

CHEMBIO DIAGNOSTICS, INC.

Form 10-Q

May 08, 2009

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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 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      (IRS  
jurisdiction of      Employer  
incorporation)      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 ☒ 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 ☒

As of May 6, 2009, 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

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 (UNAUDITED)	December 31, 2008
<b>CURRENT ASSETS:</b>		
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
<b>TOTAL CURRENT ASSETS</b>	<b>3,831,730</b>	<b>4,065,715</b>
<b>FIXED ASSETS, net of accumulated depreciation</b>	<b>783,198</b>	<b>881,406</b>
<b>OTHER ASSETS:</b>		
License agreements, net of current portion	901,875	940,000
Deposits and other assets	179,900	27,820
	\$ 5,696,703	\$ 5,914,941
<b>- LIABILITIES AND STOCKHOLDERS' EQUITY -</b>		
<b>CURRENT LIABILITIES:</b>		
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
<b>TOTAL CURRENT LIABILITIES</b>	<b>2,497,970</b>	<b>2,401,801</b>
<b>OTHER LIABILITIES:</b>		
Obligations under capital leases - net of current portion	55,697	60,808
License fee payable - net of current portion	875,000	875,000
<b>TOTAL LIABILITIES</b>	<b>3,428,667</b>	<b>3,337,609</b>
<b>COMMITMENTS AND CONTINGENCIES</b>		

**STOCKHOLDERS' EQUITY:**Preferred stock – 10,000,000 shares  
authorized, none outstanding

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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
<b>REVENUES:</b>		
Net sales	\$ 2,269,417	\$ 2,237,971
Research grant income	276,181	126,757
<b>TOTAL REVENUES</b>	<b>2,545,598</b>	<b>2,364,728</b>
Cost of sales	1,546,908	1,531,560
<b>GROSS PROFIT</b>	<b>998,690</b>	<b>833,168</b>
<b>OPERATING EXPENSES:</b>		
Research and development expenses	647,372	626,336
Selling, general and administrative expenses	675,813	1,018,400
	1,323,185	1,644,736
<b>LOSS FROM OPERATIONS</b>	<b>(324,495)</b>	<b>(811,568)</b>
<b>OTHER INCOME (EXPENSES):</b>		
Interest income	3,384	18,979
Interest expense	(4,121)	(5,593)
	(737)	13,386
<b>LOSS BEFORE INCOME TAXES</b>	<b>(325,232)</b>	<b>(798,182)</b>
Provision for income taxes	-	-
<b>NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS</b>	<b>\$ (325,232)</b>	<b>\$ (798,182)</b>
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
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:</b>		
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
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)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of and deposits on fixed assets	(151,241)	(179,272)
Net cash used in investing activities	(151,241)	(179,272)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Payment of capital lease obligation	(4,458)	(9,265)
Net cash used in financing activities	(4,458)	(9,265)
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>80,168</b>	<b>(1,062,634)</b>
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
<b>RECONCILIATION OF NET LOSS TO NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES:</b>		
Net loss	\$ (325,232)	\$ (798,182)
<b>Adjustments:</b>		
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
<b>Changes in assets and liabilities:</b>		
Accounts receivable	186,979	(22,554)
Inventories	138,613	(51,601)



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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		

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.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2009  
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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 cancellation and re-issue):				
effect as if cancelled	(1,846,500)	\$ 0.64		
effect as if re-issued	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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(UNAUDITED)

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.

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

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 collaborative arrangements. This EITF, which can be applied retrospectively, is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. 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.

NOTE 3—LICENSE FEE PAYABLE:

In February 2008, the Company entered into a sublicense agreement (the “Agreement”) with Bio-Rad Laboratories, Inc. and Bio-Rad Pasteur (collectively, “Bio-Rad”). Bio-Rad is the exclusive licensee of the HIV-2 patent portfolio held by Institute Pasteur of Paris, France. Pursuant to the terms of the Agreement, Bio-Rad sublicensed to the Company patents related to the manufacture, use or sale of HIV-2 in the Company’s HIV screening assays. In exchange for global non-exclusive rights to the patents, the Agreement provides that the Company will pay Bio-Rad a \$1,000,000 sublicense fee, \$500,000 payable during 2008, of which \$125,000 has been paid and \$375,000 was payable by December 31, 2008, with the additional \$500,000 being payable by December 31, 2009. On January 29, 2009, the Company and Bio-Rad agreed to defer the remaining \$875,000 of payments due under the HIV-2 sub-license originally granted by Bio-Rad to Chembio in February 2008 to one payment due in December 2010. The Company

will also pay Bio-Rad a royalty on net sales in the United States and Canada, if any, of rapid test immunoassay tests sold under the Company's brands of Licensed Products as defined in the Agreement. The Agreement will continue until the expiration of the last-to-expire of the sublicensed patents, unless otherwise terminated at an earlier date by the Company or Bio-Rad.

