# 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) August 14, 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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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.

- (a) On August 14, 2006 the Registrant issued the press release titled "Chembio Reports Second Quarter and First Half 2006 Financial Results"
- (b) On August 15, 2006 the Registrant issued the press release titled "Chembio to Feature New Procedure for Rapid HIV Test at International Aids Conference"

### ITEM 9.01. Financial Statements and Exhibits

- (c) Exhibits.
  - 99.1 Press Release titled "Chembio Reports Second Quarter and First Half 2006 Financial Results" issued August 14, 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: August 15, 2006 Chembio Diagnostics, Inc.

By: <u>/s/ Lawrence A. Siebert</u> Lawrence A. Siebert Chief Executive Officer



### **Chembio Reports Second Quarter and First Half 2006 Financial Results**

Net Product Sales Increase 93% Compared to the Second Quarter of 2005

MEDFORD, N.Y. - August 14, 2006 - Chembio Diagnostics, Inc. (OTCBB:CEMI) reported second quarter and first half 2006 financial results.

Revenues for the second quarter of 2006 were \$1.64 million, an 81% increase compared to second quarter 2005 revenues of \$906,000. Net product sales for the second quarter increased 93% to \$1.57 million compared to \$814,000 for the second quarter of 2005. The second quarter 2006 net loss attributable to common stockholders was \$1.34 million or \$0.13 per share compared to a net loss attributable to common stockholders of \$1.09 million or \$0.15 per share for the second quarter of 2005.

Revenues for the first six months of 2006 were \$2.87 million, a 75% increase compared to revenues for the first six months of 2005 of \$1.64 million. Net product sales for the first six months of 2006 increased 136% to \$2.74 million compared to \$1.16 million for the first six months of 2005. Net loss attributable to common stockholders for the first six months of 2006 was \$3.27 million, or \$0.34 per share, compared to a net loss attributable to common stockholders of \$4.59 million, or \$0.64 per share, for the first six months of 2005.

The second quarter and first half 2006 revenue growth was attributable to increased sales of the Company's rapid HIV and Chagas tests. Rapid HIV test revenue for the second quarter of 2006 increased approximately 79% to \$885,000 as compared to \$494,000 in the second quarter of 2005. Chagas test revenue for the second quarter of 2006 increased to \$458,000 as compared to \$11,000 in the second quarter of 2005. Rapid HIV test revenue for the first six months of 2006 increased approximately 143% to \$1.42 million as compared to \$584,000 in the first six months of 2005. Chagas test revenue for the first six months of 2006 increased to \$942,000 as compared to \$36,000 in the first six months of 2005.

#### 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 now possible after approval in May 2006 from the U.S. Food and Drug Administration (FDA) for its SURE CHECK(R) HIV 1/2 and HIV 1/2 STAT-PAK(TM). The Company also expects to generate additional revenues in 2006 from its Chagas STAT-PAK(TM) rapid test. Furthermore, the Company expects to commercially release its PrimaTB STAT-PAK(TM) rapid test in late 2006 and to begin generating revenues from that product in early 2007.

#### Recently the Company:

- Received an approval 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). Chembio is in discussions with potential partners for the marketing of these FDA approved products in the U.S. We have also submitted Clinical Laboratory Improvement Act ("CLIA") waiver applications for these products.
- · Introduced initial prototypes of a new patent pending rapid test technology, Dual Path Platform (DPP(TM)), that offers significant advantages over conventional single path lateral flow technology. Chembio intends to develop new tests using the DPP as well as license it to other companies for use in their tests. Chembio has completed initial internal studies on an HIV test using the DPP and oral fluid samples.
- · Shipped our first orders to Nigeria based upon the Nigerian Ministry of Health designating 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 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 possibility for FDA approval of over the counter sales of rapid HIV tests."

### 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(R) HIV 1/2 and HIV 1/2 STAT-PAK(TM) 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(TM)), for its next generation HIV and other rapid tests. For additional information please visit <a href="https://www.chembio.com">www.chembio.com</a>.

## 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.

#### <u>Chembio Diagnostics, Inc.</u> <u>Summary of Results of Operations</u>

First Six months of

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	Second Q	uarter 2006	Second Quarter 2005	First Six months of 2006	2005	
Total Revenues	\$	1,637,236	\$ 905,689	\$ 2,874,903	\$ 1,637,574	
Gross Profit		564,434	269,309	999,973	536,644	
Operating Loss		(1,120,352)	(886,908)	(2,375,266)	(1,510,383)	
Net Loss		(1,127,375)	(875,142)	(2,391,090)	(1,495,127)	
Preferred Dividends		207,937	212,061	420,860	394,239	
Accreted Beneficial Conversion to preferred stock		-	-	463,434	2,698,701	

Net Loss Attributable to Common Stockholders	(1,335,312)	(1,087,203)	(3,275,384)	(4,588,067)
Loss per share	\$ (0.13) \$	(0.15) \$	(0.34) \$	(0.64)

Contact:

The Investor Relations Group Investors: James Carbonara/Andrea Raetzer Media: Susan Morgenbesser 212-825-3210



#### CHEMBIO TO FEATURE NEW PROCEDURE FOR RAPID HIV TEST AT INTERNATIONAL AIDS CONFERENCE

MEDFORD, N.Y. — August 15, 2006 — Chembio Diagnostics, Inc. (OTCBB: CEMI) is featuring a new alternate procedure for performing its HIV 1/2 STAT-PAK Dipstick(TM) rapid test at this week's International AIDS Conference in Toronto, Canada.

The International AIDS Conference is the world's largest conference for HIV/AIDS with an estimated 20,000 participants including scientists, healthcare providers, political leaders and journalists. The goal of the conference is to bolster AIDS related prevention, treatment and care efforts worldwide.

Larry Siebert, CEO of Chembio commented, "We are pleased to be a part of this year's conference. There is greater recognition of how vital rapid testing is to achieving the goals of the Conference; prevention, treatment and worldwide care. The ability to know one's status within 15 minutes of utilizing a rapid HIV diagnostic test is powerful information. The increasing awareness that treatment is available is encouraging more and more people to get tested worldwide."

Chembio has three rapid HIV tests, two of which received FDA approval in May. HIV 1/2 STAT-PAK Dipstick(TM) is a lower cost version that is used in donor-funded programs; it is the only rapid HIV test offered through the Clinton Foundation's HIV/AIDS Initiative (CHAI) that is manufactured by a company with FDA-approved rapid HIV tests. This test can now be performed with two flexible testing procedures: The new procedure allows one to place the test strip on a flat laminate card and run the test like a standard cassette test, yet without the cost and weight of cassette components. Customers can still choose to use the original tube procedure that has been provided for the dipstick. These two testing procedures allow customers the convenience of choosing the method best suited to their testing environment.

 $For further information about the \ 16^{th} \ International \ AIDS \ Conference, please \ visit the \ event \ Web \ site \ at \ http://www.aids2006.org/.$ 

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