

UNITED STATES
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): April 17, 2006



(Exact name of registrant as specified in its charter)

Nevada 333-85787 88-0425691
(State or other jurisdiction (Commission File (IRS Employer Identification No.)
of incorporation) Number)

3661 Horseblock Road, Medford, NY 11763
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code (631) 924-1135

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 (see General Instruction A.2. below):

- ☐ 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 1.01. Entry into a Material Definitive Agreement

On April 17, 2006, the Compensation Committee of ChemBio Diagnostics, Inc. (the "Company") approved the cancellation of each employee stock option award issued under the 1999 Equity Incentive Plan where the exercise price was greater than \$0.75 per share of the Company's common stock, and the issuance of a new stock option award under the 1999 Equity Incentive Plan, for the same number of shares of the Company's common stock, with an exercise price of \$0.75 per share of the Company's common stock for each cancelled stock option award. The market price of the common stock of the Company on April 17, 2006 was \$0.72 per share. In total, stock option awards to acquire 795,000 shares of Company common stock were cancelled, and stock option awards to acquire 795,000 shares of Company common stock were issued. Other than the change in the exercise price, all of the terms and conditions in each newly issued stock option award are identical to the cancelled stock option award it replaces, with the following exceptions: (i) Lawrence A. Siebert's stock option award for 50,000 shares of the Company's common stock, exercisable on May 28, 2006 and terminating on May 28, 2011 was replaced with a stock option award for 50,000 shares of the Company's common stock, exercisable on January 1, 2007 and terminating on May 28, 2011; (ii) Avi Pelossof's stock option awards for 72,500 shares of the Company's common stock, exercisable on May 28, 2005 and on May 28, 2006 and both terminating on May 28, 2011 was replaced with a stock option award for 72,500 shares of the Company's common stock, exercisable on January 1, 2007 and terminating on May 28, 2011.

The following table lists the named executive officers of the Company, the number of shares of Company common stock each executive officer may acquire under the new stock option awards, and the exercise price of each stock option award cancelled.

Name of Executive Officer	Number of Shares of Common Stock	Exercise Price of Stock Option Cancelled
Lawrence Siebert	10,000	1.000
Lawrence Siebert	50,000	1.200
Lawrence Siebert	50,000	1.500
Lawrence Siebert	50,000	3.000
Avi Pelossof	50,000	0.900
Avi Pelossof	10,000	1.000
Avi Pelossof	50,000	1.350
Avi Pelossof	40,000	3.000
Avi Pelossof	10,000	4.000
Javan Esfandiari	25,000	0.800
Javan Esfandiari	25,000	0.800
Javan Esfandiari	25,000	0.900

Javan Esfandiari		5,000		1.000
Javan Esfandiari		25,000		1.200
Javan Esfandiari		25,000		1.500
Javan Esfandiari		30,000		3.000
Javan Esfandiari		5,000		4.000
Richard Bruce		5,000		1.000
Richard Bruce		20,000		2.350
Richard Bruce		10,000		3.000
Richard Bruce		5,000		4.000
Richard Bruce		12,500		0.800
Richard Bruce		12,500		0.800
Richard Larkin		25,000		0.800
Richard Larkin		25,000		0.800

ITEM 1.02 Termination of a Material Definitive Agreement

To the extent applicable, the contents of Item 1.01 above are incorporated into this Item 1.02 by reference.

ITEM 3.02 Unregistered Sales of Equity Securities

To the extent applicable, the contents of Item 1.01 above are incorporated into this Item 3.02 by reference.

The Company relied on Section 4(2) of the Securities Act of 1933 and Rule 506 promulgated thereunder as the basis for its exemption from registration of this issuance. Executive officers of the Company are considered to be “accredited investors” when purchasing securities issued by the Company.

ITEM 7.01. Regulation FD Disclosure

On April 19, 2006 the Company issued the press release titled “Chembio Receives FDA Approvable Letter for its Rapid HIV Tests” included herein as Exhibit 99.1.

ITEM 9.01 Financial Statements and Exhibits

(c) Exhibits.

99.1 Press release titled “[Chembio Receives FDA Approvable Letter for its Rapid HIV Tests](#)”

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: April 21, 2006

CHEMBIO DIAGNOSTICS, INC.

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



Chembio Receives FDA Approvable Letter for its Rapid HIV Tests

Major Hurdle for U.S. Sales and Eventual Over the Counter Sales Cleared

MEDFORD, N.Y. - April 19, 2006 - Chembio Diagnostics, Inc. (OTCBB:CEMI) has received an “approvable” letter from the U.S. Food and Drug Administration (FDA) for its SURE CHECK(R) HIV 1/2 and HIV 1/2 STAT-PAK(TM) rapid test Pre-Market Applications (PMAs). The rapid HIV tests detect HIV-1 and HIV-2 antibodies in four different sample matrices; finger-stick whole blood, venous whole blood, serum and plasma. Test results are complete within approximately 15 minutes of sample application. The FDA letter states that Chembio’s PMA approval is subject only to final review by the FDA of the package inserts for each of the products, a review which has been ongoing, and other standard conditions related to all PMAs. Chembio therefore anticipates that the PMA will be approved in the very near future. An approved PMA will allow Chembio to market its tests to clinical laboratories and hospitals in the United States.

