

CHEMBIO DIAGNOSTICS, INC.

Form 10-Q

August 06, 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 June 30, 2009

000-30379

(Commission File Number)

Chembio Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of
incorporation)

88-0425691

(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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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.

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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 August 5, 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

June 30, 2009

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PART I

Item 1. FINANCIAL STATEMENTS

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

- ASSETS -

	June 30, 2009 (UNAUDITED)	December 31, 2008
CURRENT ASSETS:		
Cash and cash equivalents	\$ 1,859,069	\$ 1,212,222
Accounts receivable, net of allowance for doubtful accounts of \$10,301 for 2009 and 2008	610,869	809,303
Inventories	1,652,850	1,819,037
Prepaid expenses and other current assets	247,083	225,153
TOTAL CURRENT ASSETS	4,369,871	4,065,715
FIXED ASSETS, net of accumulated depreciation		
	703,791	881,406
OTHER ASSETS:		
License agreements, net of current portion	863,750	940,000
Deposits and other assets	229,560	27,820
TOTAL ASSETS:	\$ 6,166,972	\$ 5,914,941

- LIABILITIES AND
STOCKHOLDERS' EQUITY -

CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 2,244,837	\$ 2,383,021
Deferred research and development revenue	494,748	-
Current portion of loan payable	9,462	-
Current portion of obligations under capital leases	20,110	18,780
TOTAL CURRENT LIABILITIES	2,769,157	2,401,801
OTHER LIABILITIES:		
Obligations under capital leases - net of current portion	50,409	60,808
Loan payable - net of current portion	19,766	-
License fee payable - net of current portion	875,000	875,000
TOTAL LIABILITIES	3,714,332	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

619,449

619,449

Additional paid-in capital

39,342,952

39,252,350

Accumulated deficit

(37,509,761)

(37,294,467)

TOTAL STOCKHOLDERS' EQUITY

2,452,640

2,577,332

TOTAL LIABILITIES AND

STOCKHOLDERS' EQUITY

\$ 6,166,972

\$ 5,914,941

See accompanying notes

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

	For the three months ended		For the six months ended	
	June 30, 2009	June 30, 2008	June 30, 2009	June 30, 2008
REVENUES:				
Net product sales	\$ 3,051,385	\$ 2,466,241	\$ 5,320,802	\$ 4,704,212
License and royalty income	52,322	-	52,322	-
Research grant income	269,817	251,543	545,998	378,300
TOTAL REVENUES	3,373,524	2,717,784	5,919,122	5,082,512
Cost of product sales	2,011,579	1,705,964	3,558,488	3,237,523
GROSS PROFIT	1,361,945	1,011,820	2,360,634	1,844,989
OPERATING EXPENSES:				
Research and development expenses	702,986	567,249	1,350,358	1,193,586
Selling, general and administrative expenses	542,449	809,830	1,218,262	1,828,231
	1,245,435	1,377,079	2,568,620	3,021,817
INCOME (LOSS) FROM OPERATIONS	116,510	(365,259)	(207,986)	(1,176,828)
OTHER INCOME (EXPENSES):				
Other (expense)	(6,696)	-	(6,696)	-
Interest income	1,531	7,391	4,915	26,371
Interest expense	(1,406)	(5,261)	(5,527)	(10,854)
	(6,571)	2,130	(7,308)	15,517
INCOME (LOSS) BEFORE INCOME TAXES	109,939	(363,129)	(215,294)	(1,161,311)
Provision for income taxes	-	-	-	-
NET INCOME (LOSS)	\$ 109,939	\$ (363,129)	\$ (215,294)	\$ (1,161,311)
Basic earnings (loss) per share	\$ -	\$ (.01)	\$ -	\$ (.02)
	\$ -	\$ (.01)	\$ -	\$ (.02)

Diluted earnings (loss)
per share

Weighted average
number of shares
outstanding, basic

61,944,901	60,616,122	61,944,901	60,576,828
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Weighted average
number of shares
outstanding, diluted

74,814,205	60,616,122	61,944,901	60,576,828
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See accompanying notes

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

	June 30, 2009	June 30, 2008
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:		
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers	\$ 6,088,328	\$ 4,593,731
Cash paid to suppliers and employees	(5,239,948)	(6,165,461)
Interest received	4,915	7,391
Interest paid	(5,527)	(5,261)
Net cash provided by (used in) operating activities	847,768	(1,569,600)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed assets	13,750	-
Acquisition of and deposits on fixed assets	(234,830)	(289,311)
Net cash used in investing activities	(221,080)	(289,311)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from loan	29,228	-
Payment of capital lease obligation	(9,069)	(14,301)
Net cash provided by (used) in financing activities	20,159	(14,301)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	646,847	(1,873,212)
Cash and cash equivalents - beginning of the period	1,212,222	2,827,369
Cash and cash equivalents - end of the period	\$ 1,859,069	\$ 954,157
RECONCILIATION OF NET LOSS TO NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES:		
Net loss	\$ (215,294)	\$ (1,161,311)

Adjustments:

Depreciation and amortization	191,999	154,101
Provision for doubtful accounts	-	256
Loss on sale of fixed asset	6,696	-
Common stock, options and warrants issued as compensation	91,850	244,338
Changes in assets and liabilities:		
Accounts receivable	198,434	(489,037)
Inventories	166,187	4,549
Prepaid expenses and other assets	(23,178)	(908,621)
Deposits and other assets	74,510	-
Deferred revenue	494,748	56,666
Accounts payable and accrued expenses	(138,184)	(345,541)
Licenses fee payable	-	875,000
Net cash provided by (used in) operating activities	\$ 847,768	\$ (1,569,600)

Supplemental disclosures for non-cash investing and financing activities:

