CHEMBIO DIAGNOSTICS, INC.
Form 10-Q
May 08, 2009

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

FORM 10 - Q

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

For the quarterly period ended March 31, 2009

000-30379
(Commission File Number)

Chembio Diagnostics, Inc.
(Exact name of registrant as specified in its charter)

Nevada	88-0425691
(State or other jurisdiction of incorporation)	(IRS Employer Identification 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 X 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 [ ] (Do not check if a smaller reporting company)	Smaller reporting company [X]

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

As of May 6, 2009, the Registrant had 61,944,901 shares outstanding of its $.01 par value common stock.

Quarterly Report on FORM 10-Q For The Period Ended

March 31, 2009

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PART I
Item 1. FINANCIAL STATEMENTS

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

- ASSETS -				
		March 31, 2009		December 31, 2008
		(UNAUDITED)		
CURRENT ASSETS:				
Cash and cash equivalents	$	1,292,390	$	1,212,222
Accounts receivable, net of allowance for doubtful accounts of $10,301 for 2009 and 2008		622,324		809,303
Inventories		1,680,424		1,819,037
Prepaid expenses and other current assets		236,592		225,153
TOTAL CURRENT ASSETS		3,831,730		4,065,715
FIXED ASSETS, net of accumulated depreciation		783,198		881,406
OTHER ASSETS:				
License agreements, net of current portion		901,875		940,000
Deposits and other assets		179,900		27,820
	$	5,696,703	$	5,914,941
- LIABILITIES AND STOCKHOLDERS' EQUITY -				
CURRENT LIABILITIES:				
Accounts payable and accrued liabilities	$	2,110,946	$	2,383,021
Deferred research and development revenue		367,591		-
Current portion of obligations under capital leases		19,433		18,780
TOTAL CURRENT LIABILITIES		2,497,970		2,401,801
OTHER LIABILITIES:				
Obligations under capital leases - net of current portion		55,697		60,808
License fee payable - net of current portion		875,000		875,000
TOTAL LIABILITIES		3,428,667		3,337,609
COMMITMENTS AND CONTINGENCIES				

STOCKHOLDERS' EQUITY:				
Preferred stock – 10,000,000 shares authorized, none outstanding		-		-
Common stock - $.01 par value; 100,000,000 shares authorized 61,944,901 shares issued and outstanding as of 2009 and 2008		619,449		619,449
Additional paid-in capital		39,268,286		39,252,350
Accumulated deficit		(37,619,699)		(37,294,467)
TOTAL STOCKHOLDERS' EQUITY		2,268,036		2,577,332
	$	5,696,703	$	5,914,941

See accompanying notes

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

	March 31, 2009	March 31, 2008
REVENUES:		
Net sales	$ 2,269,417	$ 2,237,971
Research grant income	276,181	126,757
TOTAL REVENUES	2,545,598	2,364,728
Cost of sales	1,546,908	1,531,560
GROSS PROFIT	998,690	833,168
OPERATING EXPENSES:		
Research and development expenses	647,372	626,336
Selling, general and administrative expenses	675,813	1,018,400
	1,323,185	1,644,736
LOSS FROM OPERATIONS	(324,495)	(811,568)
OTHER INCOME (EXPENSES):		
Interest income	3,384	18,979
Interest expense	(4,121)	(5,593)
	(737)	13,386
LOSS BEFORE INCOME TAXES	(325,232)	(798,182)
Provision for income taxes	-	-
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	$ (325,232)	$ (798,182)
Basic and diluted loss per share	$ (0.01)	$ (0.01)
Weighted average number of shares outstanding, basic and diluted	61,944,901	60,537,534

See accompanying notes

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

	March 31, 2009	March 31, 2008
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:		
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers	$ 2,732,577	$ 2,358,174
Cash paid to suppliers and employees	(2,495,973)	(3,245,657)
Interest received	3,384	18,979
Interest paid	(4,121)	(5,593)
Net cash provided by (used in) operating activities	235,867	(874,097)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of and deposits on fixed assets	(151,241)	(179,272)
Net cash used in investing activities	(151,241)	(179,272)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of capital lease obligation	(4,458)	(9,265)
Net cash used in financing activities	(4,458)	(9,265)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	80,168	(1,062,634)
Cash and cash equivalents - beginning of the period	1,212,222	2,827,369
Cash and cash equivalents - end of the period	$ 1,292,390	$ 1,764,735
RECONCILIATION OF NET LOSS TO NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES:		
Net loss	$ (325,232)	$ (798,182)
Adjustments:		
Depreciation and amortization	99,449	75,854
Provision for doubtful accounts	-	16,000
Common stock, options and warrants issued as compensation	17,184	174,090
Changes in assets and liabilities:		
Accounts receivable	186,979	(22,554)
Inventories	138,613	(51,601)

Prepaid expenses and other assets		(12,687)		(86,552)
Other assets and deposits		36,045		(859,806)
Deferred revenue		367,591		(12,501)
Accounts payable and accrued expenses		(272,075)		(183,845)
Licenses fee payable		-		875,000
Net cash provided by (used in) operating activities	$	235,867	$	(874,097)
Supplemental disclosures for non-cash investing and financing activities:				
NONE				

