

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 9, 2007 (August 9, 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 2.02. Results of Operations and Financial Condition

To the extent applicable, the information disclosed under Item 7.01 and Exhibit 99.1 is incorporated herein by reference.

## ITEM 7.01. Regulation FD Disclosures

On August 9, 2007, the Company issued the press release titled “Chembio Reports Second Quarter Financial Results” included herein as Exhibit 99.1.

On July 31, 2007, the Company issued the press release titled “Chembio and Pall Corporation Enter DPP™ Collaboration” included herein as Exhibit 99.2.

## ITEM 9.01. Financial Statements and Exhibits

Exhibits.

99.1 Press Release titled “[Chembio Reports Second Quarter Financial Results](#)” issued August 9, 2007.

99.2 Press Release titled “[Chembio and Pall Corporation Enter DPP™ Collaboration](#)” issued July 31, 2007.

In accordance with General Instruction B.2 of Form 8-K, the information disclosed in Items 2.02 and 7.01 of, 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: August 9, 2007

Chembio Diagnostics, Inc.

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

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## **ChemBio Reports Second Quarter Financial Results**

### ***Conference Call Scheduled for August 14 at 4:30 PM EDT***

MEDFORD, N.Y (August 9, 2007) – ChemBio Diagnostics, Inc. (OTC/BB: CEMI) today reported financial results for the three and six months ended June 30, 2007.

Revenues for the second quarter of 2007 were \$2.50 million, a 53% increase compared with revenues for the second quarter of 2006 of \$1.64 million. The second quarter 2007 net loss attributable to common stockholders was \$0.98 million, or \$0.08 per share, compared with the second quarter 2006 net loss attributable to common stockholders of \$1.34 million, or \$0.13 per share. The net losses attributable to common stockholders for the second quarter of 2007 and 2006 are net of \$0.36 million and \$0.21 million, respectively, related to dividends on the Company's convertible preferred stock, of which \$0.30 million and \$0.21 million, respectively, were non-cash dividends paid.

Revenues for the first six months of 2007 were \$4.54 million, a 58% increase compared with revenues for the first six months of 2006 of \$2.87 million. The net loss attributable to common stockholders for the first half of 2007 was \$2.07 million, or \$0.17 per share, compared with the net loss attributable to common stockholders for the first half of 2006 of \$3.28 million, or \$0.34 per share. The net losses attributable to common stockholders for the first six months of 2007 and 2006 are net of \$0.71 million and \$0.88 million, respectively, related to dividends on the Company's convertible preferred stock as well as the beneficial conversion feature, of which \$0.65 million and \$0.74 million were non-cash dividends paid.

Growth in revenues during the second quarter and first six months of 2007 was attributable to higher sales of the Company's rapid HIV products, which increased 143% and 178%, respectively, compared with the prior-year periods. Sales include the launch of two of the Company's three HIV tests in the U.S. in February 2007 by Inverness Medical Innovations.

Gross margin for the second quarter 2007 increased to \$0.99 million or 40% of total revenues, compared with gross margin of \$0.56 million or 34% of total revenues for the second quarter of 2006. Gross margin on product sales for the second quarter 2007 increased to \$0.91 million or 38%, compared with gross margin on product sales of \$0.50 million or 32% for the second quarter of 2006. The second quarter 2007 loss from operations decreased to \$0.65 million, compared with \$1.12 million for the second quarter of 2006.

Gross margin for the first six months of 2007 increased to \$1.65 million or 36% of total revenues, compared with gross margin of \$1.00 million or 35% of total revenue for the first six months of 2006. Gross margin on product sales for the first six months of 2007 increased to \$1.56 million or 35%, compared with gross margin on product sales of \$0.87 million or 32% for the first six months of 2006. The first six months of 2007 loss from operations decreased to \$1.57 million, compared with \$2.38 million for the first six months of 2006.

Several important milestones affecting the Company were achieved during the second quarter of 2007, including:

- Grant of license to ChemBio from the United States Department of Agriculture to manufacture and market ChemBio's initial rapid test for veterinary application
- Launch of Prima-TB STAT PAK™, the Company's rapid lateral flow diagnostic test for the detection of antibodies to active pulmonary tuberculosis in non-human primates
- Completion of the inspection for ISO 13.485, resulting in a recommendation that the Company be certified
- Agreement with the Partnership for Supply Chain Management System, the consortium authorized under the President's Emergency Plan for AIDS Relief to centralize certain procurements, logistics and forecasting
- Agreement with the Infectious Disease Research Institute (IDRI) for the development of rapid tests for leishmaniasis and leprosy on ChemBio's Dual Path Platform (DPP™), utilizing IDRI's proprietary antigens
- Progress in negotiations with third parties for the licensing, development and manufacturing of a number of products incorporating DPP
- Retention of a Senior Vice President of Commercial Operations to lead ChemBio's business development activities with respect to its patented DPP technology
- Agreement among ChemBio, Inverness Medical Innovations and StatSure Diagnostics to extend the carve-out, until at least September 2008, for ChemBio's direct sales of its SURE CHECK HIV 1/2 to ChemBio's distributor in Mexico, a subsidiary of Bio-Rad Laboratories, Inc.
- Completion of improvements to ChemBio's HIV barrel product that should allow for CLIA waiver of this product

