

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 2, 2007 (October 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 7.01. Regulation FD Disclosures.

On November 2, 2007, the Company issued the press release titled “Chembio Diagnostics Receives CLIA Waiver for HIV Barrel Test” included herein as Exhibit 99.1.

On November 2, 2007, the Company issued the press release titled “Chembio Reports Third Quarter Results” included herein as Exhibit 99.2.

On October 31, 2007, the Company issued the press release titled “Chembio to Host Conference Call to Discuss Third Quarter Financial Results for 2007” included herein as Exhibit 99.3.

On October 30, 2007, the Company issued the press release titled “Chembio Diagnostics, Inc. to Present at Acumen BioFin Rodman and Renshaw 9th Annual Healthcare Conference” included herein as Exhibit 99.4.

On November 5, 2007, certain officers of the Company intend to deliver an investor presentation that will include the slides attached hereto as Exhibit 99.5 to this Current Report on Form 8-K. The Company undertakes no obligation to update, supplement or amend the materials attached as Exhibit 99.5.

Attached as Exhibit 99.6 is a presentation prepared for preferred stockholders.

ITEM 9.01. Financial Statements and Exhibits

Exhibits.

99.1 Press Release titled “[Chembio Diagnostics Receives CLIA Waiver for HIV Barrel Test](#)” issued November 2, 2007.

99.2 Press Release titled “[Chembio Reports Third Quarter Results](#)” issued November 2, 2007.

99.3 Press Release titled “[Chembio to Host Conference Call to Discuss Third Quarter Financial Results for 2007](#)” issued October 31, 2007.

99.4 Press Release titled “[Chembio Diagnostics, Inc. to Present at Acumen BioFin Rodman and Renshaw 9th Annual Healthcare Conference](#)” issued October 30, 2007.

99.5 [PDF of PowerPoint Presentation to be delivered on November 5, 2007.](#)

99.6 [PDF of presentation prepared for preferred stockholders.](#)

In accordance with General Instruction B.2 of Form 8-K, the information in 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.

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 2, 2007

Chembio Diagnostics, Inc.

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



Chembio Diagnostics Receives CLIA Waiver for HIV Barrel Test

Rapid, Point-of-Care HIV Diagnostic Now Available to 189,000 Doctor's Offices and Clinics in U.S.

MEDFORD, N.Y. (November 2, 2007)– Chembio Diagnostics, Inc. (OTCBB: CEMI) today announced that the Company has received CLIA Waiver for its FDA-approved HIV Barrel test, a unique, self-contained rapid HIV test that is exclusively marketed worldwide by Inverness Medical Innovations, Inc. (AMEX: IMA) as Clearview® COMPLETE HIV 1/2. The CLIA (Clinical Laboratory Improvement Act) waiver allows Chembio to market these rapid HIV tests to a potential market of approximately 189,000 laboratory entities across the United States, including doctors' offices and clinics.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) established that some tests could be waived from certain laboratory requirements. Waived products include tests that employ methodologies that are so simple to use as to render the likelihood of erroneous results negligible; or that pose no reasonable risk of harm to the patient if the test is performed incorrectly. Rapid HIV antibody tests were only added to the list of tests that could be waived within the last few years, and this development is what created the main U.S. market opportunity for these products.

A CLIA waiver greatly expands the available potential U.S. market opportunity for a product from sites that require much greater certification and oversight (i.e. reference laboratories and hospitals) to additional venues where pointof care testing is particularly beneficial (i.e. emergency rooms, doctors offices and public health clinics). There are approximately 189,000 testing sites across the United States that can use tests that are CLIA-waived. The United States Centers for Disease Control (CDC) has issued recommendations that HIV testing become part of the routine medical care provided to all Americans between the ages of 13 and 64.

Larry Siebert, Chief Executive Officer of Chembio said, "This CLIA Waiver provides an excellent opportunity for our marketing partner, Inverness, to take advantage of the benefits inherent in the additional venues now available to Clearview® COMPLETE HIV 1/2. This, combined with the recent CDC recommendations for routine HIV testing in the United States, provides the right market dynamics for Inverness to be successful with this product."

About Chembio Diagnostics

Chembio Diagnostics, Inc., a developer and manufacturer of proprietary rapid diagnostic tests, participates in the growing \$5 Billion point-of-care (POC) testing market. Chembio's two FDA PMA-approved, CLIA-waived, rapid HIV tests are marketed in the U.S. by Inverness Medical Innovations, Inc. 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 currently available 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.

