

CHEMBIO DIAGNOSTICS, INC.  
Form 10-Q  
November 12, 2008

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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FORM 10 - Q

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QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2008

000-30379  
(Commission File Number)  
Chembio Diagnostics, Inc.  
(Exact name of registrant as specified in its charter)

Nevada                      88-0425691  
(State or other              (IRS Employer  
jurisdiction of              Identification  
incorporation)              Number)  
3661 Horseblock Road  
Medford, New York 11763  
(Address of principal executive offices including zip code)  
(631) 924-1135  
(Registrant's telephone number, including area code)

(Former Name or Former Address, if Changed Since Last Report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  
Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer                       Accelerated filer   
Non-accelerated filer                       Smaller reporting company   
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  
Yes  No

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As of November 10, 2008, the Registrant had 61,944,901 shares outstanding of its \$.01 par value common stock.

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Quarterly Report on FORM 10-Q For The Period Ended

September 30, 2008

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## PART I

## Item 1. FINANCIAL STATEMENTS

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED BALANCE SHEETS  
AS OF

- ASSETS -	September 30, 2008 (UNAUDITED)	December 31, 2007
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 999,429	\$ 2,827,369
Accounts receivable, net of allowance for doubtful accounts of \$10,301 and \$10,045 for 2008 and 2007, respectively	2,021,169	946,340
Inventories	1,192,127	1,453,850
Prepaid expenses and other current assets	256,000	243,748
<b>TOTAL CURRENT ASSETS</b>	<b>4,468,725</b>	<b>5,471,307</b>
<b>FIXED ASSETS, net of accumulated depreciation</b>	<b>953,762</b>	<b>829,332</b>
<b>OTHER ASSETS:</b>		
License agreements, net of current portion	1,035,366	255,948
Deposits and other assets	27,820	28,410
	<b>\$ 6,485,673</b>	<b>\$ 6,584,997</b>
<b>- LIABILITIES AND STOCKHOLDERS' EQUITY -</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 2,319,117	\$ 2,175,791
Deferred research and development revenue	100,000	43,334
Current portion of license fee payable	375,000	-
Current portion of obligations under capital leases	18,148	23,458
<b>TOTAL CURRENT LIABILITIES</b>	<b>2,812,265</b>	<b>2,242,583</b>
<b>OTHER LIABILITIES:</b>		
Obligations under capital leases - net of current portion	65,747	79,588
License fee payable - net of current portion	500,000	-
<b>TOTAL LIABILITIES</b>	<b>3,378,012</b>	<b>2,322,171</b>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
	619,449	605,375

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Common stock - \$.01 par value;  
 100,000,000 shares authorized 61,944,901  
 and 60,537,534 shares issued and  
 outstanding as of 2008 and 2007,  
 respectively

Additional paid-in capital	39,232,274	39,003,148
Accumulated deficit	(36,744,062)	(35,345,697)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>3,107,661</b>	<b>4,262,826</b>
	\$ 6,485,673	\$ 6,584,997

See accompanying notes

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
FOR THE THREE AND NINE MONTHS ENDED  
(UNAUDITED)

	Three months ended		Nine months ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
<b>REVENUES:</b>				
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
<b>TOTAL REVENUES</b>	<b>3,516,164</b>	<b>2,313,537</b>	<b>8,598,676</b>	<b>6,854,631</b>
Cost of sales	1,859,554	1,328,528	4,583,335	4,217,903
<b>GROSS PROFIT</b>	<b>1,656,610</b>	<b>985,009</b>	<b>4,015,341</b>	<b>2,636,728</b>
<b>OPERATING EXPENSES:</b>				
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
	1,892,139	1,657,718	5,427,698	4,875,172
<b>LOSS FROM OPERATIONS</b>	<b>(235,529)</b>	<b>(672,709)</b>	<b>(1,412,357)</b>	<b>(2,238,444)</b>
<b>OTHER INCOME (EXPENSES):</b>				
Other income (expense)	-	-	-	120,862
Interest income	3,587	30,603	29,958	125,513
Interest expense	(5,112)	(6,408)	(15,966)	(11,107)
	(1,525)	24,195	13,992	235,268
<b>LOSS BEFORE INCOME TAXES</b>	<b>(237,054)</b>	<b>(648,514)</b>	<b>(1,398,365)</b>	<b>(2,003,176)</b>
Provision for income taxes	-	-	-	-
<b>NET LOSS</b>	<b>(237,054)</b>	<b>(648,514)</b>	<b>(1,398,365)</b>	<b>(2,003,176)</b>
Dividends payable in stock to preferred stockholders	-	362,959	-	1,073,837
<b>NET LOSS ATTRIBUTABLE TO</b>	<b>\$ (237,054)</b>	<b>\$ (1,011,473)</b>	<b>\$ (1,398,365)</b>	<b>\$ (3,077,013)</b>