See accompanying notes

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2009
(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. Rapid HIV tests represented nearly 70% of the Company's product revenues in the first quarter of 2009. 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, including those licensed to the Company. All of the Company's 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. In 2008, the Company completed development of its first two products that employ the DPP® and the Company 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 year ended December 31, 2008 as compared to the same period in 2007, the Company continues to generate significant operating losses. At March 31, 2009, the Company had stockholders' equity of $2,268,000 and working capital of $1,334,000. The Company estimates that its resources are sufficient to fund its needs through the next twelve months or that, in the alternative, it could raise additional capital although the terms under which that capital could be raised would likely be very dilutive to current shareholders. The Company's liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenues; (2) the extent to which, if any, that revenue level 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 (including production equipment of $323,500 that the Company has contracted for) and the extent to which the Company improves cash flow through operating efficiencies. There are no assurances that the Company will become profitable or generate positive cash flow by the end of 2009 or, in the alternative, be successful in raising sufficient capital to fund its needs through March 31, 2010.

NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

(a) Basis of Presentation:

The consolidated interim financial information as of March 31, 2009 and for the three-month periods ended March 31, 2009 and 2008 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 accounting principles generally accepted 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-K for the fiscal year ended December 31, 2008, 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 March 31, 2009, and consolidated results of operations, and cash flows for the three month-periods ended March 31, 2009 and 2008, 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.

(b) Inventories:

Inventory consists of the following at:

	March 31, 2009	December 31, 2008
Raw materials	$ 775,060	$ 836,446
Work in process	326,303	300,986
Finished goods	579,061	681,605
	$ 1,680,424	$ 1,819,037

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2009
(UNAUDITED)

(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	
	March 31, 2009	March 31, 2008
Basic	61,944,901	60,537,534
Diluted	61,944,901	60,537,534

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-month periods ended March 31, 2009 and 2008 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 per share computations:

	For the three months ended	
	March 31, 2009	March 31, 2008
1999 & 2008 Plan Stock Options	2,377,772	2,291,269
Other Stock Options	124,625	124,625
Warrants	10,163,244	19,487,099
	12,665,641	21,902,993

(d) Reclassifications:

Certain reclassifications have been made to conform to the 2009 presentation. For the three months ended March 31, 2008 the Company reclassified its royalty and license expenses to cost of goods sold, from selling, general and administrative expenses.

(e) Employee Stock Option Plan:

The Company has a 1999 Stock Option Plan (“SOP”) that originally covered 1,500,000 shares of Common Stock. Under the terms of the SOP, the Compensation Committee of the Company’s board is authorized to grant incentive options to key employees and to grant non-qualified options to key employees and key individuals. The options become exercisable at such times and under such conditions as determined by the Compensation Committee. The SOP was amended at the Company’s 2005 stockholders’ meeting. The number of options under the SOP was increased to cover 3,000,000 shares of Common Stock. It was also amended to allow independent directors to be eligible for grants under the portion of the SOP concerning non-qualified options.

Effective June 3, 2008, the Company’s stockholders voted to approve the 2008 Stock Incentive Plan (“SIP”). Under the terms of the SIP, the Compensation Committee of the Company’s board has the discretion to select the persons to whom awards are to be granted. Awards can be incentive stock options, restricted stock and/or restricted stock units. The awards become vested at such times and under such conditions as determined by the Compensation Committee.

As a result of the adoption of FAS 123(R), the Company's results for the three-month periods ended March 31, 2009 and 2008 include share-based compensation expense totaling $17,000 and $159,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (none and $19,000, respectively), research and development ($7,000 and $59,000, respectively) and selling, general and administrative expenses ($10,000 and $81,000, respectively). No income tax benefit has been recognized in the income statement for share-based compensation arrangements due to the history of operating losses.

Stock option compensation expense in the three-month periods ended March 31, 2009 and 2008 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
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The weighted average estimated fair value of stock options granted in the three-month periods ended March 31, 2009 and 2008 was none and $.42 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 March 31, 2009	March 31, 2008
Expected term (in years)	n/a	1 to 4
Expected volatility	n/a	109.33%
Expected dividend yield	n/a	n/a
Risk-free interest rate	n/a	1.91% to 2.46%

The Company did not grant options under the Plans (SOP, SIP) during the three months ended March 31, 2009.

The following table provides stock option activity for the three months ended March 31, 2009:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2008	2,201,500	$ 0.64		
Impact of re-price (for accounting purposes treated as a cancelation and re-issue):				
effect as if cancelled	(1,846,500)	$ 0.64		
effect as if re-issiued	1,846,500	$ 0.48		
Granted	967,650	$ 0.18		
Exercised	-	-		
Forfeited/expired /cancelled	(752,500)	$ 0.58		
Outstanding at December 31, 2008	2,416,650	$ 0.36	3.23 years	$ -
Granted	-	-		
Exercised	-	-		
Forfeited/expired	(62,250)	$ 0.28		
Outstanding at March 31, 2009	2,354,400	$ 0.37	2.97 years	$ -
	1,994,400	$ 0.38	2.86 years	$ -

Exercisable at March 31, 2009

As of March 31, 2009, there was $38,500 of net unrecognized compensation cost related to stock options that had not vested, which is expected to be recognized over a weighted average period of approximately 2.12 years. The total fair value of stock options vested during the three-month periods ended March 31, 2009 and 2008, was approximately $47,000 and $139,000, respectively.