Value of common stock issued upon cashless warrant exercise	-	14,074
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See accompanying notes

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2009
(UNAUDITED)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. and its subsidiaries (referred to collectively as the “Company” or “Chembio”) 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 approximately 80% of the Company’s product revenues in the first half 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 new products are based on its patented Dual Path Platform (DPP®), a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. In 2008 and 2009 to date, the Company has completed development of its first four 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, gross margins and cash flow from operating activities increased in the six months ended June 30, 2009 as compared to the same period in 2008 and the Company was profitable for the three months ended June, 30, 2009, there can be no assurance that these trends will continue. At June 30, 2009, the Company had stockholders’ equity of \$2,453,000 and working capital of \$1,601,000. The Company estimates that its resources are sufficient to fund its needs through the next twelve months or that, in the alternative, it could attempt to raise additional capital although the terms under which that capital could be raised would likely be very dilutive to current stockholders. 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 increases net cash flow through operating efficiencies. There are no assurances that the Company will remain 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 June 30, 2010.

NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

(a) Basis of Presentation:

The consolidated interim financial information as of June 30, 2009 and for the three- and six-month periods ended June 30, 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 the Company's consolidated financial position as of June 30, 2009, its consolidated results of operations for the three and six-month periods ended June 30, 2009 and 2008 and its cash flows for the six-month periods ended June 30, 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:

	June 30, 2009	December 31, 2008
Raw materials	\$ 788,107	\$ 836,446
Work in process	343,179	300,986
Finished goods	521,564	681,605
	\$ 1,652,850	\$ 1,819,037

(c) Earnings (Loss) Per Share:

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

	For the three months ended		For the six months ended	
	June 30, 2009	June 30, 2008	June 30, 2009	June 30, 2008
Basic	61,944,901	60,616,122	61,944,901	60,576,828
Diluted	74,814,205	60,616,122	61,944,901	60,576,828

Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted-average number of common shares outstanding for the period. Diluted earnings (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 six-month period ended June 30, 2009 and the three and six-month periods ended June 30, 2008 are 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 those periods. Diluted earnings per share for the three month period ended June 30, 2009, reflects certain common stock equivalents which are not anti-dilutive. The following securities, presented on a common share equivalent basis for the three and six-month periods ended June 30, 2009 and 2008, except those presented for the three month period ended June 20, 2009, have been excluded from the per share computations:

	For the three months ended		For the six months ended	
	June 30, 2009	June 30, 2008	June 30, 2009	June 30, 2008
1999 & 2008 Plan Stock Options	4,140,554	2,605,665	3,264,033	2,323,842
Other Stock Options	124,625	124,625	124,625	124,625
Warrants	8,604,125	18,966,456	9,383,684	19,226,777
	12,869,304	21,696,746	12,772,342	21,675,244

(d) Reclassifications:

Certain reclassifications have been made to conform to the 2009 presentation. For the three and six months ended June 30, 2008 the Company reclassified its royalty and license expenses to cost of product sales, 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 other 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. Stock option compensation expense represents the estimated fair value, at their respective dates of grant, of options outstanding which are being amortized on a straight-line basis over the requisite vesting period of the entire award.

The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the six-month periods ended June 30, 2009 and 2008 was \$.09 and \$.37 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. The expected term is determined using the simplified method as permitted by SAB 110, as the Company has no history of employee exercise of options to-date.

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

	For the three months ended		For the six months ended	
	June 30, 2009	June 30, 2008	June 30, 2009	June 30, 2008
Expected term (in years)	4	4	4	4
Expected volatility	123.81%	112.33%	123.81%	109.33-112.33%
Expected dividend yield	n/a	n/a	n/a	n/a
Risk-free interest rate	1.81-1.95%	2.98%	1.81-1.95%	1.91-2.98%

As a result of the adoption of FAS 123(R), the Company's results for the three-month periods ended June 30, 2009 and 2008 include share-based compensation expense totaling \$75,000 and \$64,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of product sales (\$9,000 and none, respectively), research and development (\$29,000 and \$15,000, respectively) and selling, general and administrative expenses (\$37,000 and \$49,000, respectively). The Company's results for the six-month periods ended June 30, 2009 and 2008 include share-based compensation expense totaling \$92,000 and \$223,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of product sales (\$9,000 and \$19,000, respectively), research and development (\$36,000 and \$74,000, respectively) and selling, general and administrative expenses (\$47,000 and \$130,000, respectively). No income tax benefit has been recognized in the income statement for share-based compensation arrangements due to the history of operating losses.

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. There was no other change made to the terms of the stock options other than the reduction in the exercise price. A total of 1,036,750 options were affected and the fair value difference of the option before and after the reduced was \$31,660 and was expensed in the three months ended June 30, 2009.

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. 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 fair value of these options is being amortized over the vesting life of the options.

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. To accommodate the transition on June 3, 2009 at the annual meeting, non-employee directors that were re-elected received their five-year allotment of options and those options previously granted but not exercisable as of June 3, 2009 were cancelled. The number issued was 750,000 and the number cancelled was 216,000. The fair value of these options granted is being amortized over the vesting life of the options.

The following table provides stock option activity for the six months ended June 30, 2009:

Stock Options	Number of Shares	Weighted Average	Weighted Average	Aggregate Intrinsic
---------------	------------------	------------------	------------------	---------------------

		Exercise Price per Share	Remaining Contractual Term	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-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	\$ -
Impact of re-price (for accounting purposes treated as a cancelation and re-issue):				
effect as if cancelled	(1,036,750)	\$ 0.48		
effect as if re-issued	1,036,750	\$ 0.13		
Granted	3,675,000	\$ 0.13		
Exercised	-	-		
Forfeited/expired	(467,250)	\$ 0.32		
Outstanding at June 30, 2009	5,624,400	\$ 0.37	4.07 years	\$ -
Exercisable at June 30, 2009	2,099,400	\$ 0.38	2.75 years	\$ -

As of June 30, 2009, there was \$296,000 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 1.93 years. The total fair value of stock options vested during the three-month periods ended June 30, 2009 and 2008, was approximately \$60,000 and \$267,000, respectively.

