

CHEMBIO DIAGNOSTICS, INC.
Form 10-Q
November 03, 2011

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 September 30, 2011

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from: _____ to _____

000-30379
(Commission File Number)
Chembio Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

Nevada 88-0425691
(State or other (IRS Employer
jurisdiction of Identification
incorporation) Number)

3661 Horseblock Road
Medford, New York 11763
(Address of principal executive offices including zip code)
(631) 924-1135

(Registrant's telephone number, including area code)

___N/A___

(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

Quarterly Report on FORM 10-Q For Quarterly The Period Ended

September 30, 2011

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PART I

Item 1. FINANCIAL STATEMENTS

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

- ASSETS -		
	September 30, 2011	December 31, 2010
(UNAUDITED)		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 3,045,348	\$ 2,136,351
Accounts receivable, net of allowance for doubtful accounts of \$20,000 and \$35,000 for 2011 and 2010, respectively	2,657,781	3,946,398
Inventories	2,588,225	1,349,161
Prepaid expenses and other current assets	188,841	204,824
TOTAL CURRENT ASSETS	8,480,195	7,636,734
FIXED ASSETS, net of accumulated depreciation	848,799	813,214
OTHER ASSETS:		
License agreements, net of current portion	525,000	600,000
Deposits on manufacturing equipment	208,460	-
Deposits and other assets	36,226	36,226
TOTAL ASSETS	\$ 10,098,680	\$ 9,086,174
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 2,346,410	\$ 2,055,943
Current portion of loans payable	341,013	55,817
Deferred revenue	490,522	65,000
License fee payable	-	875,000
Current portion of obligations under capital leases	21,071	24,697
TOTAL CURRENT LIABILITIES	3,199,016	3,076,457
OTHER LIABILITIES:		
Loans payable - net of current portion	145,859	186,197
Obligations under capital leases - net of current portion	-	14,576
TOTAL LIABILITIES	3,344,875	3,277,230
COMMITMENTS AND CONTINGENCIES		

STOCKHOLDERS' EQUITY:

Preferred stock – 10,000,000 shares authorized, none outstanding	-	-
Common stock - \$.01 par value; 100,000,000 shares authorized, 63,315,096 and 62,238,983 shares issued and outstanding for 2011 and 2010, respectively	633,151	622,390
Additional paid-in capital	40,064,570	39,658,617
Accumulated deficit	(33,943,916)	(34,472,063)
TOTAL STOCKHOLDERS' EQUITY	6,753,805	5,808,944
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 10,098,680	\$ 9,086,174

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(UNAUDITED)

	For the three months ended		For the nine months ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
REVENUES:				
Net product sales	\$ 5,526,883	\$ 3,786,572	\$ 11,516,325	\$ 8,337,133
License and royalty revenue	25,000	61,789	125,322	400,758
R&D, milestone and grant revenue	369,904	656,642	1,529,972	2,299,970
TOTAL REVENUES	5,921,787	4,505,003	13,171,619	11,037,861
Cost of product sales	3,251,054	2,296,502	6,524,266	5,428,020
GROSS MARGIN	2,670,733	2,208,501	6,647,353	5,609,841
OPERATING EXPENSES:				
Research and development expenses	1,242,295	1,230,100	3,697,309	2,822,455
Selling, general and administrative expenses	949,237	801,854	2,412,867	2,143,715
	2,191,532	2,031,954	6,110,176	4,966,170
NET INCOME FROM OPERATIONS	479,201	176,547	537,177	643,671
OTHER INCOME (EXPENSES):				
Other expense	-	(3,923)	-	(3,923)
Interest income	1,278	1,018	4,315	2,747
Interest expense	(4,874)	(5,666)	(13,345)	(9,927)
	(3,596)	(8,571)	(9,030)	(11,103)
NET INCOME BEFORE INCOME TAXES	475,605	167,976	528,147	632,568
Provision for income taxes	-	-	-	-
NET INCOME	\$ 475,605	\$ 167,976	\$ 528,147	\$ 632,568
Basic net income per share	\$ 0.01	\$ 0.00	\$ 0.01	\$ 0.01

