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# 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): November 13, 2008 (November 12, 2008)



**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))
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**ITEM 7.01. REGULATION FD DISCLOSURE.**

On November 12, 2008, the Company issued a press release entitled "Chembio Reports Record Revenues in Third Quarter." A copy of the press release is furnished herewith as Exhibit 99.1.

On November 13, 2008, the Company posted a PowerPoint Presentation to their website entitled "Fourth Quarter 2008 Investor Presentation." A copy of the presentation is furnished herewith as Exhibit 99.2.

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.

**ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS**

Exhibits.

99.1 Press Release entitled "Chembio Reports Record Revenues in Third Quarter" dated November 12, 2008.

99.2 PowerPoint Presentation entitled "Fourth Quarter 2008 Investor Presentation" dated November 13, 2008.

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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: November 13, 2008

Chembio Diagnostics, Inc.

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

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## EXHIBIT INDEX

Exhibit  
Number

Description

99.1	Press Release entitled “Chembio Reports Record Revenues in Third Quarter” dated November 12, 2008.
99.2	PowerPoint Presentation entitled “Fourth Quarter 2008 Investor Presentation” dated November 13, 2008.



## Chembio Reports Record Revenues in Third Quarter

*Highest Quarterly Revenues in Company History*

*Conference Call Scheduled for Wednesday, November 12 at 4:30 p.m. Eastern Time*

**MEDFORD, N.Y (November 12, 2008) – Chembio Diagnostics, Inc. (OTC/BB: CEMI)** today reported financial results for the three and nine months ended September 30, 2008.

### Third Quarter 2008 Financial Results

Chembio reported today record revenues for the third quarter of 2008, exceeding the record revenues of the second quarter of 2008 by more than 29%, or \$800,000. In addition, the operating loss for the third quarter of 2008 was lower than the loss of the second quarter of 2008, further advancing on the Company's path toward profitability driven by improving gross margins and lower selling, general and administrative expenses ("SG&A"). At the same time, Chembio continued to invest in its future growth opportunities with increased research and development ("R&D") spending, as initial proprietary DPP® products have been transferred into the Company's manufacturing operation.

Total revenues for the third quarter of 2008 were higher than any previous quarter at \$3.52 million, a 52% increase compared with third quarter 2007 revenues of \$2.31 million. This revenue growth came from \$1.25 million of increased product revenues, partially offset by \$46,000 of decreased research and grant revenues. The increased product revenues for the third quarter of 2008 included an increase in rapid HIV test and related revenues of \$1.12 million to \$3.10 million, or 56.9%, from \$1.98 million in the same period of 2007.

Gross profit in the third quarter 2008 was \$1.66 million, an increase of 68% from \$.99 million in the same period of 2007. As a percentage of total revenues, gross margin in the third quarter 2008 was 47.1%, as compared to 42.6% in the same period of 2007. The increase in the gross profit as well as gross profit as a percentage of sales for the third quarter of 2008 primarily reflects an improved revenue mix with higher average unit selling prices and volume-related manufacturing efficiencies.

SG&A expense for the three months ended September 30, 2008 was \$1.13 million, as compared to \$1.18 million in the same period of 2007. Increases in commission, license and royalty expenses based on increased product sales were partially offset by reductions in wages and related expenses, consulting, marketing materials, investor relations, legal and accounting, travel and entertainment costs as well as other expenses. R&D expenses include costs relating to clinical and regulatory affairs, which resulted in an increase of \$.28 million to \$.76 million for the third quarter of 2008 as compared with \$.48 million for the same period in 2007. The primary reason for the increases was additional R&D personnel related to work on the Company's DPP product line.

The operating loss for the third quarter of 2008 decreased 65% to \$.24 million from an operating loss of \$.67 million in the year-ago period. The reduced operating loss reflects increased revenues, improved gross profits, and lower SG&A expenses which more than offset increased research and development expenses associated with new product development. DPP® is a promising new product platform, and Chembio continues to invest in this technology which has now advanced to the stage of two products being incorporated into the Company's manufacturing operation.

The net loss attributable to common stockholders decreased 76.6% to \$.24 million, or less than \$.01 per share, for the third quarter of 2008 compared to a net loss attributable to common stockholders of \$1.01 million, or \$0.07 per share, for the third quarter of 2007. The net loss attributable to common stockholders for the third quarter of 2007 included \$.36 million 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 third quarter of 2008.

