

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 30, 2007 (March 30, 2007)



**CHEMBIO DIAGNOSTICS, 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 3.02. Unregistered Sales of Equity Securities

On November 30, 2006, pursuant to the terms of a consulting contract with The Investor Relations Group (“IRG”), the Company issued IRG 8,334 shares of common stock and warrants to purchase 8,334 shares of common stock. The conversion price for these warrants is \$.70 per share and the warrants expire on November 30, 2010. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of these issuances. The investor in the issuance was an accredited investor.

On December 1, 2006, the Company issued to Bio Business Science and Development, LTDA, warrants to purchase 41,417 shares of common stock. The exercise price of these warrants is \$0.81 per share. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. The investor in the issuance was an accredited investor.

On December 27, 2006, Avi Pelossof exercised warrants to purchase 100,000 shares of common stock. The exercise price was \$0.60 per share and the Company received \$60,000 in cash for this exercise. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. The investor in this issuance was an accredited investor.

On January 2, 2007, as payment of dividends on the series B preferred stock, the Company issued 345,579 shares of common stock to holders of the series B preferred stock. No cash was exchanged in this issuance. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. Each of the recipients of the dividends was an accredited investor.

On January 19, 2007, Avi Pelossof exercised warrants to purchase 50,000 shares of common stock. The exercise price was \$0.62 per share and the Company received \$31,000 in cash for this exercise. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. The investor in this issuance was an accredited investor.

On March 19, 2007, the Company issued an option to acquire 36,000 shares of common stock to one of the Company’s non-employee directors: Dr. Gary Meller. The exercise price of the option is \$0.62 per share, and the option vests in three equal annual installments beginning on March 19, 2007. Each option expires on March 19, 2012. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. Dr. Meller is an accredited investor.

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## **ITEM 7.01. Regulation FD Disclosures**

On March 29, 2007, the Company issued a press release titled “Chembio Reports Fourth Quarter and Full-Year 2006 Results” included herein as Exhibit 99.1.

On March 30, 2007, the Company issued a press release titled “Chembio to Host Conference Call to Discuss Financial Results for 2006” included herein as Exhibit 99.2.

## **ITEM 9.01. Financial Statements and Exhibits**

Exhibits.

99.1 Press Release titled “[Chembio Reports Fourth Quarter and Full-Year 2006 Results](#)” issued March 29, 2007.

99.2 Press Release titled “[Chembio to Host Conference Call to Discuss Financial Results for 2006](#)” issued March 30, 2007.

In accordance with General Instruction B.2 of Form 8-K, the information disclosed in Item 7.01, and Exhibits 99.1 and 99.2 attached to, 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.

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## 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 30, 2007

Chembio Diagnostics, Inc.

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

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## ChemBio Reports Fourth Quarter and Full-Year 2006 Results

MEDFORD, N.Y.--March 29, 2007--ChemBio Diagnostics, Inc. (OTCBB:[CEMI](#) - [News](#)) reported fourth-quarter and full-year financial results for 2006.

2006 revenues were \$6.5 million, a 65% increase compared to 2005 revenues of \$3.9 million. For 2006, the net loss attributable to common stockholders was \$8.2 million or \$0.80 per share compared to a net loss attributable to common stockholders of \$6.8 million or \$0.88 per share for 2005. The net loss attributable to common stockholders for 2006 and 2005 includes \$3.0 million and \$3.52 million, respectively, for non-cash dividends as well as the beneficial conversion feature related to the Company's convertible preferred stock.

Revenues for the fourth quarter of 2006 were \$2.6 million, a 93% increase compared to fourth quarter 2005 revenues of \$1.4 million. The fourth quarter 2006 net loss attributable to common stockholders was \$2.6 million or \$.23 per share compared to a net loss attributable to common stockholders of \$1.14 million or \$.14 per share for the fourth quarter of 2005. The net loss attributable to common stockholders for the fourth quarters of 2006 and 2005 include \$1.5 million and \$.2 million, respectively for non-cash dividends as well as the beneficial conversion feature related to the Company's convertible preferred stock.

The fourth quarter and full-year revenue growth was attributable to increased sales of the Company's rapid HIV and Chagas Disease tests.

### Financial Outlook

The Company believes that sales of its HIV products will continue to increase in 2007 as a result of both sales to the United States market through our U.S. marketing agreement with Inverness Medical Innovations, Inc. (Inverness) and the international marketing strategies that were implemented in 2006. The Company also expects to begin to generate additional revenues in 2007 from its veterinary line of STAT-PAK(TM) rapid tests and from its recently patented Dual Path Platform (DPP™) technology. In view of these developments together with the financings that the Company has completed, the "going concern" qualification contained in the previous audit report from the Company's independent auditors has been removed in the current annual report.