Inverness Medical Innovations, Inc. (Amex: IMA), Chembio Diagnostics, Inc. (OTCBB:CEMI), and StatSure Diagnostic Systems, Inc. (OTCBB: SSUR) announced in October of 2006 agreements that provide Inverness with exclusive worldwide marketing rights to Chembio's FDA-cleared, point of care, rapid test for the detection of antibodies to HIV. The test utilizes Inverness' proprietary lateral flow technology as well as StatSure's patented "barrel" technology designed to maximize ease of use and minimize exposure to infectious agents.

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.

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Chembio Reports Third Quarter Results

Conference Call Begins at 11:30 a.m. Eastern Time, November 2nd

MEDFORD, N.Y (November 2, 2007) – Chembio Diagnostics, Inc. (OTC/BB: CEMI) today reported financial results for the three and nine months ended September 30, 2007.

Total revenues for the third quarter of 2007 were \$2.31 million, a 127% increase compared with total revenues for the third quarter of 2006 of \$1.02 million. The net loss attributable to common stockholders for the third quarter of 2007 was \$1.01 million, or \$0.07 per share, compared with the net loss attributable to common stockholders for the third quarter of 2006 of \$2.33 million, or \$0.21 per share. These net loss figures include \$363,000 and \$760,000, respectively, related to dividends (which includes a beneficial conversion feature in the 2006 period of \$539,000) on the Company's convertible preferred stock, of which \$363,000 and \$221,000, respectively, were non-cash dividends paid in-common stock.

Total revenues for the first nine months of 2007 were \$6.85 million, a 76% increase compared with total revenues for the first nine months of 2006 of \$3.89 million. The net loss attributable to common stockholders for the first nine months of 2007 was \$3.08 million, or \$0.24 per share, compared with the net loss attributable to common stockholders for the first nine months of 2006 of \$5.61 million, or \$0.56 per share. These net loss figures include \$1.07 million and \$1.64 million, respectively, related to dividends (which includes a beneficial conversion feature in the 2006 period of \$1.00 million) on the Company's convertible preferred stock, of which \$1.01 million and \$502,000, respectively, were non-cash dividends paid in-common stock.

Growth in revenues during the third quarter and first nine months of 2007 was attributable to higher sales of the Company's rapid HIV products, which increased 261% and 201%, respectively, compared with the prior-year periods, due primarily to sales growth in Africa and North America.

Net sales to Africa increased by \$815,000 to \$1.31 million during the quarter, primarily due to sales placed by the Partnership For Supply Chain Management, the consortium with which the Company signed a contract during the second quarter of this year and which, as expected, is increasingly centralizing procurements made with the President's Emergency Plan for AIDS Relief funds. North American sales increased \$620,000 to \$750,000 in the quarter, largely due to the launch of the Company's HIV tests in the U.S. in February 2007 by marketing partner Inverness Medical Innovations. Inverness markets the Company's two rapid HIV tests under the Clearview® label. Through September 30, 2007, only one of those tests, Clearview® HIV 1/2 STAT PAK, was "CLIA-waived" (allowing sales into public health clinics, for example), and this product represents almost all sales to Inverness for the reported periods. Chembio recently received a CLIA waiver for its HIV barrel product, marketed as Complete HIV 1/2 by Inverness. As a result, the Company anticipates sales of this product to increase in the coming quarters.

Gross profit for the third quarter of 2007 increased to \$1.0 million, or 42.5% of total revenues, compared with gross profit of \$187,000, or 18.4% of total revenues, for the third quarter of 2006. Gross profit on product sales for the third quarter of 2007 increased to \$830,000, or 38.4%, compared with gross profit on product sales of \$111,000, or 11.8%, for the third quarter of 2006. The loss from operations for the third quarter of 2007 decreased to \$673,000 from \$1.24 million in the prior-year quarter.

Gross profit for the first nine months of 2007 increased to \$2.64 million, or 38.4% of total revenues, compared with gross profit of \$1.19 million, or 30.5% of total revenues, for the first nine months of 2006. Gross profit on product sales for the first nine months of 2007 increased to \$2.39 million, or 36.1%, compared with gross profit on product sales of \$0.98 million, or 26.5%, for the first nine months of 2006. The loss from operations for the first nine months of 2007 decreased to \$2.24 million from \$3.62 million for the first nine months of 2006.