(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.

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		For the six months ended	
	June 30, 2009	June 30, 2008	June 30, 2009	June 30, 2008
Africa	\$ 999,048	\$ 1,014,119	\$ 1,458,785	\$ 2,300,880
Asia	72,458	29,731	94,599	130,740
Europe	27,087	37,780	45,772	81,720
Middle East	60,949	54,310	92,996	155,151
North America	1,252,338	407,984	2,171,365	1,043,750
South America	639,505	922,317	1,457,285	991,971
	\$ 3,051,385	\$ 2,466,241	\$ 5,320,802	\$ 4,704,212

(g) Accounts payable and accrued liabilities

Accounts payable and accrued liabilities consist of:

	June 30, 2009	December 31, 2008
Accounts payable – suppliers	\$ 661,615	\$ 634,083
Accrued commissions	113,364	67,857
Accrued royalties / license fees	1,158,222	1,400,941
Accrued payroll	121,090	95,135
Accrued vacation	129,426	91,895
Accrued legal and accounting	5,060	18,000
Accrued expenses – other	56,060	75,110
TOTAL	\$ 2,244,837	\$ 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 half 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 method of 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.

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 half 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 half 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 half of fiscal 2009.

Effective this quarter, we implemented Statement of Financial Accounting Standards No. 165, Subsequent Events, or FAS 165. This standard establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued. The adoption of FAS 165 did not impact our financial position or results of operations.

In June 2009, the FASB issued FAS No. 167 "Amendments to FASB Interpretation No. 46(R)." This statement amends the consolidation guidance applicable to variable interest entities and is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2009. The Company is evaluating the impact that FAS No. 167 will have on its financial statements, if any.

In June 2009, the FASB issued FAS No. 168, “The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles – a replacement of FASB Statement No. 162” (“FAS 168”). FAS 168 provides for the FASB Accounting Standards Codification (the “Codification”) to become the single official source of authoritative, nongovernmental U.S. generally accepted accounting principles (GAAP). The Codification did not change GAAP but reorganizes the literature. FAS 168 is effective for interim and annual periods ending after September 15, 2009. The Company does not expect that adoption of this statement will have a material impact on its financial statements.

NOTE 3 — DEFERRED RESEARCH AND DEVELOPMENT REVENUE:

In January 2009, the Company received a refundable license fee of \$340,000 from Bio-Rad Laboratories, Inc., pursuant to a license agreement, related to a specific application of our DPP® technology which will become fully earned and non-refundable based upon certain future conditions being met. In addition the Company recognizes income from research projects and grants when earned. Grants are invoiced after expenses are incurred. Any projects or grants funded in advance are deferred until earned. As of June 30, 2009, \$154,748 of advanced revenues was unearned.

NOTE 4 — VEHICLE FINANCING AND LICENSE FEE PAYABLE:

In June 2009, the Company purchased a vehicle for use by its CEO and obtained financing in the amount of \$29,228. The financing is for a period of 3 years, is secured by the vehicle and is guaranteed by the CEO. The financing agreement provides for monthly principal and interest payments of \$849 at an interest rate of 2.9% per annum. The balance due on this loan as of June 30, 2009 was \$29,228.

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 these patents, the Agreement initially provided that the Company will pay Bio-Rad a \$1,000,000 sublicense fee, \$500,000 payable during 2008, of which \$125,000 was paid and \$375,000 payable by December 31, 2008, with the remaining \$500,000 being payable by December 31, 2009. On January 29, 2009, the Company and Bio-Rad agreed to amend the Agreement so as to defer the remaining \$875,000 of payments due under the Agreement 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.

NOTE5—COMMITMENTS AND CONTINGENCIES:

(a) Economic Dependency:

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

	For the three months ended				For the six months ended				Accounts
	June 30, 2009		June 30, 2008		June 30, 2009		June 30, 2008		Receivable
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	As of June 30, 2009
Customer 1	\$ 1,160,765	38	\$ 424,126	17	\$ 2,004,872	38	\$ 964,961	21	\$ 363,980
Customer 2	\$ 728,640	24	*	*	\$ 728,640	14	*	*	\$ -
Customer 3	\$ 556,600	18	\$ 913,916	37	\$ 1,349,800	25	\$ 982,880	21	\$ 446
Customer 4	*	*	\$ 717,255	29	*	*	\$ 1,499,121	32	*

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

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

	For the three months ended				For the six months ended				Accounts
	June 30, 2009		June 30, 2008		June 30, 2009		June 30, 2008		Payable
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	As of June 30, 2009
Vendor 1	\$ 134,526	20	\$ 99,565	16	\$ 259,588	22	\$ 218,009	17	\$ 28,798
Vendor 2	*	*	\$ 114,750	18	*	*	*	*	*

In the table above the asterisk (*) indicates that purchases from the vendor did not exceed 10% for the period indicated.

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 could adversely affect operating results.

(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 U.S., 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.