Javan Esfandiari, Chembio’s Vice President of Research & Development, stated, “I am pleased that our development efforts, now fully supported by the FDA review of our clinical data and inspection of our facility, have brought us within clear sight of the goal of PMA approval. I am very proud to be associated with these products and the supporting cast at Chembio. Rapid tests allow greater access to testing, which results in more people being diagnosed earlier, when treatment is most effective.”

Chembio is currently in discussions with a potential U.S. marketing partner that, if successful, Chembio anticipates will exclusively market these products in the U.S. These discussions are continuing, though there is no assurance that these discussions will result in a definitive agreement.

“Estimates are that as much as 1/3 of those infected with HIV in the US population are not aware of their HIV-positive status. We believe that these individuals are much likelier to access testing services if test results and counseling can be delivered at the point of care, rather than having to wait days or weeks for laboratory results. HIV can be managed very effectively with treatment, but people cannot get access to treatment without first knowing their status, nor can we bring down the rate of new infections without greater awareness of HIV positive status in this affected population,” said Lawrence Siebert, President and CEO of Chembio. Mr. Siebert continued, “The U.S. is a very important market for Chembio and those that need to be tested, as there are only two competitive products currently approved. Moreover, we believe PMA approval, when granted, will provide further impetus to our international marketing efforts, including opening markets not currently available. We are committed to serving all markets where this technology is needed with appropriate and reasonable pricing as needed.”

Chembio believes that the U.S. rapid HIV test professional market will exceed \$50 million within the next couple of years. The U.S. market opportunity has been developing first in the public health and hospital emergency room segments. As a result of increased advocacy for routine testing, this will likely increase to expand use of this technology in the physician’s offices, prisons, and in other venues. In the State of the Union Address this year, President Bush proposed more than \$90 million for the purchase and distribution of rapid HIV tests for the testing of more than 3 million additional Americans. Worldwide, based upon an analysis done by the Global Business Coalition of HIV/AIDS (www.businessfightsaids.org) hundreds of million people will need to be tested over the next several years in order to insure that funded treatment targets are achieved. FDA approval also allows Chembio to expand its international marketing efforts into countries that require regulatory approval in the manufacturer’s country of domicile.

SURE CHECK HIV 1/2 and HIV 1/2 STAT-PAK rapid tests are easy-to-perform. They are highly sensitive (99.7% for HIV-1 and 100% for HIV-2 when compared to a Western Blot assay) and specific (99.9%). The tests have a rapid turnaround time of approximately 15 minutes. They are safe to use, requiring a very small sample of whole blood (as little as 2.5-5.0 micro-liters), easily obtained with a finger prick. Chembio’s FDA PMA approval, when granted, will be for use not only with finger-stick whole blood samples however, but also with venous whole blood, serum and plasma samples. Both products have a built-in internal control (a true IgG) which gives confirmation of sample addition and proper test performance.

Chembio’s tests uniquely offer a 24-month shelf life at 8 to 30°C (46 to 86°F) which is a significant advantage. This advantage may become more important if rapid HIV tests such as Chembio’s are approved for the over the counter markets in accordance with guidelines that the FDA’s Blood Products Advisory Committee (BPAC) recommended last month. Based on that recommendation, the Company is beginning to explore this market opportunity.

ABOUT CHEMBIO

Chembio Diagnostics, Inc. possesses expertise in the development and manufacture of rapid diagnostic tests for various infectious diseases. Chembio is on the frontline of the global battle against the devastating AIDS pandemic. This battle, to which the United States alone has pledged \$15 billion in international aid, is the impetus behind Chembio’s development of rapid HIV tests. Because rapid tests can detect HIV antibodies within minutes, the massive prevention and treatment programs that are now scaling up can be much more effective by providing results for earlier treatment. Chembio is one of four recommended global rapid HIV test suppliers under the Clinton HIV/AIDS Initiative (www.clintonfoundation.org). The Company also manufactures additional rapid tests that it has developed for other deadly diseases, including human and veterinary Tuberculosis and Chagas Disease. References to Chembio Diagnostics, Inc. may actually refer to Chembio Diagnostic Systems, Inc., the wholly owned subsidiary of Chembio Diagnostics, Inc. Chembio is located at 3661 Horseblock Road, Medford, NY 11763. 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: Vince Daniels/James Carbonara
The Investor Relations Group 212-825-3210