

# 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) **May 9, 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))

#### ITEM 2.02. Results of Operations and Financial Condition.

- (a) To the extent applicable, the information disclosed under Item 7.01 (a) is incorporated herein by reference.

#### ITEM 7.01. Regulation FD Disclosures.

- (a) On May 15, 2006 the Registrant issued the press release titled "ChemBio Reports First Quarter 2006 Financial Results" included herein as Exhibit 99.1.
- (b) On May 9, 2006 the Registrant issued the press release titled "ChemBio Supports CDC's Recommendation For Routine HIV Testing" included herein as Exhibit 99.2.

#### ITEM 9.01. Financial Statements and Exhibits

- (c) Exhibits.

- 99.1 Press Release titled "[ChemBio Reports First Quarter 2006 Financial Results](#)" issued May 15, 2006.
- 99.2 Press Release titled "[ChemBio Supports CDC's Recommendation For Routine HIV Testing](#)" issued May 9, 2006.

#### 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: May 16, 2006

ChemBio Diagnostics, Inc.

By: /s/ Lawrence A. Siebert





## ChemBio Reports First Quarter 2006 Financial Results

*Net Product Sales Increase 238% Compared to the First Quarter of 2005*

MEDFORD, N.Y. - May 15, 2006 - ChemBio Diagnostics, Inc. (OTCBB:CEMI) reported first quarter 2006 financial results. Revenues for the first quarter of 2006 were \$1.24 million, a 69% increase compared to first quarter 2005 revenues of \$732,000. Net product sales for the first quarter increased 238% to \$1.17 million compared to \$346,000 for the first quarter of 2005. The first quarter 2006 net loss attributable to common stockholders was \$1.94 million or \$0.22 per share compared to a net loss attributable to common stockholders of \$3.5 million or \$0.50 per share for the first quarter of 2005.

The first quarter revenue growth was attributable to increased sales of the Company's rapid HIV tests. Rapid HIV test revenue for the first quarter of 2006 increased approximately 496% to \$537,000 as compared to \$90,000 in the first quarter of 2005. The Company also received its first significant order for its Chagas STAT-PAK(TM) rapid test, in the amount of \$1.2 million, of which it shipped \$480,000 in the first quarter of 2006 and expects to ship the balance in the second and third quarters of 2006.

### Financial Outlook

The Company believes that sales of its HIV products will continue to increase in 2006 as a result of both the international marketing strategies that were implemented in 2005 and sales to the United States market after anticipated approval from the U.S. Food and Drug Administration (FDA). The Company also expects to generate additional revenues in 2006 from its Chagas STAT-PAK(TM) rapid test. Furthermore, with the commercial release in late 2006 of the PrimaTB STAT-PAK(TM) rapid test, the Company expects to begin generating revenues from that product in early 2007.

### Recent Highlights:

- Received an "approvable" letter from the FDA for its SURE CHECK(R) HIV 1/2 and HIV 1/2 STAT-PAK(TM) rapid test Pre-Market Applications (PMAs). 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, and other standard conditions related to all PMAs. The Company therefore anticipates that the PMA will be approved in the very near future. ChemBio is in discussions with a marketing partner for distribution of the products in the U.S.
- Developed a Dual Path Platform technology for rapid diagnostic tests that offers significant advantages over the lateral flow technology used in commercially available rapid diagnostic tests. ChemBio expects to develop new tests using the technology as well as license the technology to other companies for use in their tests.
- The Nigerian Ministry of Health designated ChemBio's HIV 1/2 STAT-PAK(TM) as a screening test in four out of the eight testing protocols that comprise Nigeria's Interim National Testing Algorithm.
- ChemBio's rapid HIV tests were evaluated and recommended for use in Kenya. The tests were evaluated by the National AIDS/STD Control Programme of the Kenyan Ministry of Health and met their sensitivity and specificity requirements.
- The FDA's Blood Products Advisory Committee proposed regulatory requirements for the approval of over the counter distribution of rapid HIV tests.
- The U.S. Centers for Disease Control and Prevention plans to issue revised HIV testing guidelines, which recommend that doctors begin voluntary HIV testing as a part of routine medical care, for everyone in the United States between the ages of 13 to 64.

"ChemBio Diagnostics is very well positioned in all of its markets," said Lawrence Siebert, President and CEO. "The international market is growing rapidly as funded HIV treatment programs strive to reach treatment goals. Internationally, there is an expected overall demand for several hundred million rapid HIV tests over the next few years. The U.S. market is also growing rapidly and is expected to expand even further in the coming years boosted by CDC's recommendation for routine HIV testing and the progress being made towards approval of over the counter sales of rapid HIV tests."

### 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](http://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](http://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.

#### **ChemBio Diagnostics, Inc.** **Summary of Results of Operations**

	<b>First Quarter 2006</b>	<b>First Quarter 2005</b>
<b>Total Revenues</b>	<b>\$ 1,237,667</b>	<b>\$ 731,885</b>
<b>Gross Profit</b>	<b>435,539</b>	<b>267,335</b>
<b>Operating Loss</b>	<b>(1,254,913)</b>	<b>(623,476)</b>
<b>Net Loss</b>	<b>(1,263,714)</b>	<b>(619,986)</b>
<b>Preferred Dividends</b>	<b>212,923</b>	<b>182,178</b>
<b>Accreted Beneficial Conversion to preferred stock</b>	<b>463,434</b>	<b>2,698,701</b>

<b>Net Loss Attributable to Common Stockholders</b>	<b>\$</b>	<b>(1,940,071)</b>	<b>\$</b>	(3,500,865)
<b>Loss per share</b>	<b>\$</b>	<b>(0.22)</b>	<b>\$</b>	(0.50)

Contact:  
Investor Relations: Vince Daniels/James Carbonara  
Media Relations: Judy Katz/Susan Morgenbesser  
The Investor Relations Group  
(212) 825-3210

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## ChemBio Supports CDC's Recommendation For Routine HIV Testing

MEDFORD, N.Y. - May 9, 2006 - ChemBio Diagnostics, Inc. (OTCBB:CEMI) supports the U.S. Centers for Disease Control and Prevention (CDC) plans to issue revised HIV testing guidelines which recommend that doctors begin voluntary HIV testing as a part of routine medical care, for everyone in the United States between the ages of 13 to 64.

Lawrence Siebert, President and CEO of ChemBio, commented, "We are pleased the CDC will be revising its guidelines so as to recommend routine HIV testing. Routine testing will lead to early diagnosis, which is essential in the battle against AIDS. Individual awareness of HIV status reduces the spread of the disease and prolongs life. With the cost of antiretroviral drugs declining, it makes sense for everyone to be tested and receive appropriate treatment."

On April 19<sup>th</sup> ChemBio announced it had 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). These 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 appear 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, and other standard conditions related to all PMAs. ChemBio therefore anticipates that the PMA will be approved in the very near future. ChemBio is in discussions with a marketing partner for distribution of the products in the U.S.

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### Contact:

Investors - Vince Daniels/James Carbonara  
Media - Judy Katz/Susan Morgenbesser  
The Investor Relations Group 212-825-3210