(c) Agreement with Inverness:

On June 25, 2009, the Company and Inverness Medical Innovations, Inc. (Inverness) entered into a letter agreement whereby certain obligations aggregating approximately \$1,010,000 as of December 31, 2008 were agreed to be paid from future revenues. The obligations include the Company's share under its agreements with Inverness for the amount of HIV-2 royalties that Inverness paid when Inverness entered into an HIV-2 license agreement with Bio-Rad Laboratories, Inc. of approximately \$485,000 and royalties owed by Chembio on lateral flow licenses to Inverness of approximately \$525,000 as of December 31, 2008. Under the agreement Inverness will retain an additional 10% of Clearview® HIV 1/2 STAT-PAK® net sales and 5% of Clearview® Complete HIV 1/2 net sales until these obligations are extinguished. The approximate aggregate balance due is \$723,000 as of June 30, 2009.

(d) Employment Agreement:

Effective May 11, 2009, the Company's Board of Directors approved the Company's extension of the June 15, 2006 employment agreement (the "Employment Agreement") with the Company's President and Chief Executive Officer. The Employment Agreement, which had been extended for an additional one-year term from May 11, 2008, provides that this officer will continue to serve as the Chief Executive Officer and President of the Company for an additional three-year term.

Other than the dates and salary amounts, the terms of the extended Employment Agreement are substantially similar to the June 15, 2006 Employment Agreement. Under the terms of the extended Employment Agreement this officer will (i) continue as the Company's Chief Executive Officer and President for an additional term of three years from May 11, 2009; (ii) will earn a salary of \$265,000, which will be reduced temporarily to \$225,250 in connection with his agreement to a 15 percent salary reduction until the later to occur of July 1, 2009, or the date upon which other employees' salaries are restored to the levels that existed prior to January 14, 2009 when the Company implemented payroll reductions; (iii) will continue to be eligible for a bonus of up to 50% of his salary, consisting of (a) a bonus of up to 25% of his salary that is at the complete discretion and determination of the Board, and (b) a bonus of up to an additional 25% of his salary that will be determined based upon revenue and earnings performance criteria established by the Board.

(e) 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 June 30, 2009, \$200,000 has been paid and is included in deposits and other assets on the Company's balance sheet.

(f) Research and Development Projects and Grants:

In June 2009, the Company received a \$3 million, three year grant from the United States National Institutes of Health to complete development of a test for Leptospirosis. Grants are invoiced after expenses are incurred. In addition the Company has several development contracts with third parties related to its DPP® technology. These development projects are funded in advance and are presented as deferred revenue until earned (see Note 3).

NOTE6—SUBSEQUENT EVENTS:

We evaluated all events or transactions that occurred after June 30, 2009 up through August 6, 2009, the date we issued these financial statements. During this period we did not have any material recognizable or disclosable subsequent events.

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 June 30, 2009, (and 80% of product revenues for the six months ended June 30, 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

During the first half of 2009 and 2008, \$1,350,000 and \$1,194,000, respectively, was spent on research and development activities. All of the Company's research & development activities are based on its patented Dual Path Platform (DPP®). The DPP® is a unique, simple, rapid diagnostic point-of-care platform that has certain advantages over lateral flow technology. For example a diagnostic test employing the DPP® technology can provide improved features 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.

The Company has completed development of four products that employ the DPP® technology, two of which will be marketed under Chembio's label (DPP® HIV 1/2 Screening Assay and DPP® Syphilis Screen & Confirm) and two that have been developed pursuant to private label agreements with The Oswaldo Cruz Foundation ("FIOCRUZ") for the Brazilian public health market, as explained below. The Company has a number of additional products under development that employ the DPP® technology. These product development activities are further explained below.

- o DPP® Hepatitis C and DPP® Hepatitis C/HIV Oral Fluid Antibody Tests - Prototypes of these products have been developed and are being evaluated in a study that has been organized by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) at the Centers for Disease Control and Prevention (CDC) of the Department Of Health and Human Services. The evaluation will be completed during 2009 and the results should be useful in helping to ascertain the performance characteristics of these products in comparison to other products that will also be in this evaluation. Chembio's DPP® HIV 1/2 test is also being submitted to this study.
- o DPP® Influenza –Research & development efforts are ongoing with respect to the development of antigen (Flu A & B) detection and antibody detection (multiplexed strains to ascertain specific immune status in connection with vaccine programs) assays. Chembio is developing its own test, is working with a potential commercial partner that already has a Flu A/B test in the market. Chembio is also developing a multiplex antibody test pursuant to a funded pilot program with the Influenza division of the CDC which, if successfully developed, could be used to determine immune status in connection with vaccine administration.
- o DPP® Leptospirosis – In June we were awarded a three-year \$3 million Small Business Innovative Research (SBIR) Phase II grant from the United States National Institutes of Health (NIH) to fully develop, validate, and commercialize a rapid diagnostic test for leptospirosis for general use worldwide. The test will be developed with DPP® and will utilize proprietary reagents developed by Cornell University and the Oswaldo Cruz Foundation at the Brazilian Ministry of Health. Development of the test will be in collaboration with the Division of Infectious Diseases, Weill Medical College, Cornell University in New York and the Oswaldo Cruz Foundation, the largest biomedical research institution in Latin America. In the Phase I work completed in 2008, which occurred with this same collaborative group, novel diagnostic targets were identified and evaluated in a prototype test in Chembio's patented DPP® format. The studies demonstrated that the test prototype had an overall sensitivity of 85% and a specificity of 90% using serum samples of leptospirosis patients from Brazil and Thailand. Furthermore, the DPP® prototype had a sensitivity of 78% in identifying leptospirosis in the first 7 days of illness, the "window-of-opportunity" during which initiation of antimicrobial therapy provides the greatest benefit.
- 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. These programs have subsidized the Company's development expenses while expanding the applications for and know-how related to DPP® and creating important collaborative relationships. In April 2008 we entered into a development agreement with Bio-Rad Laboratories, Inc. ("Bio-Rad"), to develop a multiplex test on our DPP®. In January of this year, based on our achievement of the initial milestones in 2008 that established product feasibility, we entered into a license agreement with Bio-Rad related to this specific application and we received a \$340,000 refundable license fee which will become non-refundable based upon certain future conditions being met. Based on our having achieved the most recent milestones in July of this year, we anticipate receiving approximately \$165,000 more in development funds from Bio-Rad in the third and fourth quarters of 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 2009 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 anticipate delivering this prototype during the third quarter. 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