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

## NOTE 4—COMMITMENTS AND CONTINGENCIES:

## (a) Economic Dependency:

The following table delineates sales the Company had to customers in excess of 10% of net sales for the periods indicated:

	For the three months ended				Accounts Receivable	
	March 31, 2009		March 31, 2008		As of	
	Sales	% of Sales	Sales	% of Sales	March 31, 2009	March 31, 2008
Customer 1	\$ 844,208	37	\$ 540,836	24	\$ 297,600	\$ 317,455
Customer 2	\$ 793,200	35	*	*	\$ 119,737	*
Customer 3	\$ 370,278	16	\$ 781,866	35	\$ -	\$ 258,606
Customer 4	*	*	\$ 272,045	12	*	-

In the table above the asterisk (\*) indicates that sales to the customer did not exceed 10% for the period indicated.

The following table delineates purchases the Company made from vendors in excess of 10% of total purchases for the periods indicated:

	For the three months ended				Accounts Payable	
	March 31, 2009		March 31, 2008		As of	
	Purchases	% of Purc.	Purchases	% of Purc.	March 31, 2009	March 31, 2008
Vendor 1	\$ 125,062	25	\$ 118,444	18	\$ 1,778	\$ 10,450

The Company currently buys materials which are purchased under intellectual property rights agreements and are important components in its products. Management believes that other suppliers could provide similar materials on comparable terms. A change in suppliers, however, could cause a delay in manufacturing and a possible loss of sales, which would affect operating results adversely.

## (b) Governmental Regulation:

All of the Company's existing and proposed diagnostic products are regulated by the U.S. Food and Drug Administration, U.S. Department of Agriculture, certain state and local agencies, and/or comparable regulatory bodies in other countries. Most aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and record keeping are subject to review. After marketing approval has been granted, Chembio must continue to comply with governmental regulations. Failure to comply with these regulations can result in significant penalties.

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

(c) Nigeria Algorithm:

During the first quarter of 2008, the Nigerian Ministry of Health published a report indicating that our designation in Nigeria as one of the screening tests would be changed to that of a confirmatory and/or tie-breaker test (Many countries use a serial algorithm with tests from different manufacturers. A serial algorithm uses a screening test from one manufacturer, and if there is a positive result from the screening test, a second confirmatory test, from another manufacturer is used. As a result the number of confirmatory tests used is equal to the positivity rate in the testing venue. A tie-breaker test, from a third manufacturer, resolves discrepancies between the screen and the confirmatory test). This change became effective in the first quarter of 2009. Consequently, our sales to Nigeria decreased significantly in the first quarter of 2009 as compared to the first quarter of 2008 (see Note 2(f)). We anticipate that this trend will continue for the remainder of the fiscal year.

(d) Equipment Purchase Commitment:

In January of 2009, the Company entered into an agreement with an equipment manufacturer to design and build equipment that will be used to automate the assembling of our tests and lower our production costs. The estimated cost of \$323,500 is being paid in installments. As of March 31, 2009, \$150,000 has been paid and is reflected in deposits and other assets.

NOTE 5—SUBSEQUENT EVENTS:

(a) Operating Lease for Facilities:

On May 7, 2009, the Company entered into a new lease, beginning May 1, 2009, for its administrative offices and research facilities, an 18,160 square foot space located in Medford, NY. The principal terms of this lease are as follows: (a) a lease term of five years; (b) an initial rent of \$11,350 per month; (c) the monthly rent for year two of the lease will increase by the lower of (i) the change in the consumer price index, or (ii) five percent; and (d) the monthly rent for years three through five of the lease will increase each year by the lower of (i) the change in the consumer price index, or (ii) two and one half percent.

(b) Employee Options:

On May 7, 2009, the Compensation Committee of the Company reduced, to \$0.13 per share, the exercise price of each outstanding employee option that was issued under the 1999 Equity Incentive Plan (the "1999 Plan") for which the exercise price was greater than \$0.44 per share of the Company's common stock. The greater of 110% of the closing market price of the Company's common stock on May 7, 2009 or 110% of the volume weighted average trading price for the 10 trading days ending May 7, 2009 rounded to the nearest penny was used to determine the exercise price of \$.13 per share. There was no other change made to the terms of the stock options other than the reduction in the exercise price.

In addition, on May 7, 2009 in accordance with the terms of the Company's 2008 Stock Incentive Plan, the Company granted certain employees of the Company, options to purchase an aggregate of 2,925,000 shares of the Company's common stock. The exercise price for these options is equal to \$0.13 per share, which was the greater of 110% of the closing market price of the Company's common stock on May 7, 2009 or 110% of the volume weighted average trading price for the 10 trading days ending May 7, 2009 rounded to the nearest penny. The options become exercisable in thirds on the first, second and third anniversaries of the date of the grant. Each option granted will

expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the date of grant.

(c) Director Compensation:

On May 7, 2009, the Board of Directors of the Company revised the compensation of non-employee directors to increase the number of options to be acquired every five years from 180,000 to 375,000 options to purchase the Company's common stock. In addition the exercise price was changed from the closing market price on the date of the grant to the greater of 110% of the closing market price of the Company's common stock on the date of grant or 110% of the volume weighted average trading price for the 10 trading days ending on the date of the grant.