### Company Highlights

#### In 2006 ChemBio:

- Received FDA approval of SURE CHECK(TM) HIV and HIV 1/2 STAT-PAK(TM) in May 2006.
- Received Clinical Laboratory Improvement Act (CLIA) waiver of HIV 1/2 STAT-PAK in November 2006, allowing this test to be sold into approximately 189,000 laboratory entities across the United States, including doctors' offices and clinics. CLIA waiver for SURE CHECK (now under Inverness brand) is still pending.
- Concluded in September 2006 three agreements with Inverness Medical Innovations, Inc., a leader in point of care diagnostics for both consumer and professional markets. Inverness launched this quarter ChemBio's two FDA approved rapid HIV tests. Inverness also granted ChemBio a license to its lateral flow intellectual property and invested \$2 million in the ChemBio Series C Convertible Preferred Stock financing.
- Completed private placement transactions in the total amount of approximately \$10 million, including \$8.25 million of Series C 7% Convertible Preferred Stock together with warrants to purchase common stock.
- Settled costly litigation with StatSure Diagnostic Systems (SDS) which settlement combines each company's HIV barrel intellectual property, including an exclusive manufacturing license from StatSure to ChemBio of its barrel patent for all HIV applications.
- Was the only U.S.-based manufacturer of rapid HIV tests selected by the Clinton Foundation HIV/AIDS Initiative (CHAI) and was also selected in four of the eight parallel testing algorithms adopted by the Nigerian Ministry of Health, the latter resulting in significant revenues in 2006. The possible selection of ChemBio's tests in additional African countries is pending.
- Received an order for 990,000 of our Sure Check product from our distributor in Mexico. Approximately one-half of this order was shipped during the fourth quarter of 2006 and the balance was shipped during the first quarter of 2007.
- Shipped its first significant order for the Chagas STAT-PAK™ rapid test, in the amount of \$1.2 million, in 2006.

"2006 was a landmark year for ChemBio Diagnostics, and 2007 has begun splendidly with the issuance of our Dual Path Immunoassay Device patent as recently announced," said Lawrence Siebert, President and CEO. "We believe the US rapid HIV test market will grow as a result of the September 2006 recommendations issued by the United States Centers for Disease Control for routine HIV testing as well as the March 2006 decision by the US Food & Drug Administration to allow qualifying HIV tests to be submitted for approval for the over-the-counter market. These developments should help drive the expansion of the U.S. market for our products and technologies, and we believe our US marketing partner is well positioned to maximize this opportunity. We also have completed the facility inspection by the United States Department of Agriculture, which should result in our first veterinary product approval very soon. With increasing US-market revenues from our HIV tests and initial sales from our veterinary products, we believe that our operating results should improve, due both to increased unit volumes and higher average unit selling prices. Regardless we are focused on driving our manufacturing costs down with better plant utilization, more automation and other strategies."

Mr. Siebert further stated, "We also would like to thank both our shareholders for the confidence that they have expressed in ChemBio during this past year and our employees for their dedication and hard work."

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

	2006	2005	Fourth Quarter 2006	Fourth Quarter 2005
<b>Total Revenues</b>	<b>\$ 6,502,480</b>	<b>\$ 3,940,730</b>	<b>\$ 2,609,387</b>	<b>\$ 1,358,443</b>

<b>Gross Profit</b>	<b>2,016,568</b>	1,332,146	<b>829,224</b>	520,606
<b>Operating Loss</b>	<b>(4,580,193)</b>	(3,297,987)	<b>(964,453)</b>	(946,766)
<b>Net Loss</b>	<b>(4,995,020)</b>	(3,252,000 )	<b>(1,029,944)</b>	(923,366)
<b>Preferred Dividends</b>	<b>3,210,046</b>	3,517,022	<b>1,566,283</b>	217,826
<b>Net Loss Attributable to Common Stockholders</b>	<b>\$ (8,205,066)</b>	<b>\$ (6,769,022)</b>	<b>\$ (2,596,227)</b>	<b>(1,141,192)</b>
<b>Loss per share</b>	<b>\$ (0.80)</b>	<b>\$ (0.88)</b>	<b>\$ (0.23)</b>	<b>(0.14)</b>

## ABOUT CHEMBIO

Chembio Diagnostics, Inc., 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 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. References to Chembio may also include its wholly owned operating subsidiary, Chembio Diagnostic Systems, Inc. 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.

*CONTACT:* Chembio Diagnostics, Inc.  
Matty Arce, 631-924-1135 ext 123.

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## **ChemBio to Host Conference Call to Discuss Financial Results for 2006**

MEDFORD, NY--(MARKET WIRE)—March 30, 2007 -- ChemBio Diagnostics, Inc. (OTC BB:[CEML.OB](#) - [News](#)) will host a conference call on Tuesday, April 3, 2006 at 4:30pm EST. The call will be held to discuss the reported fourth quarter and full-year financial results for 2006.

The conference call can be accessed by dialing (877) 407-0728 or by visiting ChemBio's website at [www.chembio.com](http://www.chembio.com) for a live webcast. A recording of this webcast can also be accessed by using the same link.

### **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 veterinary Tuberculosis and Chagas Disease, and has developed a patent-pending technology, the Dual Path Platform (DPP<sup>TM</sup>), for its next generation HIV and other rapid tests. References to ChemBio may also include its wholly owned operating subsidiary, ChemBio Diagnostic Systems, Inc. For additional information please visit [www.chembio.com](http://www.chembio.com).

### **FORWARD-LOOKING STATEMENTS**

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### **Contact:**

ChemBio Diagnostics, Inc.  
Matty Arce (631) 924-1135 ext. 123