- CE Mark for FDA approved HIV tests – During the second quarter we were informed that due to changes that occurred in the EU regulatory requirements that we would need to compare the results of a CE marked rapid test to our tests based upon the samples we used during our US clinical trial. We have nearly completed this analysis and anticipate that this will be the final item we need to complete our filing for the CE Mark. Under our agreement with Inverness we are to obtain a CE Marking for the Clearview® Complete HIV 1/2.
- Regulatory Approvals in Brazil through the Oswaldo Cruz Foundation (FIOCRUZ) – We anticipate that FIOCRUZ will receive required approvals from its regulatory agencies during 2009 for the DPP® Leishmaniasis, HIV Confirmatory, and the DPP® HIV screening tests. This will trigger approximately \$900,000 of technology transfer fees payable to the Company. While there have been some delays in this project, based on our most recent information we believe that this will occur as anticipated.
- DPP® HIV 1/2 Screening Assay for Oral Fluid - This product is now being evaluated in Africa in two separate studies in sub-Saharan Africa, one contracted by the Company and one being conducted by the CDC Global AIDS Program. We also intend to begin during 2009 the steps to obtain regulatory approval for this product in the United States. We expect to complete a portion of the clinical trials in support of a Pre-Marketing Approval (PMA) application for this product during the fourth quarter of fiscal 2009. This product will enable Chembio to participate in the oral fluid testing market segments in the United States and globally, where we believe there is a significant opportunity.

- DPP® Syphilis Screen & Confirm - The first phase of a multi-center evaluation sponsored by the World Health Organization is commencing during the current quarter, and we expect to have the first phase results during the fourth quarter. We are also finalizing internal documentation in order to submit a proposed clinical plan to the FDA during the third quarter.

The table below provides a preliminary summary timetable for the regulatory approval and commercialization of the DPP® HIV Screening Assay and the DPP® Syphilis Screen & Confirm Assay in major markets.

Market	DPP® HIV 1/2 Screening Assay	DPP® Syphilis Screen & Confirm
Developing World	2009-2010	2009-2010
CE Mark	1st Half 2011	First Half 2010
US FDA	1st Half 2011	First Half 2011

We are also pursuing additional registrations with the USDA to expand the claims and thus the available market 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 JUNE 30, 2009 AS COMPARED WITH THE THREE MONTHS ENDED JUNE 30, 2008

Revenues:

Selected Product Categories:

	For the three months ended			
	June 30, 2009	June 30, 2008	\$ Change	% Change
HIV	\$ 2,799,644	\$ 2,210,031	\$ 589,613	26.68 %
DPP	-	-	-	n/a
Other	251,741	256,210	(4,469)	-1.74 %
Net Product Sales	3,051,385	2,466,241	585,144	23.73 %
License and royalty income	52,322	-	52,322	-
Research grant income	269,817	251,543	18,274	7.26 %
Total Revenues	\$ 3,373,524	\$ 2,717,784	\$ 655,740	24.13 %

Revenues for our HIV tests during the three months ended June 30, 2009 increased by approximately \$590,000 over the same period in 2008. This was primarily attributable to increased sales in North America, primarily from sales to

Inverness of our HIV products which increased by \$737,000 to \$1,161,000, and partially offset by a decrease in sales to Brazil of \$357,000. During the second quarter of 2009 we had no sales of product based on our DPP® technology, although sales based on DPP® are anticipated during the balance of 2009. The increase in research grant income was due to revenue generated from grant and feasibility studies that are related to potential new products utilizing our patented DPP™ technology. In addition, research grant income includes some funds from our recent NIH grant for Leptospirosis, which was effective as of June 1, 2009. License and royalty income represents our first royalties from Brazil under our 2004 technology transfer agreement.

Gross Profit:

Gross Profit related to Net Product Sales:	For the three months ended		\$ Change	% Change	
	June 30, 2009	June 30, 2008			
Gross Profit per Statement of Operations	\$ 1,361,945	\$ 1,011,820	\$ 350,125	34.60	%
Less: Research grant, license and royalty income	322,139	251,543	70,596	28.07	%
Gross Profit from Net Product Sales	\$ 1,039,806	\$ 760,277	\$ 279,529	36.77	%
Gross Profit %	34.08	% 30.83	%		

For the year ended December 31, 2008, the Company reclassified its royalty and license expenses to cost of sales. For all periods prior to December 31, 2008 these expenses were previously reflected in selling, general and administrative expenses. Included in our royalty expense for the three-month period ended June 30, 2009 is our share of the royalties paid by Inverness to Bio-Rad Laboratories, Inc. with respect to Inverness' HIV-2 sublicense.

