## 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 6, 2008 (August 1, 2008)



(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 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 5.02. DEPARTURE OF DIRECTORS OR CERTAIN OFFICERS; ELECTION OF DIRECTORS; APPOINTMENT OF CERTAIN OFFICERS; COMPENSATORY ARRANGEMENTS OF CERTAIN OFFICERS.

(b) On August 6, 2008, Chembio Diagnostics, Inc. (the "Company") and Mr. Robert L. Aromando, Jr., Senior Vice President of Commercial Operations of the Company, announced that Mr. Aromando's final day of employment with the Company will be August 8, 2008.

#### ITEM 7.01. REGULATION FD DISCLOSURE.

On August 4, 2008, the Company issued a press release entitled "Chembio Reports Record Total Revenues in Second Quarter." A copy of the press release is furnished herewith as Exhibit 99.1.

#### ITEM 8.01. OTHER EVENTS

On August 1, 2008 at a meeting of the Company's Board of Directors (the "Board"), Katherine Davis, a current member of the Board, was appointed as Chairperson of the Board's Audit Committee, and Jim Merselis, a current member of the Board, was appointed to serve on each of the Board's Audit Committee, Compensation Committee and Nominating And Corporate Governance Committee.

### ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

- (d) Exhibits.
  - 99.1 Press Release entitled "Chembio Reports Record Total Revenues in Second Quarter" dated August 4, 2008.

The information in this Item 7.01 of this Form 8-K is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that section. The information in this Item 7.01 of this Form 8-K also shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, except to the extent that the Company specifically incorporates it by reference.

#### **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 6, 2008 Chembio Diagnostics, Inc.

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

## EXHIBIT INDEX

Exhibit
Number

Description

99.1 Press Release entitled "Chembio Reports Record Total Revenues in Second Quarter" dated August 4, 2008.



# **Chembio Reports Record Total Revenues in Second Quarter**

Conference Call Scheduled for Monday, August 4 at 4:30 p.m. Eastern Time

MEDFORD, N.Y (August 4, 2008) – Chembio Diagnostics, Inc. (OTC/BB: CEMI) today reported financial results for the three and six months ended June 30, 2008.

Total revenues for the second quarter of 2008 were higher than any previous quarter at \$2.72 million, an 8.6% increase compared with second quarter 2007 revenues of \$2.50 million. This revenue growth came from \$46,000 of increased product revenues and \$169,000 of increased research and grant revenues. The increased product revenues for the second quarter of 2008 included an increase in rapid HIV test revenues of \$61,500 to \$2.21 million or 2.9% from \$2.15 million in the same period of 2007.

The net loss attributable to common stockholders decreased 63% to \$363,000, or \$0.01 per share, for the second quarter of 2008 compared to a net loss attributable to common stockholders of \$983,000, or \$0.08 per share, for the second quarter of 2007. The net loss attributable to common stockholders for the second quarter of 2007 included \$357,000 in non-cash dividends to preferred stockholders. As previously reported, all of the Company's convertible preferred stock was converted into common stock in December 2007, which resulted in no preferred stock dividends in the second quarter of 2008.

Total revenues for the first half of 2008 were \$5.08 million, an 11.9% increase compared with first half 2007 total revenues of \$4.54 million. First half 2008 revenue growth came from \$259,000 of increased product revenues and \$283,000 of increased research and grant revenues. The increased product revenues for the first half of 2008 included an increase in rapid HIV test revenue of \$171,000 to \$4.13 million or 4.3% from \$3.96 million in the same period of 2007. In addition, revenues from Tuberculosis tests increased by \$59,000 in the first half of 2008 compared with the same period in 2007.

The net loss attributable to common stockholders decreased 43.8% to \$1,161,000, or \$0.02 per share, for the first half of 2008 compared to a net loss attributable to common stockholders of \$2.07 million or \$0.17 per share for the first half of 2007. The net loss attributable to common stockholders for the first half of 2007 included \$711,000 in non-cash dividends to preferred stockholders. As previously reported, all of the Company's convertible preferred stock was converted into common stock in December 2007, which resulted in no preferred stock dividends in the first half of 2008.