Diluted net income per share	\$ 0.01	\$ 0.00	\$ 0.01	\$ 0.01
Weighted average number of shares outstanding, basic	63,304,584	62,146,847	62,887,212	62,068,204
Weighted average number of shares outstanding, diluted	68,137,033	67,264,551	67,645,878	67,226,283

See accompanying notes to condensed consolidated financial statements

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

	September 30, 2011	September 30, 2010
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:		
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	\$ 14,460,236	\$ 10,179,232
Cash paid to suppliers and employees	(12,897,517)	(9,964,407)
Interest received	1,278	1,110
Interest paid	(4,874)	(2,204)
Net cash provided by operating activities	1,559,123	213,731
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of and deposits on fixed assets	(282,175)	(188,193)
Net cash used in investing activities	(282,175)	(188,193)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option and warrant exercises	280,393	27,073
Payment of license obligation	(875,000)	-
(Payment of) and proceeds from loan obligation, net	244,858	231,010
Payment of capital lease obligation	(18,202)	(15,873)
Net cash (used in) provided by financing activities	(367,951)	242,210
INCREASE IN CASH AND CASH EQUIVALENTS	908,997	267,748
Cash and cash equivalents - beginning of the period	2,136,351	1,068,235
Cash and cash equivalents - end of the period	\$ 3,045,348	\$ 1,335,983
RECONCILIATION OF NET INCOME TO NET CASH PROVIDED BY OPERATING ACTIVITIES:		
Net Income	\$ 528,147	\$ 632,568
Adjustments:		

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Depreciation and amortization	321,590	212,838
Provision for doubtful accounts	(15,000)	-
Loss on retirement/sale of fixed asset	-	3,923
Share based compensation	136,321	141,864
Changes in assets and liabilities:		
Accounts receivable	1,303,617	(858,629)
Inventories	(1,239,064)	(327,538)
Prepaid expenses and other current assets	15,983	76,122
Deposits and other assets	(208,460)	101,234
Accounts payable and accrued liabilities	290,467	510,509
Deferred research and development revenue	425,522	(279,160)
Net cash provided by operating activities	\$ 1,559,123	\$ 213,731
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	\$ -	\$ 300,000

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2011
(UNAUDITED)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. (the “Company” or “Chembio”) and its subsidiary, Chembio Diagnostic Systems, Inc., develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company’s primary products include three rapid tests employing lateral flow technology 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. More recently the Company has begun commercializing products using the Company’s patented Dual Path Platform technology (DPP®), which included products that detect other infectious diseases as well as HIV. Lateral flow rapid HIV tests represented approximately 76% of the Company’s net product sales in the nine months ended September 30, 2011 compared with nearly 93% for the nine months ended September 30, 2010. DPP® rapid tests represented approximately 23% of the Company’s net product sales in the nine months ended September 30, 2011 compared with less than 1% for the nine months ended September 30, 2010. The Company also has other rapid tests that together represented approximately 1% and 7% of net product sales in the first nine months of 2011 and 2010, respectively. The Company’s products are sold, directly and through distributors, to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, and medical professionals both domestically and internationally. Chembio’s products are sold under the Company’s STAT PAK®, SURE CHECK® or DPP® registered trademarks, or under the private labels of its marketing partners, for example the Clearview® label owned by Alere North America, Inc. (“Alere”), which is the Company’s exclusive marketing partner for its rapid HIV lateral flow test products in the United States. These products employ lateral flow technologies that are proprietary and/or licensed to the Company. All of the Company’s new products and all of those 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 2009, 2010 and 2011 to date, the Company has completed development of its first five products that employ the DPP®, and the Company has additional products under development that employ the DPP®.

NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of Presentation:

The following (a) condensed balance sheet as of December 31, 2010, which has been derived from audited financial statements, and (b) the unaudited interim condensed financial statements as of September 30, 2011 and for the three- and nine-month periods ended September 30, 2011 and 2010 have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”). Certain information and footnote disclosures, which are 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, 2010, 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 condensed consolidated financial position as of September 30, 2011, its condensed consolidated results of operations for the three- and nine-month periods ended September 30, 2011 and 2010 and its cash flows for the nine-month periods ended September 30, 2011 and 2010, 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) Revenue Recognition

The Company recognizes revenue for product sales in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, "Revenue Recognition" ("SAB 104"). Under SAB 104, revenue is recognized when there is persuasive evidence of an arrangement, delivery has occurred or services have been rendered, the sales price is determinable, and collectability is reasonably assured. Revenue typically is recognized at time of shipment. Sales are recorded net of discounts, rebates and returns.