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	
	June 30, 2009	June 30, 2008			
Clinical & Regulatory Affairs:					
Wages and related costs	\$ 65,480	\$ 66,623	\$ (1,143)	-1.72	%
Consulting	-	981	(981)	-100.00	%
Share-based compensation	3,582	-	3,582	-	
Clinical Trials	15,000	23,307	(8,307)	-35.64	%
Other	2,195	23,323	(21,128)	-90.59	%
Total Regulatory	\$ 86,257	\$ 114,234	\$ (27,977)	-24.49	%
R&D Other than Regulatory:					
Wages and related costs	\$ 344,005	\$ 301,183	\$ 42,822	14.22	%
Consulting	32,538	35,000	(2,462)	-7.03	%
Share-based compensation	30,554	12,234	18,320	149.75	%
Materials and supplies	143,710	45,317	98,393	217.12	%
Other	65,922	59,281	6,641	11.20	%
Total other than Regulatory	\$ 616,729	\$ 453,015	\$ 163,714	36.14	%
Total Research and Development	\$ 702,986	\$ 567,249	\$ 135,737	23.93	%

Total expenses for Clinical & Regulatory Affairs for the three months ended June 30, 2009 decreased by approximately \$28,000 as compared to the same period in 2008. This was primarily due to regulatory fees paid in the second quarter of 2008 and clinical trial expenses in the second quarter of 2008 related to an amendment of our PMA (Pre-Marketing Approval) age claims to include the 12 -17 year old age group.

Total expenses for Other than Clinical & Regulatory Affairs increased by approximately \$164,000 in the three months ended June 30, 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.

Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended		\$ Change	% Change
	June 30, 2009	June 30, 2008		
Wages and related costs	\$ 200,171	\$ 333,999	\$ (133,828)	-40.07 %
Consulting	46,129	52,293	(6,164)	-11.79 %

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Commissions	82,333	113,968	(31,635)	-27.76	%
Share-based compensation	36,563	58,013	(21,450)	-36.97	%
Marketing Materials	3,505	7,599	(4,094)	-53.88	%
Investor Relations	4,276	10,621	(6,345)	-59.74	%
Legal, Accounting and Sox 404 compliance	61,658	91,519	(29,861)	-32.63	%
Travel, Entertainment and Trade Shows	7,808	21,300	(13,492)	-63.34	%
Other	100,006	120,518	(20,512)	-17.02	%
Total S, G &A	\$ 542,449	\$ 809,830	\$ (267,381)	-33.02	%

Selling, general and administrative expenses for the three months ended June 30, 2009 decreased by 33% as compared with the same period in 2008. During the second half of 2008 and continuing in 2009 the Company implemented a series of cost reductions that have resulted in lower S,G&A expenses in every category in 2009 year to date, except the decreased sales commissions which resulted from a decrease in commissionable sales (and not from the Company's cost reductions) as compared with the 2008 period.

Other Income and (Expense):

Other Income and Expense:	For the three months ended					
	June 30, 2009	June 30, 2008	\$ Change	% Change		
Other (expense)	\$ (6,696)	\$ -	\$ (6,696)	-		
Interest income	1,531	7,391	(5,860)	-79.29	%	
Interest expense	(1,406)	(5,261)	3,855	-73.28	%	
Total Other Income and (Expense)	\$ (6,571)	\$ 2,130	\$ (8,701)	-408.50	%	

Other income and (expenses) for the three months ended June 30, 2009 decreased approximately \$9,000 as compared with the same period in 2008 primarily as a result of a loss on the sale of a fixed asset as well as a decrease in interest income due to a decrease in available funds to invest in interest bearing accounts.

RESULTS OF OPERATIONS FOR THE SIX MONTHS ENDED JUNE 30, 2009 AS COMPARED WITH THE SIX MONTHS ENDED JUNE 30, 2008

Revenues:

Selected Product Categories:

	For the six months ended				
	June 30, 2009	June 30, 2008	\$ Change	% Change	
HIV	\$ 4,396,439	\$ 4,131,017	\$ 265,422	6.43	%
DPP	415,835	-	415,835	-	
Other	508,528	573,195	(64,667)	-11.28	%
Net Product Sales	5,320,802	4,704,212	616,590	13.11	%
License and royalty income	52,322	-	52,322	-	
Research grant income	545,998	378,300	167,698	44.33	%
Total Revenues	\$ 5,919,122	\$ 5,082,512	\$ 836,610	16.46	%

Revenues for our HIV tests during the six months ended June 30, 2009 increased by approximately \$265,000 over the same period in 2008. This was primarily attributable to increased sales to Inverness of our HIV products which increased by \$1,040,000 to \$2,005,000, and by sales to Brazil of \$367,000, which were partially offset by decreased sales in Africa, primarily Nigeria, which decreased in the first quarter of 2009 by approximately \$1,544,000 compared to the first quarter of 2008 (see Note 2(f) and Note 4(c)) along with decreased sales to Uganda of approximately \$435,000, which was offset by increased sales to Ethiopia of approximately \$1,104,000. 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. In addition, grant and development revenue includes some funds from our recent NIH grant for Leptospirosis which grant was effective as of June 1, 2009. License and royalty income represents our first royalties from Brazil under our 2004 technology transfer agreement.

Gross Margin:

Gross Margin related to

	For the six months ended				
Net Product Sales:	June 30, 2009	June 30, 2008	\$ Change	% Change	
Gross Margin per Statement of Operations	\$ 2,360,634	\$ 1,844,989	\$ 515,645	27.95	%
Less: Research grant, license and royalty income	598,320	378,300	220,020	58.16	%
Gross Margin from Net Product Sales	\$ 1,762,314	\$ 1,466,689	\$ 295,625	20.16	%
Gross Margin %	33.12 %	31.18 %			

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. Included in our royalty expense for the six-month period ended June 30, 2009 is our share of the royalties paid by Inverness to Bio-Rad Laboratories, Inc. with respect to an HIV-2 sublicense agreement. Because we were not informed of such agreement including amounts due for the past royalties, until the fourth quarter of 2008, the quarterly reports for the first three quarters of 2008 do not reflect this expense. If this expense had been reflected in the six-month period ended June 30, 2008, the it would have increased royalty expense for that period by approximately \$135,000 or 2.87%. This would have increased the dollar change (“\$ Change”) in Gross Margin over the six-month period ended June 30, 2008 from approximately \$296,000 to \$431,000 and changed the Gross Margin percentage (“Gross Margin %”) for the 2008 period to 28.31%.