## Nine Months Ended September 30, 2008

Total revenues for the first nine months of 2008 were \$8.60 million, a 25.4% increase compared with the first nine months 2007 total revenues of \$6.85 million. First nine months 2008 revenue growth came from \$1.51 million of increased product revenues and \$.24 million of increased research and grant revenues. The increased product revenues for the first nine months of 2008 included an increase in rapid HIV test and related revenue of \$1.29 million to \$7.23 million or 21.8% from \$5.94 million in the same period of 2007. In addition, revenues from veterinary tuberculosis tests increased by \$.16 million in the first nine months of 2008 compared with the same period in 2007.

Gross profit in the first nine months of 2008 was \$4.02 million, an increase of 52% from \$2.64 million in the same period of 2007. As a percentage of total revenues, gross margin in the first nine months of 2008 was 46.7%, as compared to 38.5% in the same period of 2007. The increase in the gross profit as well as gross profit as a percentage of sales for the first nine months of 2008 primarily reflects an increase in total revenues, an improved revenue mix, and volume-related manufacturing efficiencies.

SG&A expense for the first nine months of 2008 was \$3.48 million, as compared to \$3.49 million in the same period of 2007. Increases in commission, license and royalty expenses, based on increased product sales, were partially offset by reductions in wages and related expenses, consulting, marketing materials, investor relations, legal and accounting, travel and entertainment costs as well as other expenses. R&D expenses which include clinical and regulatory affairs, increased \$.56 million to \$1.95 million for the first nine months of 2008 as compared with \$1.39 million for the same period in 2007. The primary reason for the increases was additional R&D personnel related to work on the Company's DPP product line. R&D expenses are funded in part by grant and development income, which increased \$.24 million, or 94%, to \$.49 million for the first nine months of 2008 as compared to \$.25 million in the same period of 2007.

The operating loss for the first nine months of 2008 decreased 37% to \$1.41 million from an operating loss of \$2.24 million in the year-ago period. The reduced operating loss reflects increased revenues, improved gross profits, and lower SG&A expenses which more than offset increased research and development expenses associated with new product development.

The net loss attributable to common stockholders decreased 54.5% to \$1.40 million, or \$0.02 per share, for the first nine months of 2008 compared to a net loss attributable to common stockholders of \$3.08 million, or \$0.24 per share, for the first nine months of 2007. The net loss attributable to common stockholders for the first nine months of 2007 included \$1.07 million 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 nine months of 2008.

## **Management Comments**

Commenting on the third quarter 2008 financial results, Lawrence Siebert, President and CEO of Chembio, said, "We are pleased with our performance in the third quarter as we expand our business through our new technology, improve manufacturing efficiencies, and control costs. We are developing a sustainable business model with our DPP® point-of-care testing technology. We are very pleased to have announced a new technology transfer supply and license agreement with the Oswaldo Cruz Foundation in Brazil for our DPP® HIV 1-2 rapid test for use with oral fluid or whole blood samples. This is a product which we also hope to begin clinical trials soon for entering the US market with this test in 2010 with our selected marketing partner. We are also making excellent progress for additional products pursuant to our strategy for branded and OEM products."

## Conference Call

As previously announced, Chembio has scheduled a conference call and webcast for 4:30 p.m. Eastern time on Wednesday, November 12, 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 November 19, 2009 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 302539. The conference call may also be accessed via the internet at <http://www.investorcalendar.com/IC/CEPage.asp?ID=137317>. An archive of the webcast will be available for 90 days on the Company's website at [www.chembio.com](http://www.chembio.com).