COMMON  
STOCKHOLDERS

Basic and diluted loss per share	\$	(0.00)	\$	(0.07)	\$	(0.02)	\$	(0.24)
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Weighted average number of shares outstanding, basic and diluted	61,944,901	14,043,208	61,036,181	12,701,494
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See accompanying notes

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
FOR THE NINE MONTHS ENDED  
(UNAUDITED)

	September 30, 2008	September 30, 2007
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:</b>		
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Cash received from customers	\$ 7,523,847	\$ 6,935,884
Cash paid to suppliers and employees	(8,982,976)	(8,760,425)
Interest received	29,958	125,513
Interest paid	(15,966)	(11,107)
Net cash used in operating activities	(1,445,137)	(1,710,135)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of fixed assets	(363,652)	(171,501)
Net cash used in investing activities	(363,652)	(171,501)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of warrants	-	31,000
Payment of accrued interest	-	(90,000)
Payment of dividends	-	(60,000)
Payment of capital lease obligation	(19,151)	(34,443)
Net cash used in financing activities	(19,151)	(153,443)
<b>NET (DECREASE) IN CASH AND CASH EQUIVALENTS</b>		
	(1,827,940)	(2,035,079)
Cash and cash equivalents - beginning of the period	2,827,369	4,290,386
Cash and cash equivalents - end of the period	\$ 999,429	\$ 2,255,307
<b>RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:</b>		
Net Loss	\$ (1,398,365)	\$ (2,003,176)
<b>Adjustments:</b>		
Depreciation and amortization	239,222	213,158
Loss on retirement of fixed assets	-	12,146
Provision for doubtful accounts	256	(11,210)
Common stock, options and warrants issued as compensation	268,159	275,360



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Changes in assets and liabilities:

Accounts receivable	(1,075,085)	(75,037)
Inventories	261,723	(60,786)
Prepaid expenses and other assets	(816,039)	(24,912)
Other assets and deposits	-	(8,056)
Deferred revenue	56,666	-
Accounts payable and accrued expenses	143,326	(27,622)
Licenses fee payable	875,000	-
Net cash used in operating activities	\$ (1,445,137)	\$ (1,710,135)

Supplemental disclosures for non-cash investing and financing activities:

Value of common stock issued upon cashless warrant exercise	\$ 14,074	\$ -
Value of warrants/options/stock issued allocated to additional paid-in capital	-	61,181
Accreted dividend to preferred stock	-	1,073,837
Value of Common stock issued as payment of dividend	-	1,072,157
Value of Preferred stock converted to common stock	-	178,733
Assets acquired under capital leases	-	102,860

See accompanying notes

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 2008  
(UNAUDITED)

NOTE 1—DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. (the “Company” or “Chembio”) and its subsidiaries develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company’s main products are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA in 2006; the third is sold for export only. The Company also has a rapid test for Chagas disease (a parasitic disease endemic in Latin America) as well as a line of rapid tests for veterinary tuberculosis. Two of the veterinary tests are USDA approved. The Company’s products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. Chembio’s products are sold under the Company’s STAT PAK® or SURE CHECK ® registered trademarks or under the private labels of its marketing partners, for example the Clearview® label owned by Inverness Medical Innovations, Inc., which is the Company’s exclusive marketing partner for its rapid HIV lateral flow test products in the United States. These products employ lateral flow technologies that are proprietary and/or licensed to the Company. All of the Company’s future products that are currently being developed are based on its patented Dual Path Platform (DPP®), which is a unique diagnostic point of care platform that has certain advantages over lateral flow technology. The Company has recently completed its first two products that employ the DPP® and has a number of additional products under development that employ the DPP®.

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. Although revenues and gross margins increased in the nine months ended September 30, 2008 as compared to the same period in 2007, the Company continues to generate significant operating losses through September 30, 2008. At September 30, 2008, the Company had a positive stockholders’ equity of \$3,108,000 and working capital of \$1,656,000. The Company estimates that its resources are sufficient to fund its needs through the end of 2008 and it is considering alternatives to provide for its capital requirements for 2009 and beyond in order to continue as a going concern. The Company’s liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) the Company’s investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make; and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that the Company will be successful in raising sufficient capital.

NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

(a) Basis of Presentation:

The consolidated interim financial information as of September 30, 2008 and for the nine-month periods ended September 30, 2008 and 2007 have been prepared without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”). Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles in the United States of America, have been condensed or omitted pursuant to such rules and regulations, although we believe that the disclosures made are adequate to provide for fair presentation. The interim financial information should be read in conjunction with the Financial Statements and the notes thereto, included in the Company’s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2007, previously filed with the SEC.