Several important milestones were achieved during the third quarter of 2007, including:

- **Financial Results**– Revenues for the first nine months of 2007 have already exceeded full-year 2006 revenues. The Company has improved gross margin on product sales to 38.4% and 36.1% for the three and nine months ended September 30, 2007, respectively. The expanded gross margin is attributable to higher average selling prices of the Company’s HIV tests in the U.S., as well as to improved operating efficiencies that are beginning to be realized through the ERP production planning and cost-management system Chembio installed last year.
- **Dual Platform Technology Business Development**–Since the latter half of the second quarter, the Company has entered into five externally funded research and development or feasibility agreements with clinical diagnostics, life science, companion animal, academic and government-affiliated public health entities, all related to potential applications for point-of-care tests employing Chembio’s Dual Path Platform (DPP™) technology. These agreements represent total financial commitments of \$600,000 (approximately \$200,000 of which was earned in the second and third quarters of 2007). Results from these feasibility studies, as well as from the Company’s internal research and development activities, are confirming the potential of this platform technology for a broad range of point-of-care/point-of-use diagnostics.
 - o DPP HIV 1/2 – The Company completed a prototype of its DPP™ HIV 1/2 test for whole blood, serum and plasma, and is conducting studies with various components to optimize oral fluid features. Chembio is considering various regulatory pathways and potential marketing and distribution strategies for this product.
 - o DPP Syphilis – Chembio entered into a Cooperative Research and Development Agreement (CRADA) with the U.S. Centers for Disease Control and Prevention (CDC) in November 2006. The goal of the CRADA was to develop a DPP™ multiplex test that could be used both to screen for antibodies to Syphilis (known as treponomal) and to confirm them (known as non-treponomal). During the third quarter the Company completed validation work for the treponomal screening test and submitted several thousand treponomal tests for use in a large overseas CDC study; Chembio is awaiting results of the study.
 - o Reader Technologies – The Company has made significant progress in employing proprietary reflectance and fluorescence reader devices that can measure, record and report results of DPP™ tests with greater consistency than interpretation through visual observation. These readers are being customized for its DPP™ platform and will be further customized, as needed, for specific DPP™ applications. This will be particularly important with the development of multiplex tests on DPP™, which we believe to be a significant advantage of DPP™ due to the independently-controlled, direct, even and simultaneous delivery of sample material to the test zone area that is unique to DPP™. The DPP™ technology demonstrates much improved multiplexing results and membrane clearance compared with conventional single path lateral flow technologies. This substantially increases the utility and accuracy of readers. Chembio has made significant progress in adapting these reading instruments to DPP™, using both colored and fluorescent labels. In addition, the Company has entered into a collaboration with a development-stage company that has a patent-pending technology believed to increase detection levels by using that company’s unique fluorescence labeling methodology.
 - o Foreign DPP Patent Filings – In support of Chembio’s strategy to build its pipeline of DPP™ product-development opportunities, the Company filed for protection of its DPP™ intellectual property in several foreign jurisdictions where it believes patent protection is warranted, including portions of Europe, Asia and South America.
- **CLIA Waiver**– Earlier this week the Company received a CLIA waiver for its HIV barrel product. A CLIA waiver greatly expands a product’s potential U.S. market opportunity from sites with highly regulated certification and oversight (i.e., reference laboratories and hospital laboratories) to include venues where point-of-care testing is particularly beneficial (i.e., emergency rooms, physician offices and public health clinics). There are approximately 189,000 testing sites across the U.S. that can use tests that are CLIA-waived.
- **ISO 13.485 Certification**– During the third quarter Chembio received its ISO 13.485 certification, underscoring the quality of Chembio’s systems and demonstrating its ability to produce point-of-care diagnostics in accordance with widely accepted global quality standards. ISO 13.485 is the quality system most recognized globally, including throughout the European Union for products seeking a CE marking. Chembio has engaged a European Notified Body in connection with its plans to obtain a CE marking for certain of its products.

Lawrence Siebert, Chairman and President of Chembio, commented, “We are pleased with our progress during the third quarter, as we achieved exceptionally strong revenue growth, continued to improve our gross margins, controlled our operating expenses and made significant headway in developing significant new DPP™-related product opportunities.”