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## 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 demonstrated 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™. 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](http://www.chembio.com)

(Tables to follow)

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**Chembio Diagnostics, Inc.**  
**Summary of Results of Operations**

	For the three months ended		For the nine months ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Net sales	\$ 3,406,803	\$ 2,158,438	\$ 8,111,015	\$ 6,603,976
Research grant income	109,361	155,099	487,661	250,655
Total Revenues	\$ 3,516,164	\$ 2,313,537	\$ 8,598,676	\$ 6,854,631
Gross Profit	\$ 1,656,610	\$ 985,009	\$ 4,015,341	\$ 2,636,728
Research and development expenses	\$ 758,851	\$ 483,188	\$ 1,952,436	\$ 1,385,073
Selling, general and administrative expenses	\$ 1,133,288	\$ 1,174,530	\$ 3,475,262	\$ 3,490,099
Operating Loss	\$ (235,529)	\$ (672,709)	\$ (1,412,357)	\$ (2,238,444)
Net Loss	\$ (237,054)	\$ (648,514)	\$ (1,398,365)	\$ (2,003,176)
Preferred Dividends, Deemed Dividends and Beneficial Conversion Feature	-	\$ 362,959	-	\$ 1,073,837
Net Loss Attributable to Common Stockholders	\$ (237,054)	\$ (1,011,473)	\$ (1,398,365)	\$ (3,077,013)
Loss per share	\$ (0.00)	\$ (0.07)	\$ (0.02)	\$ (0.24)

**Chembio Diagnostics, Inc.**  
**Summary of Balance Sheet**

	<u>September 30, 2008</u>	<u>December 31, 2007</u>
<b>CURRENT ASSETS:</b>		
Cash	\$ 999,429	\$ 2,827,369
Accounts receivable, net of allowances	2,021,169	946,340
Inventories	1,192,127	1,453,850
Other current assets	256,000	243,748
<b>TOTAL CURRENT ASSETS</b>	<b>4,468,725</b>	<b>5,471,307</b>
<b>NET FIXED ASSETS</b>	<b>953,762</b>	<b>829,332</b>
<b>OTHER ASSETS</b>	<b>1,063,186</b>	<b>284,358</b>
	<u><u>\$ 6,485,673</u></u>	<u><u>\$ 6,584,997</u></u>
<b>TOTAL CURRENT LIABILITIES</b>	<b>\$ 2,812,265</b>	<b>\$ 2,242,583</b>
<b>TOTAL OTHER LIABILITIES</b>	<b>565,747</b>	<b>79,588</b>
<b>TOTAL LIABILITIES</b>	<b>3,378,012</b>	<b>2,322,171</b>
<b>TOTAL STOCKHOLDERS' EQUITY (DEFICIENCY)</b>	<b>3,107,661</b>	<b>4,262,826</b>
	<u><u>\$ 6,485,673</u></u>	<u><u>\$ 6,584,997</u></u>

**Chembio Diagnostics, Inc.**  
**Summary Cash Flow**

	<b>For the nine months ended</b>	
	<u>September 30, 2008</u>	<u>September 30, 2007</u>
Net cash used in operating activities	\$ (1,445,137)	\$ (1,710,135)
Net cash used in investing activities	(363,652)	(171,501)
Net cash utilized by financing activities	(19,151)	(153,443)
<b>NET (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b><u><u>\$ (1,827,940)</u></u></b>	<b><u><u>\$ (2,035,079)</u></u></b>

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[SEE PDF OF PRESENTATION](#)

SLIDE 1-

**CHEMBIO DIAGNOSTICS, INC.**  
**Fourth Quarter 2008**  
**Investor Presentation**

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### **Forward Looking Statements**

Statements contained herein that are not historical facts are forward-looking statements within the meaning of the Securities Act of 1933, as amended. Those statements include statements regarding the intent, belief or current expectations of Chembio 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 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.

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(Picture)

**DPP® POC Test Platform**  
**US Patent Issued 2007**

## **Chembio's Business Strategy**

- **OEM Contracts**
    - Chembio is Licensor, Developer and Manufacturer; Several Opportunities Pending
  - **DPP® Branded POC tests in Defined Markets**
    - Market through Selected Marketing & Distribution Partners
  - **Base Business of Lateral flow POC Tests**
    - Comprised Primarily of Rapid HIV tests Sold Globally
    - Exclusive with Inverness in US
-