#### **Second Quarter and Recent Highlights**

- · In addition to posting record quarterly total revenue, in the second quarter of 2008 the Company posted its lowest quarterly operating loss since the merger with Chembio Diagnostic Systems, Inc. in May 2004.
- · Strong sales of rapid HIV tests to Brazil and Africa offset decreased sales of these products in the US. The decreased sales in the US are due to a slower ramp in US rapid HIV test sales. The slower ramp is partially due to the delay in obtaining the approval of our PMA supplement to expand our HIV age testing range to include 13 to 17 year olds. As reported in June we completed the required clinical study for submitting this. In July we submitted the PMA supplement to the FDA, and we are now waiting for its review to be completed. This change, together with multiple initiatives by our marketing partner to expand distribution of our products, and now new studies by the United States Centers for Disease Control reported this past weekend of a 40% under-reporting of HIV incidence in the United States, should increase potential sales opportunities in the U.S. over the long term.
- · We remain bullish about our potential increased participation in the global, as well as domestic, rapid HIV test market. We are pleased with the more than tripling of the PEPFAR (U.S. President's Emergency Plan for AIDS Relief) program signed into law last week by the President to \$48 billion over the next five years, and with the increased emphasis on testing that is in the new legislation. As the only US-based manufacturer of competitively priced rapid HIV tests, we look forward to the potential of increased participation in PEPFAR.
- · Gross Profit increased 30.75% to \$1,296,000 reflecting improved average unit selling prices and continued improvements in manufacturing efficiencies compared to a year ago.
- · Operating Loss decreased 44% to \$365,259 as operating expenses (R&D and SG&A) increased less than 1% from the second quarter of 2007.
- · All studies required to file for CE Marking of our FDA-approved HIV tests are now complete. The **CE marking** certifies that a product has met European Union health, safety, and environmental requirements. We anticipate submitting the technical file very soon and therefore receiving CE marking this year
- · Our patented DPP® platform is providing the Company with an historic number of new product opportunities:
  - o We have completed development of the three DPP® products in connection with our contract with the Brazilian Ministry of Health; tests for antibody detection of canine Leishmaniasis, Leptospirosis and our first multiplex DPP® test, which is a point of care test for the confirmation (as compared with screening) of HIV. We are in the process of validating these initial products in order to scale up their manufacture during the third and fourth quarter. Our current forecast is to generate at least \$500,000 of product and license revenues from these products during the balance of 2008.
  - o We have completed development of our DPP® HIV screening test as a result of the successful conclusion of preclinical trials we conducted during the second quarter. We are now validating this product for production scale-up as well, and finalizing product inserts and packaging so that export sales can begin as soon as possible. We also are in discussions with potential marketing partners for this product in the United States, which would require a new PMA submission.
  - o We have made excellent progress on the product development project we entered with Bio-Rad Laboratories, Inc. We anticipate completing the initial phase of this development during the next couple of months, and thereupon proceeding to a long-term development and license agreement with Bio Rad.
  - o We are also completing development of our Syphilis screen and confirm test and have several new OEM product opportunities under discussion for DPP®. We are seeing an increasing interest in the combination of our intellectual property with our development and manufacturing capabilities.
  - o During the second quarter we also received from the United States National Institutes of Health a \$296,000 grant for development of a DPP® TB test.
  - o The United States Patent and Trademark Office (USPTO) issued Chembio an additional patent during the second quarter covering a point of care rapid test platform that serves to broaden our intellectual property coverage.
  - o The USPTO also issued us the registration of our DPP® trademark, enabling increased protection for this intellectual property.

Lawrence Siebert, President and CEO, commented, "We are pleased at the continued improvements from our base lateral flow business as we approach realizing new revenue streams from our DPP® products. We expect to continue this momentum despite a difficult economic environment as our products serve a global market. On a personal note, I am deeply saddened by the passing of Alan Carus who was an outstanding and valued member of our Board of Directors and chairman of our Audit Committee since 2005. Al worked tirelessly, was a tremendous asset to Chembio, and he will be sorely missed."