To accommodate the transition as of the June 3, 2009 annual meeting, any non-employee director who is re-elected will receive the five-year allotment of options and those options currently granted but not exercisable as of June 3, 2009 will be cancelled.

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## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Overview

This discussion and analysis should be read in conjunction with the accompanying Condensed Consolidated Financial Statements and related notes. Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of any contingent liabilities at the financial statement date and reported amounts of revenue and expenses during the reporting period. On an ongoing basis we review our estimates and assumptions. Our estimates were based on our historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results are likely to differ from those estimates under different assumptions or conditions, but we do not believe such differences will materially affect our financial position or results of operations. Our critical accounting policies, the policies we believe are most important to the presentation of our financial statements and require the most difficult, subjective and complex judgments, are outlined below in "Critical Accounting Policies," and have not changed significantly from December 31, 2008.

In addition, certain statements made in this report may constitute "forward-looking statements". These forward-looking statements involve known or unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Specifically, (1) our ability to obtain necessary regulatory approvals for our products; and (2) our ability to increase revenues and operating income, is dependent upon our ability to develop and sell our products, general economic conditions, and other factors. You can identify forward-looking statements by terminology such as "may," "could", "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continues" or the negative of these terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

Except as may be required by applicable law, we do not undertake or intend to update or revise our forward-looking statements, and we assume no obligation to update any forward-looking statements contained in this report as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the Securities and Exchange Commission that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

The following management discussion and analysis relates to the business of the Company, including its subsidiaries, which develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company's main products presently commercially available are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, all of which employ lateral flow technology and two of which were approved by the FDA in 2006. In addition, we have a fourth rapid HIV test, more recently developed on our patented Dual Path Platform (DPP®) technology, for the detection of antibodies to HIV in oral fluid samples, as well as in whole blood, serum and plasma samples. The products which employ lateral flow technology are manufactured and sold under a non-exclusive license we have from Inverness Medical Innovations, Inc. ("Inverness"), which is also our exclusive marketing partner for the FDA-approved products that are sold in the United States (as well as Europe and Asia for the product that is known as the "barrel" format product) under Inverness' Clearview® brand. Inverness launched its marketing of these products in the United States in February 2007. Chembio's two HIV STAT-PAK® rapid HIV tests (in cassette and



dipstick formats) are marketed outside the United States through different partners and channels under our license from Inverness.

Rapid HIV tests represented nearly 70% of the Company's product revenues in the quarter ended March 31, 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.

#### Research and Development Activities

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. In 2008 the Company completed development of its first two products that employ the DPP® technology and it has a number of additional products under development that employ the DPP® technology. These product development activities are further explained below.

During the first quarter of 2009 and 2008, \$647,000 and \$626,000, respectively, were spent on research and development activities. Substantially all of our new product development activities involve employment of our Dual Path Platform (DPP®) technology for which we were awarded a U.S. patent in 2007. We believe that this platform enables us to pursue many new product development and licensing opportunities. The DPP® technology can provide improved features on certain tests developed with it that include higher sensitivity, earlier detection, improved performance with more challenging sample types (such as oral fluid), and the improved ability to detect multiple analytes (multiplexing) in one test device.

During the first quarter of 2009 we continued developing a portfolio of products based on the DPP® technology as are explained below.

- o DPP® Oral Fluid HIV Test - During the first quarter we made further progress on but did not finalize a term sheet with a large in vitro diagnostics marketing organization concerning U.S. marketing rights to this product.
- o DPP® Syphilis Screen and Confirm Test – Through the use of our DPP® technology, we have developed the first point of care screen and confirm test that can detect active syphilis cases. Given this progress, we are developing a plan for commercialization of this product, including regulatory approval in the U.S. and internationally
- o DPP® Agreements with Oswaldo Cruz Foundation - We have now completed development of the Leishmaniasis, HIV Confirmatory, and HIV oral fluid screening tests in connection with the four agreements we signed with Oswaldo Cruz Foundation in 2008. Based upon the results of testing, we anticipate approval of the Leishmaniasis test by the Brazilian Ministry of Agriculture, Livestock and Supply (MAPA) during the second quarter of 2009. Evaluations of the other two products are now in process and we expect that all of these products will be approved by ANVISA for distribution by FIOCRUZ in Brazil during 2009, generating initial orders as well as approximately \$1MM in technology transfer fee payments to the Company in 2009, although there is no certainty that this will occur. During the first quarter we shipped approximately \$400,000 of the Leishmaniasis product to FIOCRUZ.
- o Other Research & Development Activities -Chembio continues to work with commercial, governmental and private organizations in order to obtain research grants and other funding for development projects. In this regard, we have entered into a development agreement with Bio-Rad, which, subject to continued achievement of milestones and other conditions, could result in approximately \$200,000 of development funds for Chembio in 2009. We also have DPP® grants from governmental agencies for \$55,000 for leprosy research and \$110,000 for Human TB Serology research in 2009. In April we entered into a Services Agreement with the Infectious Disease Research Institute to develop DPP® products for Leishmaniasis and Leprosy for which we have received \$125,000 and which, subject to attainment of development milestones, will additionally provide us with approximately \$125,000 within the next twelve months. During the first quarter we entered into a funded feasibility study agreement with the Foundation for Innovative and Novel Diagnostics (FIND), a non-profit organization funded by the Gates Foundation, related to development of serological tests for Tuberculosis and Malaria using our DPP®. Subject to achievement of additional milestones, additional funding will be provided by FIND for this project. The CDC has issued a purchase order to Chembio for a multiplex test related to pandemic influenza which, if the product meets certain initial performance expectations, could result in a broader funded collaboration with CDC in this field. We are also working on a new product to enter the research animal testing market.