See Note 5(b) regarding additional options issued to employees and a re-pricing of existing employee options subsequent to March 31, 2009.

(f) Geographic Information:

SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information" establishes standards for the way that business enterprises report information about operating segments in financial statements and requires that those enterprises report selected information. It also establishes standards for related disclosures about product and services, geographic areas, and major customers.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
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The Company produces only one group of similar products known collectively as “rapid medical tests”. As per the provisions of SFAS 131, management believes that it operates in a single business segment. Net sales by geographic area are as follows:

	For the three months ended	
	March 31, 2009	March 31, 2008
Africa	$ 459,737	$ 1,286,762
Asia	22,141	101,009
Europe	18,685	43,940
Middle East	32,047	100,841
North America	919,027	635,765
South America	817,780	69,654
	$ 2,269,417	$ 2,237,971

(g) Accounts payable and accrued liabilities

Accounts payable and accrued liabilities consist of:

	March 31, 2009	December 31, 2008
Accounts payable – suppliers	$ 422,767	$ 634,083
Accrued commissions	71,721	67,857
Accrued royalties / license fees	1,283,318	1,400,941
Accrued payroll	139,511	95,135
Accrued vacation	113,989	91,895
Accrued legal and accounting	30,000	18,000
Accrued expenses – other	49,640	75,110
TOTAL	$ 2,110,946	$ 2,383,021

(h) Recent Accounting Pronouncements affecting the Company

In September 2006, the Financial Accounting Standards Board (“FASB”) issued Statement of Financial Accounting Standards (“FAS”) No. 157, Fair Value Measurements, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. This statement does not require any new fair value measurements, but provides guidance on how to measure fair value by providing a fair value hierarchy used to classify the source of the information. FAS No. 157 is effective for fiscal years beginning after November 15, 2007, and all interim periods within those fiscal years. In February 2008, the FASB released FASB Staff Position (FSP FAS 157-2 – Effective Date of FASB Statement No. 157) which delays the effective date of FAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), to fiscal years beginning after November 15, 2008 and interim periods within those fiscal years. The implementation of FAS No. 157 for financial assets and liabilities, effective January 1, 2008, did not have an impact on the Company's financial position and results of operations. The Company has evaluated the impact of adoption of this statement on its nonfinancial assets and liabilities and concluded that it did not have an impact on the Company's financial position, results of operations, or cash flows for the first quarter of fiscal 2009.

In December 2007, the FASB issued FAS No. 141 (revised 2007), Business Combinations, which replaces FAS No 141. The statement retains the purchase method of accounting for acquisitions, but requires a number of changes, including changes in the way assets and liabilities are recognized in the purchase accounting. It also changes the recognition of assets acquired and liabilities assumed arising from contingencies, requires the capitalization of in-process research and development at fair value, and requires the expensing of acquisition-related costs as incurred. FAS No. 141R is effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The adoption of FAS 141R has not had an impact on the Company's financial statements.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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In December 2007, the FASB issued FAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements – an Amendment of ARB No. 51." FAS 160 establishes accounting and reporting standards pertaining to ownership interests in subsidiaries held by parties other than the parent, the amount of net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest, and the valuation of any retained noncontrolling equity investment when a subsidiary is deconsolidated. This statement also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. FAS 160 is effective for fiscal years beginning on or after December 15, 2008. The Company has evaluated the impact of adoption of this statement and concluded that it did not have an impact on the Company's financial position, results of operations, or cash flows for the first quarter of fiscal 2009.

In March 2008, the FASB issued FAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities – an Amendment of FASB Statement No. 133." The new standard is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. It is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. The Company has evaluated the impact of adoption of this statement which did not have an impact on the Company's financial position, results of operations, or cash flows for the first quarter of fiscal 2009.

In December 2007, the Emerging Issues Task Force ("EITF") reached a consensus with respect to Issue No. 07-1 "Accounting for Collaborative Arrangements". This EITF applies to participants in a collaborative arrangement. A collaborative arrangement is a contractual arrangement that involves a joint operating activity. These arrangements involve two (or more) parties who are both (a) active participants in the activity and (b) exposed to significant risks and rewards dependent on the commercial success of the activity. Many collaborative arrangements involve licenses of intellectual property, and the participants may exchange consideration related to the license at the inception of the arrangement. Participants in a collaborative arrangement shall report costs incurred and revenue generated from transactions with third parties (that is, parties that do not participate in the arrangement) in each entity's respective income statement pursuant to the guidance in EITF No. 99-19. An entity should not apply the equity method of accounting under APB 18 to activities of collaborati