Research and Development:

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

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Selected expense
lines:

	For the six months ended			
	June 30, 2009	June 30, 2008	\$ Change	% Change
Clinical & Regulatory Affairs:				
Wages and related costs	\$ 131,029	\$ 133,459	\$ (2,430)	-1.82 %
Consulting	15,181	7,416	7,765	104.71 %
Share-based compensation	3,582	-	3,582	-
Clinical Trials	16,780	97,487	(80,707)	-82.79 %
Other	9,455	44,564	(35,109)	-78.78 %
Total Regulatory	\$ 176,027	\$ 282,926	\$ (106,899)	-37.78 %
R&D Other than Regulatory:				
Wages and related costs	\$ 698,720	\$ 580,969	\$ 117,751	20.27 %
Consulting	49,970	40,000	9,970	24.93 %
Share-based compensation	37,736	65,458	(27,722)	-42.35 %
Materials and supplies	254,492	116,513	137,979	118.42 %
Other	133,413	107,719	25,694	23.85 %
Total other than Regulatory	\$ 1,174,331	\$ 910,660	\$ 263,671	28.95 %
Total Research and Development	\$ 1,350,358	\$ 1,193,586	\$ 156,772	13.13 %

Total expenses for Clinical & Regulatory Affairs for the six months ended June 30, 2009 decreased by approximately \$107,000 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(Pre-Marketing Approval) age claims to include the 12 -17 year old age group.

Total expenses Other than Clinical & Regulatory Affairs increased by approximately \$264,000 in the six months ended June 30, 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 (as compared with the 2008 period) of equity-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 six months ended			
	June 30, 2009	June 30, 2008	\$ Change	% Change
Wages and related costs	\$ 437,253	\$ 684,234	\$ (246,981)	-36.10 %
Consulting	107,871	96,610	11,261	11.66 %
Commissions	166,296	141,419	24,877	17.59 %

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Share-based compensation	46,564	159,743	(113,179)	-70.85	%
Marketing Materials	9,938	16,501	(6,563)	-39.77	%
Investor Relations	7,315	69,701	(62,386)	-89.51	%
Legal, Accounting and Sox 404 compliance	222,018	350,944	(128,926)	-36.74	%
Travel, Entertainment and Trade Shows	24,756	42,219	(17,463)	-41.36	%
Other	196,251	266,860	(70,609)	-26.46	%
Total S, G &A	\$ 1,218,262	\$ 1,828,231	\$ (609,969)	-33.36	%

Selling, general and administrative expenses for the six months ended June 30, 2009 decreased by 33% as compared with the same period in 2008. During the second half of 2008 and continuing in 2009, the Company implemented a series of cost reductions that have resulted in lower S,G&A expenses in almost every category in 2009 year to date. These reductions were partially offset by increases in sales commissions that resulted from increased commissionable sales as compared with the 2008 period. Our periodic review of our allowance for doubtful accounts resulted in no change to the allowance in the six months ended June 30, 2009.

Other Income and (Expense):

Other Income and Expense	For the six months ended					
	June 30, 2009	June 30, 2008	\$ Change	% Change		
Other (expense)	\$ (6,696)	\$ -	\$ (6,696)	-		
Interest income	4,915	26,371	(21,456)	-81.36	%	
Interest expense	(5,527)	(10,854)	5,327	-49.08	%	
Total Other Income and (Expense)	\$ (7,308)	\$ 15,517	\$ (22,825)	-147.10	%	

Other income and (expense) for the six months ended June 30, 2009 decreased approximately \$23,000 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 as well as a loss on the sale of a fixed asset.

LIQUIDITY AND CAPITAL RESOURCES

For the six months ended

	June 30, 2009	June 30, 2008	\$ Change	% Change
Net cash provided by (used in) operating activities	\$ 847,768	\$ (1,569,600)	\$ 2,417,368	-154.01 %
Net cash used in investing activities	(221,080)	(289,311)	68,231	-23.58 %
Net cash provided by (used) in financing activities	20,159	(14,301)	34,460	-240.96 %
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	\$ 646,847	\$ (1,873,212)	\$ 2,520,059	-134.53 %

The Company had an increase in cash for the six months ended June 30, 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 period is primarily attributable to the cash provided or used in operations, including the receipt during the first quarter of 2009 of a \$340,000 DPP® license fee deposit from Bio-Rad Laboratories, Inc.

The Company had working capital of approximately \$1,601,000 at June 30, 2009 and working capital 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 remain 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 June 30, 2010.

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

During the first half of 2009 our net sales to Inverness of our FDA approved rapid HIV tests that Inverness markets under their Clearview® brand increased by \$1,040,000, or 108%, to \$2,005,000, from \$965,000 in the first half of 2008. This increase, together with new business we received from Ethiopia (underwritten by the Global Fund), and the continuation and expansion of contract research and development activity at Chembio funded by commercial, governmental, and non-governmental organizations, together more than offset the non-recurrence of our business in Nigeria that had been anticipated by the Company since early 2008. Furthermore, a more favorable sales mix, continued manufacturing improvements, and the benefit of a significant cost reduction effort that began in 2008 and that is continuing, has resulted in the Company's first profitable quarter since commencement of the Chembio business as a result of the merger in May 2004.