In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present a fair statement of consolidated financial position as of September 30, 2008, and consolidated results of operations, and cash flows for the nine month periods ended September 30, 2008 and 2007, as applicable, have been made. The interim results of operations are not necessarily indicative of the operating results for the full fiscal year or any future periods.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 2008  
(UNAUDITED)

## (b) Inventories:

Inventory consists of the following at:

	September 30, 2008	December 31, 2007
Raw Materials	\$ 645,364	\$ 705,873
Work in Process	415,586	234,077
Finished Goods	131,177	513,900
	\$ 1,192,127	\$ 1,453,850

## (c) Earnings Per Share

The following weighted average number of shares was used for the computation of basic and diluted loss per share:

	For the three months ended		For the nine months ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Basic	61,944,901	14,043,208	61,036,181	12,701,494
Diluted	61,944,901	14,043,208	61,036,181	12,701,494

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted loss per share reflects the potential dilution from the exercise or conversion of other securities into Common Stock, but only if dilutive. Diluted loss per share for the three and nine month periods ended September 30, 2008 and 2007 is the same as basic loss per share, since the effects of the calculation were anti-dilutive due to the fact that the Company incurred losses for all periods presented. The following securities, presented on a common share equivalent basis, have been excluded from the diluted per share computations:

	For the three months ended		For the nine months ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
1999 & 2008 Plan Stock Options	2,797,482	2,396,136	2,565,655	1,929,471
Other Stock Options	124,625	124,625	124,625	124,625
Warrants	10,163,244	26,196,085	16,183,547	26,191,683
Convertible Preferred Stock	-	26,553,340	-	26,811,978

## (d) Employee Stock Option Plan:

The Company's Stock Option Plans (the "Plans") are accounted for in accordance with the recognition and measurement provisions of Statement of Financial Accounting Standards Share-Based Payment ("FAS 123(R)", which replaces FAS No. 123, Accounting for Stock-Based Compensation, and supersedes Accounting Principles Board Opinion ("APB") No. 25, Accounting for Stock Issued to Employees, and related interpretations. FAS 123(R) requires compensation costs related to share-based payment transactions, including employee stock options, to be recognized in the financial statements. In addition, the Company adheres to the guidance set forth within SEC Staff Accounting Bulletin No. 107 ("SAB 107"), which provides the Staff's views regarding the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides interpretations with respect to the valuation of share-based payments for public companies.

As a result of the adoption of FAS 123(R), the Company's results for the three-month periods ended September 30, 2008 and 2007 include share-based compensation expense totaling \$24,000 and \$70,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within research and development (\$14,000 and \$29,000, respectively) and selling, general and administrative expenses (\$10,000 and \$41,000, respectively). The nine-month periods ended September 30, 2008 and 2007 include share-based compensation expense totaling \$268,000 and \$275,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$19,000 and none, respectively), research and development (\$75,000 and \$161,000, respectively) and selling, general and administrative expenses (\$175,000 and \$114,000, respectively). No income tax benefit has been recognized in the income statement for share-based compensation arrangements due to the history of operating losses.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 2008  
(UNAUDITED)

Stock option compensation expense in the three- and nine-month periods ended September 30, 2008 and 2007 represent the estimated fair value of options outstanding which are being amortized on a straight-line basis over the requisite vesting period of the entire award.

The weighted average estimated fair value of stock options granted in the nine-month periods ended September 30, 2008 and 2007 was \$.13 and \$.44 per share, respectively. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon historical volatility of our stock and other contributing factors. The expected term is determined using the simplified method as permitted by SAB 107, as the Company has no history of employee exercise of options to-date.

The assumptions made in calculating the fair values of options are as follows:

	For the three months ended		For the nine months ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Expected term (in years)	n/a	5	1 to 4	5
Expected volatility	n/a	106.31%	109.33-112.33%	102.84-104.80%
Expected dividend yield	n/a	n/a	n/a	n/a
Risk-free interest rate	n/a	4.60%	1.91 to 2.98%	4.50-5.06%

The Company granted 967,650 options under the Plans during the nine-months ended September 30, 2008 at exercise prices ranging from \$.13 to \$0.22 per share. On February 15, 2008 the Compensation Committee of the Company's Board of Directors approved the reduction of the exercise price to \$.48 of all employee options for which the exercise price was greater than \$.48 per share (an aggregate of 1,846,500 options). The expense related to this modification was \$18,000 and was expensed in the first quarter of 2008.

The following table provides stock option activity for the nine months ended September 30, 2008:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Stock Options Outstanding at December 31, 2007	2,201,500	\$ 0.64	3.52 years	