There can be no assurance that any of these projects will continue, meet regulatory or other technical requirements and specifications, and/or that if continued, will result in completed products, or that such products, if successfully completed, will be successfully commercialized.

#### Regulatory Activities

We continue to make progress on obtaining a Community European (CE) marking for our products to indicate conformity with European Union health, safety and environmental requirements. We have submitted the HIV 1/2 STAT-PAK® technical file to our notified body and should complete all required steps for CE Marking of this product during the second quarter of 2009. Under our agreement with Inverness we are to obtain a CE Marking for the Clearview® Complete HIV 1/2. We are prepared to submit the technical file for this product on behalf of Inverness once we have received final proposed labeling from Inverness.

We are pursuing registrations of our lateral flow and DPP® HIV products in a number of other jurisdictions, and also pursuing registrations with the USDA of additional claims for our veterinary tuberculosis products.

#### Critical Accounting Policies and Estimates

We believe that there are several accounting policies that are critical to understanding our historical and future performance, as these policies affect the reported amounts of revenue and the more significant areas involving management's judgments and estimates. These significant accounting policies relate to revenue recognition, research and development costs, valuation of inventory, valuation of long-lived assets, accounting for complex financial instruments and income taxes. For a summary of our significant accounting policies, which have not changed from December 31, 2008, see our annual report on Form 10-K for the period ended December 31, 2008, which was filed with the SEC on March 18, 2009.

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2009 AS COMPARED WITH THE THREE MONTHS ENDED MARCH 31, 2008

Revenues:

Selected Product  
Categories:

	For the three months ended			
	March 31, 2009	March 31, 2008	\$ Change	% Change
HIV	\$ 1,596,795	\$ 1,920,986	\$ (324,191)	-16.88%
DPP	415,800	-	415,800	n/a
Other	256,822	316,985	(60,163)	-18.98%
Net Product Sales	2,269,417	2,237,971	31,446	1.41%
Research grant income	276,181	126,757	149,424	117.88%
Total Revenues	\$ 2,545,598	\$ 2,364,728	\$ 180,870	7.65%

Revenues for our HIV tests during the three months ended March 31, 2009 decreased by approximately \$324,000 over the same period in 2008. This was primarily attributable to decreased sales in Africa, primarily Nigeria, which decreased in the first quarter of 2009 by approximately \$820,000 compared to the first quarter of 2008 (see Note 2(f) and Note 4(c)), which were partially offset by increased sales to Inverness of our HIV products which increased by \$304,000 to \$844,000, and by sales to Brazil of \$258,000. During the first quarter of 2009 we had our first significant sales of product based on our DPP® technology. The increase in grant and development income was due to revenue generated from grant and feasibility studies that are related to potential new products utilizing our patented DPP™ technology.

Gross Margin:

Gross Margin related  
to

	For the three months ended			
Net Product Sales:	March 31, 2009	March 31, 2008	\$ Change	% Change
Gross Margin per Statement of Operations	\$ 998,690	\$ 833,168	\$ 165,522	19.87%
Less: Research grant income	276,181	126,757	149,424	117.88%
Gross Margin from Net Product Sales	\$ 722,509	\$ 706,411	\$ 16,098	2.28%
Gross Margin %	31.84%	31.56%		

For the year ended December 31, 2008, the Company reclassified its royalty and license expenses to cost of goods sold. For all periods prior to December 31, 2008 these expenses were previously reflected in selling, general and administrative expenses. Because we were not informed of the agreement for the past royalties for the HIV-2 license between Inverness and Bio-Rad until the quarter ended December 31, 2008, the quarterly reports for the first three quarters of 2008 do not reflect this expense. If such an expense was reflected in the three-month period ended March 31, 2008, the impact of the past royalties would have been approximately \$75,000 or 3.35%. This would have resulted in changes between the three-month periods ended March 31, 2009 versus 2008 of approximately \$91,000 and an improved margin percentage of 3.63%. In addition, sales of our Veterinary TB line of products in the quarter ended March 31, 2009 were negligible but contributed approximately \$72,000 to the gross margin in the quarter ended March 31, 2008. Finally, an additional \$31,000, or 1.37% of product sales, in expense was related to the termination of employees during the three months ended March 31, 2009, which also reduced the gross margin for the period ended in 2009.

## Research and Development:

This category includes costs incurred for regulatory approvals, product evaluations and registrations.