Lawrence Siebert, chairman and president of ChemBio, commented, "We are pleased with our progress during the second quarter, as we achieved strong revenue growth, improved our gross margins and controlled our operating expenses. We believe that the combination of increased sales from the higher-margin HIV and veterinary TB rapid tests being marketed in the U.S., together with the contract development and license revenues we anticipate from our DPP business-development efforts, should bring us closer to profitability in the periods ahead."

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## CONFERENCE CALL

The Company has scheduled a conference call and web-cast for 4:30 p.m. Eastern Daylight time on Tuesday August 14, 2007. Participants may access the call by dialing (877) 407-9205 in the U.S. or (201) 689-8054 outside the U.S. The conference call may also be accessed via the internet [in the Investor Center](#) section of [www.chembio.com](http://www.chembio.com).

## 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™), 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 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 for its products 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

	For the three months ended		For the six months ended	
	June 30, 2007	June 30, 2006	June 30, 2007	June 30, 2006
<b>Total Revenues</b>	<b>\$ 2,502,773</b>	<b>\$ 1,637,236</b>	<b>\$ 4,541,093</b>	<b>\$ 2,874,903</b>
<b>Gross Profit</b>	<b>991,900</b>	<b>564,434</b>	<b>1,651,718</b>	<b>999,973</b>
<b>Operating Loss</b>	<b>(654,597)</b>	<b>(1,120,352)</b>	<b>(1,565,735)</b>	<b>(2,375,266)</b>
<b>Net Loss</b>	<b>(625,856)</b>	<b>(1,127,375)</b>	<b>(1,354,662)</b>	<b>(2,391,090)</b>
<b>Preferred Dividends</b>	<b>356,900</b>	<b>207,937</b>	<b>710,878</b>	<b>884,294</b>
<b>Net Loss Attributable to Common Stockholders</b>	<b>\$ (982,756)</b>	<b>\$ (1,335,312)</b>	<b>\$ (2,065,540)</b>	<b>\$ (3,275,384)</b>
<b>Loss per share</b>	<b>\$ (0.08)</b>	<b>\$ (0.13)</b>	<b>\$ (0.17)</b>	<b>\$ (0.34)</b>

### Contacts:

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## ChemBio and Pall Corporation Enter DPP™ Collaboration

New York, July 31, 2007- (OTCBB: CEMI) – ChemBio Diagnostic, Inc. (OTC BB: CEMI.OB – News) announced today it has signed an initial research and development collaboration with Pall Corporation employing ChemBio's new Dual Path Platform (DPP™). Pall Corporation has a number of potential applications for DPP™ although the initial collaboration will be focused on the feasibility of one such application. Pall selected DPP™ because of its unique functional design that could facilitate high levels of analyte detection capability.

The Dual Path Platform immunoassay is a next generation lateral flow technology that employs separate membrane strips for sample migration and test reagents. The DPP™ immunoassay design allows for complete control and management of the sample flow, and as a result the immunological reaction is much more efficient than conventional single path lateral flow (SPLF) tests. These key technological features enable the DPP™ immunoassay to demonstrate improved detectability, sensitivity and specificity when compared with SPLF tests.

The collaborative agreement with Pall is a two-phase funded feasibility study that will help ascertain certain performance characteristics of DPP™ when used in conjunction with certain markers that are of interest to Pall. If performance meets or exceeds certain levels, ChemBio anticipates that the parties would proceed to negotiation of license, development and manufacturing agreements related to these and potentially other markers.

According to ChemBio Chief Executive Officer, Larry Siebert, "We are very proud and excited to be working with Pall Corporation as we look to bring our DPP™ technology to commercialization in a wide variety of applications." ChemBio Senior Vice President of Commercial Operations Bob Aromando further commented, "Our collaboration with Pall is a major milestone achievement for us, and is further confirmation of the clear advantages of DPP™."

### 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 both human and veterinary Tuberculosis and Chagas Disease, and has developed a patent-pending technology, the Dual Path Platform (DPP™), for its next generation HIV and other rapid tests. For additional information please visit [www.chembio.com](http://www.chembio.com).

### ABOUT PALL CORPORATION

For additional information please visit [www.pall.com](http://www.pall.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:

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