV test employing DPP™ test technology can be viewed at <http://www.chembio.com/newtechnologies.html>.

Based upon these advantages, patent-protected DPP™ tests can now be developed and/or licensed by ChemBio for a diverse range of rapid tests. As ChemBio's core competency is in development and manufacture of serological tests for infectious diseases, studies demonstrating the advantages of the DPP™ test have so far focused in this area; an oral fluid HIV test, an HIV confirmatory test, a screen-and-confirm rapid test for syphilis (in conjunction with the United States Centers for Disease Control), and new tests for human tuberculosis, Chagas Disease and a number of other neglected diseases, are all in the pipeline.

ChemBio's approved PMAs for two rapid HIV tests by the CBER division of the FDA and the expected approval by the US Department of Agriculture (USDA) for its facility and first product line for veterinary tuberculosis should also facilitate new business development activities for rapid tests developed using the DPP™ test technology. With these approvals, ChemBio cannot only license and/or develop products for others, but also manufacture these regulated products in a facility already inspected by these agencies. ChemBio further believes that the DPP™ test technology will be attractive in other fields, such as the detection of antigens in biological samples, food and the environment. Studies are in progress in order to confirm advantages expected of DPP™ tests in these areas as well.

Finally, ChemBio believes that this patent provides it with the freedom to operate outside of all single path lateral flow technologies, a field that is unusually crowded with many overlapping patents issued over the last 20 years. ChemBio believes that products developed within the scope of the Dual Path Immunoassay System claims are outside of the scope of all existing single path lateral flow patents. As such, prospective licensees will enjoy a lower overall cost of goods as compared to the cost of multiple single path lateral flow patent licenses, assuming single path lateral licenses are even available.

ABOUT CHEMBIO

ChemBio Diagnostics, Inc. is a developer and manufacturer of rapid diagnostic tests for infectious diseases. The Company has received marketing approval from the FDA for two of its rapid HIV tests. The Company also manufactures rapid tests for both human and veterinary Tuberculosis and Chagas Disease, and has developed a patented technology, the Dual Path Platform (DPP™) test, for its next generation HIV and other rapid tests. References to ChemBio Diagnostics, Inc. may also include its wholly owned operating subsidiary, ChemBio Diagnostic Systems, Inc. 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:

Matty Arce - 631-924-1135 ext 123.