Selected expense lines:	For the three months ended		\$ Change	% Change
	March 31, 2009	March 31, 2008		
Clinical & Regulatory Affairs:				
Wages and related costs	\$ 65,549	\$ 66,836	\$ (1,287)	-1.93%
Consulting	15,181	6,435	8,746	135.91%
Clinical Trials	1,780	74,180	(72,400)	-97.60%
Other	7,260	21,241	(13,981)	-65.82%
Total Regulatory	\$ 89,770	\$ 168,692	\$ (78,922)	-46.78%
R&D Other than Regulatory:				
Wages and related costs	\$ 354,714	\$ 279,786	74,928	26.78%
Consulting	17,432	5,000	12,432	248.64%
Share-based compensation	7,182	53,224	(46,042)	-86.51%
Materials and supplies	110,782	71,197	39,585	55.60%
Other	67,492	48,437	19,055	39.34%
Total other than Regulatory	\$ 557,602	\$ 457,644	\$ 99,958	21.84%
Total Research and Development	\$ 647,372	\$ 626,336	\$ 21,036	3.36%

Expenses for Clinical & Regulatory Affairs for the three months ended March 31, 2009 decreased by approximately \$79,000 as compared to the same period in 2008. This was primarily due to clinical trial expenses in the first quarter of 2008 related to an amendment of our PMA claims to include the 12 -17 year old age group.

Expenses other than Clinical & Regulatory Affairs increased by approximately \$100,000 in the three months ended March 31, 2009 as compared with the same period in 2008. These increases were primarily related to an increase in the work related to feasibility studies for our DPP™ platform and to work related to grant income received, both resulting in an increase in our personnel and material costs, partially offset by the reduced cost of share-based compensation related to the value of common stock and employee stock options issued to employees.

## Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended		\$ Change	% Change
	March 31, 2009	March 31, 2008		
Wages and related costs	\$ 237,082	\$ 350,235	\$ (113,153)	-32.31%
Consulting	61,742	44,316	17,426	39.32%

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Commissions	83,963	27,450	56,513	205.88%
Share-based compensation	10,001	101,730	(91,729)	-90.17%
Marketing Materials	6,432	8,902	(2,470)	-27.75%
Investor Relations	3,039	59,080	(56,041)	-94.86%
Legal, Accounting and Sox 404 compliance	160,360	259,425	(99,065)	-38.19%
Travel, Entertainment and Trade Shows	16,947	20,919	(3,972)	-18.99%
Bad Debt Allowance	-	6,062	(6,062)	-100.00%
Other	96,247	140,281	(44,034)	-31.39%
Total S, G &A	\$ 675,813	\$ 1,018,400	\$ (342,587)	-33.64%

Selling, general and administrative expenses for the three months ended March 31, 2009 decreased by 34% as compared with the same period in 2008. The Company implemented a cost savings program during the first quarter of 2009 that reduced personnel expenses, investor relations expenses, and professional fees, along with a reduction in share-based compensation were partially offset by increases in sales commissions that resulted from commissionable sales in Brazil that increased in 2009 as compared with 2008. Our periodic review of our allowance for doubtful accounts resulted in no change to the allowance in the three months ended March 31, 2009.

## Other Income and Expense:

Other Income and Expense	For the three months ended			
	March 31, 2009	March 31, 2008	\$ Change	% Change
Interest income	\$ 3,384	\$ 18,979	\$ (15,595)	-82.17%
Interest expense	(4,121)	(5,593)	1,472	-26.32%
Total Other Income and Expense	\$ (737)	\$ 13,386	\$ (14,123)	-105.51%

Other income for the three months ended March 31, 2009 decreased approximately \$14,000 as compared with the same period in 2008 primarily as a result of a decrease in interest income due to a decrease in available funds to invest in interest bearing accounts.

## LIQUIDITY AND CAPITAL RESOURCES

	For the three months ended			
	March 31, 2009	March 31, 2008	\$ Change	% Change
Net cash provided by (used in) operating activities	\$ 235,867	\$ (874,097)	\$ 1,109,964	-126.98%
Net cash used in investing activities	(151,241)	(179,272)	28,031	-15.64%
Net cash utilized by financing activities	(4,458)	(9,265)	4,807	-51.88%
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	\$ 80,168	\$ (1,062,634)	\$ 1,142,802	-107.54%

The Company had an increase in cash for the three months ended March 31, 2009 as compared to a decrease in cash for the same period in 2008. The increase during the 2009 and the decrease during the 2008 periods are primarily attributable to the cash provided or used in operations.

The Company had a working capital surplus of approximately \$1,334,000 at March 31, 2009 and a working capital surplus of \$1,664,000 at December 31, 2008. 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.

## RECENT DEVELOPMENTS AND CHEMBIO'S PLAN OF OPERATIONS FOR THE NEXT TWELVE MONTHS

During the first quarter of 2009 our net sales to Inverness increased more than \$300,000, or approximately 56%, as compared to the first quarter of 2008. These increased sales suggest to us that our sales to Inverness will resume an



upward trajectory in 2009 after we experienced a slight decrease in sales to Inverness during 2008 as compared to our first year of sales to Inverness in 2007. The actions that we took last year to expand the regulatory claims of these products and provide the regulatory and technical support to Inverness' introductory marketing efforts are beginning to pay off. These increases, together with a 117% increase in research and development revenues and a 20% decrease in total operating expenses as compared to the first quarter of 2008, enabled Chembio to reduce its operating loss in the first quarter of 2009 by approximately 60%, or \$487,000, as compared to the first quarter of 2008.