**Executive Management & Directors**

<b>Lawrence Siebert Chairman &amp; CEO</b>	<b>25 years experience in private equity, venture capital, mergers and acquisitions &amp; finance. CEO since 2002.</b>
<b>Javan Esfandiari Senior VP R&amp;D</b>	<b>20 years experience in in-vitro and rapid diagnostic product development. Masters in Molecular Biology.</b>
<b>Richard Larkin Chief Financial Officer</b>	<b>25 years experience in independent accounting and in financial and information systems</b>
<b>Katherine Davis Director</b>	<b>Public and private sector financial and operational experience and former Lieutenant Governor of Indiana.</b>
<b>Dr. Gary Meller Director</b>	<b>Broad experience in medical and information technology and pharmaceutical product development. Affil. With Crestview Capital</b>
<b>James Merselis Director</b>	<b>CEO of Alverix, Inc. 30 Years of IVD industry experience. Formerly CEO of Hemosense (AMEX) sold to Inverness Medical in 2007</b>

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**Organization**  
**Producing & Selling ~1.5MM Tests/Qtr**  
**Total Employment 113**

**VPs & CEO 6**  
**SG&A 9**  
**R&D, Reg, QA/QC 26**  
**Manuf. 72**

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**Selected Financial Data**  
**Product Revenues YTD from Lateral Flow Products**  
**R&D Primarily in DPP® Products**

( in \$000's)	<u>QI 2008</u>	<u>QI 2007</u>	<u>QII 2008</u>	<u>QII 2007</u>	<u>QIII 2008</u>	<u>QIII 2007</u>	<u>9 mos 2008</u>	<u>9 mos 2007</u>
<b>Total Revenues</b>	\$ 2,365	\$ 2,038	\$ 2,718	\$ 2,503	\$ 3,516	\$ 2,314	\$ 8,599	\$ 6,855
<b>Cost of Sales</b>	1,303	1,378	1,421	1,511	1,859	1,329	4,583	4,218
<b>Gross Profit</b>	1,062	660	1,297	992	1,657	985	4,016	2,637
<b>%</b>	44.90%	32.38%	47.72%	39.63%	47.13%	42.57%	46.70%	38.47%
<b>Overhead Costs</b>								
<b>SG&amp;A</b>	1,248	1,252	1,095	1,063	1,133	1,175	3,476	3,490
<b>R&amp;D &amp; Regulatory</b>	626	319	567	583	759	483	1,952	1,385
<b>Total Overhead</b>	1,874	1,571	1,662	1,646	1,892	1,658	5,428	4,875
<b>Net Loss To Common Stockholders</b>								
	\$ (798)	\$ (1,083)	\$ (363)	\$ (983)	\$ (237)	\$ (1,011)	\$ (1,398)	\$ (3,077)

## **Point of Care Test Market**

- n \$5B 2008 Point of Care Test Market**
    - 12.5% CAGR
    - Part of >\$30B IVD Market
  - n Provide Immediate Information**
    - Simply, Accurately, Cost Effectively
  - n Enable Improved Outcomes**
    - Earlier Detection, Earlier Treatment
-

**Chembio's Regulatory Approvals**  
**Enable Access to**  
**Large, Diverse & Global POCT Markets**

**FDA – 2 APPROVED PMA's**

**USDA – USDA APPROVED FACILITY & PRODUCTS**

**ISO – ISO 13.485 CERTIFIED For CE Marking**

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**DPP® DUAL PATH PLATFORM**  
**KEY DESIGN AND PERFORMANCE ADVANTAGES**  
**FOR CHEMBIO'S POCT PLATFORM**

- n Independent Sample Flow Path Enables Improved Sample Control**
    - Improved Sensitivity vs. Lateral Flow
    - Use of More Challenging Sample Types
  - n Improved Multiplexing Facilitated**
    - Direct Binding (i.e., without conjugate)
    - Even & Uniform Delivery of Samples
  - n Freedom to Operate**
-

**DPP® ANTIBODY TEST DESIGN**  
**(Diagram of the DPP flow)**

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## **DPP® Business Development Activity**

- n Oral Fluid HIV Test
    - 5MM Test US Rapid Test Market – 15-20% Growth
  - n Syphilis Screen & Confirm
    - No POCT in US – 15MM Clinical Test Market
  - n Women's Health OEM
    - New Markets for Multiplexed STD Tests @ OBGYN
  - n Veterinary Products OEMs
    - Applications for both Companion & Production Animals
  - n Global Health Products
    - TB & Neglected Diseases (IDRI, NIH, FIND, CDC)
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**Thank You**  
**For further information please visit our web site**  
**[www.Chembio.com](http://www.Chembio.com)**

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