Based on our current backlog, anticipated product orders and the attainment of milestones in funded contract development work, we anticipate improved results of operations in the second half of 2009 as compared with the second half of 2008. These improved results, if realized, are likely to be as a result of continued increased sales to Inverness, increased sales from our DPP® technology (primarily as a result of the four contracts we signed with the Oswaldo Cruz Foundation in 2008), increased revenues from research and development contracts, improved manufacturing efficiencies, and decreased operating expenses, all in comparison to 2008. We anticipate that these improved results over the comparable prior periods should also continue into the first half of 2010, during which period we should start to realize more DPP® product revenues from Brazil and potentially some initial revenues from our DPP® HIV Screening Assay and DPP® Syphilis Screen and Confirm Assay as a result of completions of studies and approvals related to the developing world markets.

During these next twelve months, our regulatory 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. We anticipate that regulatory approval of our DPP® Canine Leishmaniasis, HIV Screening and HIV Confirmatory tests registered under the label of our Brazilian partner, Oswaldo Cruz Foundation, will be obtained before the end of 2009. If these three products are approved by the applicable regulatory authorities, we will be due technology transfer fees of approximately \$900,000, and are also likely to begin receiving initial orders for the products approved in accordance with our contracts with this organization. These funds, if received, will help to underwrite the costs of our DPP® HIV and Syphilis regulatory submissions in the United States.

In addition to the DPP® products we anticipate launching in Brazil through our technology transfer, supply and license agreements with the Oswaldo Cruz Foundation, we have several other contract development programs with third parties which are expanding the applications for our technology while also providing us with non-dilutive funding. These programs principally include our work for Bio-Rad Laboratories, Inc., which work has achieved an additional milestone and will likely result in additional funded development work during the balance of 2009, and our \$3 million, three year grant from the United States National Institutes of Health to complete development of a test for Leptospirosis which was awarded in June 2009.

Equipment Purchase Commitment:

In January 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 June 30, 2009, \$200,000 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 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

At the Company's annual stockholder meeting on June 3, 2009, stockholders elected directors of the Company to serve until the next annual meeting of stockholders or until their respective successors are elected and qualified. Stockholders also ratified the selection of Parente Randolph, LLC as the Company's independent registered certified accountants to audit the Company's financial statements as of and for the year ending December 31, 2009. A tabulation of the matters voted on at this annual stockholder meeting is set forth below.

P Proposal #1:—	Kathy L.	Dr. Gary	Lawrence
Election of	Davis	Meller	A. Siebert
Directors			
For	43,108,947	43,108,447	41,860,287
Withheld	7,373,875	7,274,375	8,522,535
Abstain/broker	-	-	-
non votes			

Proposal	Ratifying Parente Randolph, LLC as the Company's Independent Registered Public Accountants	Vote to Adjourn Or Postpone the meeting	Vote on Other Business
For	43,932,044	44,242,482	7,015,219
Against	4,254,171	4,543,289	91,200
Withheld	2,206,607	1,597,049	95,951
Abstain/broker non votes	-	-	-

ITEM 6. EXHIBITS.

Number	Description
3.1	Articles of Incorporation, as amended. (2)
3.2	Amended and Restated Bylaws. (1)
4.1	Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement. (7)
4.2	Amended Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement. (9)
4.3	Registration Rights Agreement, dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (7)
4.4	Form of Warrant, dated June 29, 2006, issued pursuant to Company and purchasers of the Company's Secured Debentures. (3)
4.5	Registration Rights Agreement, dated June 29, 2006. (3)
4.6	Registration Rights Agreement, dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (5)
4.7	Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated September 29, 2006 (5).
4.8	Amended Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated October 5, 2006. (9)
4.0	Amended Form of Common Stock Warrant issued to Placement Agents pursuant to the October 5, 2005 Securities Purchase Agreement. (9)
4.10*	Form of Employee Option Agreement. (9)
4.11	1999 Equity Incentive Plan (11)
4.12	2008 Stock Incentive Plan. (12)
10.1*	Employment Agreement dated June 15, 2006 with Lawrence A. Siebert. (4)
10.2*	Employment Agreement dated April 23, 2007 with Javan Esfandiari. (10)
10.3	Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (7)
10.4	Amendment No. 1 to Securities Purchase Agreement, dated as of January 28, 2005 by and among the Registrant and the purchasers listed therein. (8)
10.5	Security Purchase Agreement, dated June 29, 2006, among the Company and purchasers of the Company's Secured Debentures. (3)
10.6	Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (5)
10.7	Letter of Amendment to Securities Purchase Agreements dated as of September 29, 2006 by and among the Registrant and the Purchasers listed therein. (5)
10.8	HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Inverness and StatSure. (5)
10.9	HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (5)
10.10	Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (5)
10.11	Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (5)
10.12	License and Supply Agreement dated as of August 30, 2002 by and between Chembio Diagnostic Systems Inc. and Adaltis Inc. (6)
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 annual report on Form 10-KSB filed with the Commission on March 31, 2005.
- (3) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on July 3, 2006.
- (4) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 21, 2006.
- (5) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.
- (6) Incorporated by reference to the Registrant's registration statement on Form SB-2 filed with the Commission on June 7, 2004.
- (7) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on January 31, 2005.
- (8) Incorporated by reference to the Registrant's registration statement on Form SB-2 filed with the Commission on March 28, 2005.
- (9) Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 12, 2008.
- (10) Incorporated by reference to the Registrant's Current Report on Form 8-K/A filed with the Commission on May 3, 2007.
- (11) Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on May 11, 2005.
- (12) 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: August 6, 2009 By: /s/ Lawrence A. Siebert
Lawrence A. Siebert
Chief Executive Officer
(Principal Executive Officer)

Date: August 6, 2009 By: /s/ Richard J. Larkin
Richard J. Larkin
Chief Financial Officer
(Principal Financial and Accounting Officer)