#### **Conference Call**

As previously announced, Chembio has scheduled a conference call and webcast for 4:30 a.m. Eastern time on Monday, August 4, 2008. Participants may access the call by dialing (877) 407-0782 from the U.S. or (201) 689-8567 from outside the U.S. In addition, following the completion of the call, a telephone replay will be accessible until August 11, 2008 at 11:59 p.m. Eastern Time by dialing (877) 660-6853 from the U.S. or (201) 612-7415 from outside the U.S. and entering reservation account number 286 and conference ID 292790. The conference call may also be accessed via the internet at http://www.investorcalendar.com/IC/CEPage.asp?ID=132435. An archive of the webcast will be available for 90 days on the Company's website at www.chembio.com.

#### **ABOUT CHEMBIO**

Chembio Diagnostics, Inc. develops, manufactures, licenses and markets proprietary rapid diagnostic tests in the growing \$5 billion point-of-care testing market. Chembio's two FDA PMA-approved, CLIA-waived, rapid HIV tests are marketed in the U.S. by a third-party company. Chembio markets its HIV STAT-PAK® line of rapid HIV tests internationally to government and donor-funded programs directly and through distributors. Chembio also has rapid tests for veterinary tuberculosis and chagas disease. In 2007 Chembio received a U.S. patent for its Dual Path Platform (DPP®) technology which has significant advantages over lateral-flow technologies. This technology is providing Chembio with a significant pipeline of business opportunities for the development and manufacture of new products based on DPP<sup>TM</sup>. Headquartered in Medford, NY, with approximately 100 employees, Chembio is licensed by the U.S. Food and Drug Administration (FDA) as well as the U. S. Department of Agriculture (USDA), and is certified for the global market under the International Standards Organization (ISO) directive 13.485.

#### **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.

#### **Contacts:**

Company Contact: Chembio Diagnostics, Inc. Susan Norcott 631-924-1135 ext 125 www.chembio.com

(Tables to follow)

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

		For the three months ended				For the six months ended			
		June 30, 2008		June 30, 2007		June 30, 2008		June 30, 2007	
Total Revenues	\$	2,717,784	\$	2,502,773	\$	5,082,512	\$	4,541,093	
Gross Profit	\$	1,296,809	\$	991,900	\$	2,358,731	\$	1,651,718	
Operating Loss	\$	(365,259)	\$	(654,597)	\$	(1,176,828)	\$	(1,565,735)	
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Net Loss	\$	(363,129)	\$	(625,856)	\$	(1,161,311)	\$	(1,354,662)	
Dueferund Dividende Deemed									
Preferred Dividends, Deemed Dividends and Beneficial Conversion									
Feature		_	\$	356,900		_	\$	710,878	
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Net Loss Attributable to Common									
Stockholders	\$	(363,129)	\$	(982,756)	\$	(1,161,311)	\$	(2,065,540)	
Loss per share	\$	(0.01)	\$	(0.08)	\$	(0.02)	\$	(0.17)	

## <u>Chembio Diagnostics, Inc.</u> <u>Summary of Balance Sheet</u>

	June 30, 2008		December 31, 2007	
CURRENT ASSETS:				
Cash	\$	954,157	\$	2,827,369
Other current assets		3,195,964		2,643,938
TOTAL CURRENT ASSETS		4,150,121		5,471,307
NET FIXED ASSETS		964,542		829,332
OTHER ASSETS		1,103,970		284,358
	'			
	\$	6,218,633	\$	6,584,997
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TOTAL CURRENT LIABILITIES	\$	2,323,476	\$	2,242,583
TOTAL OTHER LIABILITIES		570,519		79,588
TOTAL LIABILITIES		2,893,995		2,322,171
TOTAL STOCKHOLDERS' EQUITY (DEFICIENCY)		3,324,638		4,262,826
	\$	6,218,633	\$	6,584,997