Over the next twelve months we expect to reflect improvements in our sales and operating results due to continued increased sales to Inverness, as compared with the last twelve months, increased sales from our DPP® technology (primarily as a result of the contracts we signed with the Oswaldo Cruz Foundation in 2008), increased revenues from research and development contracts, improved manufacturing efficiencies, and decreased operating expenses. We believe that we will be able to at least partially offset sales decreases to Nigeria with opportunities we have in other markets.

Our R&D efforts will be focused on our DPP® HIV 1/2 screening test for use with oral fluids and our DPP® Syphilis Screen and Confirm test, in addition to the DPP® products we anticipate launching in Brazil through the Oswaldo Cruz Foundation, our contract development work for Bio-Rad Laboratories, and several other research and development programs. During the first quarter we made progress in finalizing a term sheet with a large in vitro diagnostics marketing organization. If an agreement is completed, of which there is no assurance, the agreement would fund all external regulatory costs, would co-brand this product with our DPP® trademark, and would commit to minimum sales volumes of the product in exchange for our granting them exclusive U.S. marketing rights. We are also actively pursuing opportunities for our oral fluid HIV test in the international markets that we already participate in. We have completed development of our prototype DPP® Syphilis Screen and Confirm Test, and we are developing a plan for commercialization of this product including regulatory approval in the U.S., and we are very encouraged by the interest we have received in this product. We believe either or both of these products will begin to provide revenues this year.

Equipment Purchase Commitment:

In January of 2009, the Company entered into an agreement with an equipment manufacturer to design and build equipment that will be used to automate the assembling of our tests and lower our production costs. The estimated cost of \$323,500 is being paid in installments. As of March 31, 2009, \$150,000 has been paid and is reflected in deposits and other assets.

ITEM 4. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures. Under the supervision and with the participation of our senior management, consisting of our chief executive officer and our chief financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this report (the "Evaluation Date"). Based on that evaluation, the Company's management, including our chief executive officer and chief financial officer, concluded that as of the Evaluation Date our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our Exchange Act reports is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

(b) Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 under the Exchange Act that occurred during the Company's last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

## Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

To the extent applicable, the contents of Item 5 below are incorporated into this Item 2 by reference

## Item 5. OTHER INFORMATION.

## Employee options:

On May 7, 2009, the Compensation Committee of the Company reduced, to \$0.13 per share, the exercise price of each employee and option issued under the 1999 Equity Incentive Plan (the “1999 Plan”) for which the exercise price was greater than \$0.44 per share of the Company’s common stock. The greater of 110% of the closing market price of the Company’s common stock on May 7, 2009 or 110% of the volume weighted average trading price for the 10 trading days ending May 7, 2009 rounded to the nearest penny was used to determine the exercise price of \$.13 per share. There was no other change made to the terms of the stock options other than the reduction in the exercise price.

The following table lists the number of shares of Company common stock underlying options with a previous exercise price greater than \$0.44 per share that are held by officers and the previous exercise price of each such stock option.

Executive Officer or Board Member	Number of Shares of Common Stock Options under the 1999 Plan	Previous Exercise Price	New Exercise Price
Javan Esfandiari (1)	100,000	\$0.48	\$0.13
Javan Esfandiari (1)	100,000	\$0.48	\$0.13
Javan Esfandiari (1)	100,000	\$0.48	\$0.13
Javan Esfandiari (1)	18,750	\$0.48	\$0.13
Javan Esfandiari (1)	18,750	\$0.48	\$0.13
Javan Esfandiari (1)	30,000	\$0.48	\$0.13
Javan Esfandiari (1)	5,000	\$0.48	\$0.13
Javan Esfandiari (1)	25,000	\$0.48	\$0.13
Javan Esfandiari (1)	25,000	\$0.48	\$0.13
Javan Esfandiari (1)	25,000	\$0.48	\$0.13
Javan Esfandiari (1)	25,000	\$0.48	\$0.13
Javan Esfandiari (1)	25,000	\$0.48	\$0.13
Lawrence Siebert (2)	10,000	\$0.48	\$0.13
Lawrence Siebert (2)	50,000	\$0.48	\$0.13
Lawrence Siebert (2)	50,000	\$0.48	\$0.13
Lawrence Siebert (2)	50,000	\$0.48	\$0.13
Richard Bruce (3)	20,000	\$0.48	\$0.13
Richard Bruce (3)	12,500	\$0.48	\$0.13
Richard Bruce (3)	12,500	\$0.48	\$0.13
Richard Bruce (3)	12,500	\$0.48	\$0.13
Richard Bruce (3)	12,500	\$0.48	\$0.13
Richard Bruce (3)	10,000	\$0.48	\$0.13
Richard Bruce (3)	5,000	\$0.48	\$0.13
Richard J. Larkin (4)	18,750	\$0.48	\$0.13
Richard J. Larkin (4)	18,750	\$0.48	\$0.13

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Richard J. Larkin (4)	50,000	\$0.45	\$0.13
Richard J. Larkin (4)	25,000	\$0.48	\$0.13
Richard J. Larkin (4)	25,000	\$0.48	\$0.13
Tom Ippolito (5)	15,000	\$0.48	\$0.13

(1) Javan Esfandiari is Senior Vice President of Research and Development for the Company.