CONFERENCE CALL

Chembio has scheduled a conference call and webcast for 11:30 a.m. Eastern time on Friday November 2, 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 at <http://www.vcall.com/IC/CEPage.asp?ID=122663>. 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., a developer and manufacturer of proprietary rapid diagnostic tests, participates in the growing \$5 billion point-of-care (POC) testing market. Chembio's two FDA PMA-approved, CLIA-waived, rapid HIV tests are marketed in the U.S. by Inverness Medical Innovations, Inc. 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 currently available 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.

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[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, 2007	September 30, 2006	September 30, 2007	September 30, 2006
Total Revenues	\$ 2,313,537	\$ 1,018,190	\$ 6,854,631	\$ 3,893,093
Gross Profit	985,009	187,371	2,636,728	1,187,344
Operating Loss	(672,709)	(1,240,474)	(2,238,444)	(3,615,740)
Net Loss	(648,514)	(1,573,986)	(2,003,176)	(3,965,076)
Preferred Dividends and Beneficial Conversion Feature	362,959	759,469	1,073,837	1,643,763
Net Loss Attributable to Common Stockholders	\$ (1,011,473)	\$ (2,333,455)	\$ (3,077,013)	\$ (5,608,839)
Loss per share	\$ (0.07)	\$ (0.21)	\$ (0.24)	\$ (0.56)

Chembio Diagnostics, Inc.
Summary of Balance Sheet

	September 30, 2007	December 31, 2006
CURRENT ASSETS:		
Cash	\$ 2,255,307	\$ 4,290,386
Other current assets	2,876,408	2,663,282
TOTAL CURRENT ASSETS	5,131,715	6,953,668
NET FIXED ASSETS	652,658	603,603
OTHER ASSETS	357,362	349,306
	\$ 6,141,735	\$ 7,906,577
TOTAL CURRENT LIABILITIES	\$ 1,694,416	\$ 1,840,435
TOTAL OTHER LIABILITIES	245,284	456,758
TOTAL LIABILITIES	1,939,700	2,297,193
PREFERRED STOCK -Series C	6,837,479	6,549,191
TOTAL STOCKHOLDERS' EQUITY (DEFICIENCY)	(2,635,444)	(939,807)
	\$ 6,141,735	\$ 7,906,577

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Chembio to Host Conference Call to Discuss Third Quarter Financial Results for 2007

MEDFORD, NY--(MARKET WIRE)—October 31, 2007 -- Chembio Diagnostics, Inc. (OTC BB:CEMI.OB - News) will host a conference call Friday, November 2, 2007 at 11:30am EST to discuss the third quarter financial results for 2007.

Chembio invites all those interested in hearing management's discussion of the financial results to join the call by dialing (877) 407-9205. International participants may access the call by dialing (201) 689-8054.

A live webcast can be accessed by clicking on the following link <http://www.vcall.com/IC/CEPage.asp?ID=122663>. An archive of the webcast will be available for 90 days on the Company's website at www.chembio.com.

ABOUT CHEMBIO

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CHEMBIO DIAGNOSTICS, INC. TO PRESENT AT ACUMEN BIOFIN RODMAN & RENSHAW 9TH ANNUAL HEALTHCARE CONFERENCE

MEDFORD, NY, October 30, 2007 – Chembio Diagnostics Inc.(OTCBB: CEMI) today announced that its Chief Executive Officer, Lawrence Siebert, will present at the upcoming Acumen BioFin Rodman & Renshaw 9th Annual Healthcare Conference. The presentation is scheduled for 2:20 PM (Eastern Time) on Monday, November 5, 2007. The event will be held from November 5-7, 2007 at the New York Palace Hotel in New York.

Individuals may listen to a live webcast of the presentation by logging on to the Investors section of Chembio Diagnostic's Inc.'s website, www.chembio.com, a few minutes prior to start time. The presentation will be archived for 90 days.

The conference will feature presentations from more than 350 public and privately held emerging growth healthcare companies presenting data on an array of therapeutic topics including oncology, cardiovascular disease, central nervous system disorders, infectious diseases and medical device technology. Details regarding the conference can be obtained at www.rodmanandrenshaw.com.

About Chembio Diagnostics, Inc.

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