(2) Lawrence A. Siebert is the Company's Chief Executive Officer and a Director.

(3) Richard Bruce is Vice President of Operations for the Company.

(4) Richard J. Larkin is the Company's Chief Financial Officer.

(5) Tom Ippolito is Vice President of Regulatory Affairs, QA & QC for the Company.

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In addition, on May 7, 2009 in accordance with the terms of the Company's 2008 Stock Incentive Plan, the Company granted certain employees of the Company options to purchase an aggregate of 2,925,000 shares of the Company's common stock. The exercise price for these options is equal to \$0.13 per share, which was the greater of 110% of the closing market price of the Company's common stock on May 7, 2009 or 110% of the volume weighted average trading price for the 10 trading days ending May 7, 2009 rounded to the nearest penny. The options become exercisable in thirds on the first, second and third anniversaries of the date of the grant. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the date of grant. The following table identifies the portions of these options issued to officers of the Company.

Name of Executive Officer	Number of Shares of Common Stock Options	Exercise Price of Stock Option	Expiration Date of Stock Option	Vesting Date of Stock Option
Javan Esfandiari – Senior Vice President of Research and Development	100,000	\$0.13	5/7/2014	5/7/2010
	100,000	\$0.13	5/7/2014	5/7/2011
	100,000	\$0.13	5/7/2014	5/7/2012
Lawrence A. Siebert - Chief Executive Officer	133,333	\$0.13	5/7/2014	5/7/2010
	133,333	\$0.13	5/7/2014	5/7/2011
	133,334	\$0.13	5/7/2014	5/7/2012
Richard Bruce - Vice President of Operations	75,000	\$0.13	5/7/2014	5/7/2010
	75,000	\$0.13	5/7/2014	5/7/2011
	75,000	\$0.13	5/7/2014	5/7/2012
Richard J. Larkin – Chief Financial Officer	91,666	\$0.13	5/7/2014	5/7/2010
	91,667	\$0.13	5/7/2014	5/7/2011
	91,667	\$0.13	5/7/2014	5/7/2012
Tom Ippolito - Vice President of Regulatory Affairs, QA & QC	75,000	\$0.13	5/7/2014	5/7/2010
	75,000	\$0.13	5/7/2014	5/7/2011
	75,000	\$0.13	5/7/2014	5/7/2012

These issuances were granted based on exemptions from registration under the Securities Act of 1933, as amended (the "Securities Act"), and applicable state laws pursuant to Section 4(2) of the Securities Act and Rule 506 of Regulation D. These issuances qualified for this exemption from registration because (i) the Company did not engage in any general solicitation or advertising to market the securities; (ii) all the Company's reports filed under the Securities Exchange Act of 1934 were made available to the recipients; (iii) each recipient was provided the opportunity to ask questions and receive answers from the Company regarding the offering; (iv) the securities were issued to persons with knowledge and experience in financial and business matters so that he or she is capable of evaluating the merits and risks of an investment in the Company; and (v) the recipients received "restricted securities" that include a restrictive legend on the certificate.

Director Compensation:

On May 7, 2009, the Board of Directors of the Company revised the compensation of non-employee directors to increase the number of stock options to be granted every five years from 180,000 to 375,000 options to purchase the Company's common stock. In addition, the exercise price was changed from the closing market price on the date of the grant to the greater of 110% of the closing market price of the Company's common stock on the date of grant or

110% of the volume weighted average trading price for the 10 trading days ending on the date of the grant. The new director compensation is now as follows:

All non-employee directors are paid an \$18,000 annual retainer, payable semi-annually, and in addition once every five years stock options to acquire 375,000 shares of the Company's common stock, with an exercise price equal to the greater of 110% of the closing market price of the Company's common stock on the date of grant or 110% of the volume weighted average trading price for the 10 trading days ending on the date of the grant. With respect to this stock option grant, stock options to acquire 75,000 shares become exercisable on the date of grant, and options to acquire an additional 75,000 shares become exercisable on the date of each of the four succeeding annual meetings of stockholders if and to the extent that the non-employee director is reelected as a director at each such annual meeting. If in any year the Company does not hold an annual meeting of stockholders within 30 days after the anniversary date for the current year of the original stock option grant, then the options that are scheduled to become exercisable in that current year shall become exercisable on the 30th day after such anniversary date. If a person becomes a member of the Board at a time other than at an annual meeting, then that person is granted options to purchase that number of shares of common stock that is the same percentage of 75,000 that the number of days remaining until the one-year anniversary of the most recent annual meeting of stockholders is of 365. The audit committee chairman is paid an annual retainer of \$2,500, paid semi-annually. In addition, the non-employee directors are paid \$1,000 in cash for each board of directors meeting attended in person, and paid \$500 in cash for each telephonic board of directors meeting exceeding 20 minutes in which they participate. The non-employee directors who are members of a committee of the board of directors are paid \$500 in cash for each committee meeting exceeding 20 minutes in which they participate in person or by telephone or, in the case of the chairperson of the committee, \$750 in cash for each committee meeting attended exceeding 20 minutes in which they participate in person or by telephone.

To accommodate the transition as of the June 3, 2009 annual meeting, any non-employee director who is re-elected will receive the five-year allotment of options and those options currently granted but not exercisable as of June 3, 2009 will be cancelled.

Item 6. EXHIBITS.

NumberDescription

- 3.1 Articles of Incorporation, as amended. (3)
- 3.2 Amended and Restated Bylaws. (1)
- 4.1 Registration Rights Agreement, dated as of May 5, 2004, by and among the Registrant and the Purchasers listed therein. (2)
- 4.2 Form of \$0.90 Warrant issued to Mark L. Baum pursuant to the Consulting Agreement dated as of May 5, 2004 between the Registrant and Mark L. Baum. (2)
- 4.3 Form of \$0.60 Warrant issued to Mark L. Baum pursuant to the Consulting Agreement dated as of May 5, 2004 between the Registrant and Mark L. Baum. (2)
- 4.4 Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement. (8)
- 4.5 Amended Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement. (10)
- 4.6 Registration Rights Agreement, dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (8)
- 4.7 Form of Warrant, dated June 29, 2006, issued pursuant to Company and purchasers of the Company's Secured Debentures. (4)
- 4.8 Registration Rights Agreement, dated June 29, 2006. (4)
- 4.9 Registration Rights Agreement, dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (6)
- 4.10 Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated September 29, 2006 (6).
- 4.11 Amended Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated October 5, 2006. (10)
- 4.12 Amended Form of Common Stock Warrant issued to Placement Agents pursuant to the October 5, 2005 Securities Purchase Agreement. (10)
- 4.13\* Form of Employee Option Agreement. (10)
- 4.14 Amended Form of Warrant used for Consultant Services, and in connection with the Company's 2004 merger. (10)
- 4.15 1999 Equity Incentive Plan (12)
- 4.16 2008 Stock Incentive Plan. (13)
- 10.1\* Employment Agreement dated June 15, 2006 with Lawrence A. Siebert. (5)
- 10.2\* Employment Agreement dated April 23, 2007 with Javan Esfandiari. (11)
- 10.3 Series A Convertible Preferred Stock and Warrant Purchase Agreement (the "Stock and Warrant Purchase Agreement"), dated as of May 5, 2004, by and among the Registrant and the purchasers listed therein. (2)
- 10.4 Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (8)
- 10.5 Amendment No. 1 to Securities Purchase Agreement, dated as of January 28, 2005 by and among the Registrant and the purchasers listed therein. (9)
- 10.6 Security Purchase Agreement, dated June 29, 2006, among the Company and purchasers of the Company's Secured Debentures. (4)
- 10.7 Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (6)
- 10.8 Letter of Amendment to Securities Purchase Agreements dated as of September 29, 2006 by and among the Registrant and the Purchasers listed therein. (6)
- 10.9 HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Inverness and StatSure. (6)
- 10.10

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- HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (6)
- 10.11 Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (6)
- 10.12 Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (6)
- 10.13 License and Supply Agreement dated as of August 30, 2002 by and between Chembio Diagnostic Systems Inc. and Adaltis Inc. (7)
- 31.1 Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- (1) Incorporated by reference to the Registrant's registration statement on Form SB-2 filed with the Commission on August 23, 1999 and the Registrant's Forms 8-K filed on May 14, 2004, December 20, 2007 and April 18, 2008.
- (2) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on May 14, 2004.
- (3) Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 31, 2005.
- (4) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on July 3, 2006.
- (5) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 21, 2006.
- (6) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.
- (7) Incorporated by reference to the Registrant's registration statement on Form SB-2 filed with the Commission on June 7, 2004.
- (8) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on January 31, 2005.
- (9) Incorporated by reference to the Registrant's registration statement on Form SB-2 filed with the Commission on March 28, 2005.
- (10) Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 12, 2008.
- (11) Incorporated by reference to the Registrant's Current Report on Form 8-K/A filed with the Commission on May 3, 2007.
- (12) Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on May 11, 2005.
- (13) Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on April 14, 2008.
- (\*) An asterisk (\*) beside an exhibit number indicates the exhibit contains a management contract, compensatory plan or arrangement which is required to be identified in this report.



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.

Chembio Diagnostics, Inc.

Date: May 7, 2009      By: /s/ Lawrence A. Siebert  
Lawrence A. Siebert  
Chief Executive Officer  
(Principal Executive Officer)

Date: May 7, 2009      By: /s / Richard J. Larkin  
Richard J. Larkin  
Chief Financial Officer  
(Principal Financial and Accounting Officer)