For certain contracts, the Company recognizes revenue from non-milestone contracts and grant revenues when earned. Grants are invoiced after expenses are incurred. Revenues from projects or grants funded in advance are deferred until earned.

For the recognition of revenues for certain collaborative research projects defining milestones at the inception of the agreement, the Company applies the milestone method of revenue recognition. Revenues from milestones funded in advance are deferred until the milestone is completed.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2011
(UNAUDITED)

(c) Inventories:

Inventories consist of the following at:

	September 30, 2011	December 31, 2010
Raw materials	\$ 1,358,241	\$ 785,693
Work in process	595,421	235,548
Finished goods	634,563	327,920
	\$ 2,588,225	\$ 1,349,161

(d) Earnings Per Share:

Basic earnings per share is computed by dividing net income or loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted income or (loss) per share reflects the potential dilution from the exercise or conversion of other securities into common stock, but only if dilutive. The following securities, presented on a common share equivalent basis for the three- and nine-month periods ended September 30, 2011 and 2010, have been included in the diluted per share computations:

	For the three months ended		For the nine months ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
Basic	63,304,584	62,146,847	62,887,212	62,068,204
Diluted	68,137,033	67,264,551	67,645,878	67,226,283

The following securities, presented on a common share equivalent basis for the three- and nine-month periods ended September 30, 2011 and 2010, have been included in the diluted per share computations as these securities exercise prices were less than the stock price as of September 30, 2011 and 2010, respectively:

	For the three months ended		For the nine months ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
1999 and 2008 Plan Stock Options	4,832,449	5,117,704	4,758,666	5,158,079
Other Stock Options	-	-	-	-
Warrants	-	-	-	-
	4,832,449	5,117,704	4,758,666	5,158,079

There were 1,946,937 and 3,373,354 options and warrants outstanding as September 30, 2011 and 2010, respectively, that were not included in the calculation of diluted income per share for the nine months ended because their effect would have been anti-dilutive. There were 1,902,981 and 3,373,354 options and warrants outstanding as of September 30, 2011 and 2010, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended September 30, 2011 and 2010, respectively, because the effect would have been

anti-dilutive as of September 30, 2011 and 2010, respectively.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2011
(UNAUDITED)

(e) Employee Stock Option Plan:

The Company had a 1999 Stock Option Plan (“SOP”). The number of options available under the SOP was 3,000,000 shares of Common Stock. As of September 30, 2011, there were 1,588,500 outstanding options under this SOP. No additional options may be issued under the SOP more than 10 years after its adoption.

Effective June 3, 2008, the Company’s stockholders voted to approve the 2008 Stock Incentive Plan (“SIP”), with 5,000,000 shares of Common Stock available to be issued. At the Annual Stockholder meeting on September 22, 2011 the Company’s stockholders voted to approve an increase to the shares of Common Stock issuable under the SIP by 1,000,000 to 6,000,000. 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 of September 30, 2011, there were 84,995 options exercised, 4,601,568 options outstanding and 1,313,437 options still available to be issued under the SIP.

The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the three-month periods ended September 30, 2011 and 2010 was \$.26 and none per share, respectively and for the nine-month periods ended September 30, 2011 and 2010 was \$.20 and \$.22 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 the historical volatility of our stock. The expected term is determined using the simplified method as permitted by SAB 107, as the Company has limited history of employee exercise of options to date.

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

	For the three months ended		For the nine months ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
Expected term (in years)	3.75	n/a	3.75	5
Expected volatility	92.11-117.9 %	n/a	97.11-117.9 %	116.82 %
Expected dividend yield	n/a	n/a	n/a	n/a
Risk-free interest rate	.57-1.39 %	n/a	.57-1.24 %	1.43 %

The Company's results for the three-month periods ended September 30, 2011 and 2010 include share-based compensation expense totaling \$80,000 and \$28,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$6,000 and \$4,000, respectively), research and development (\$14,000 and \$13,000, respectively) and selling, general and administrative expenses (\$60,000 and \$11,000, respectively). The results for the nine-month periods ended September 30, 2011 and 2010 include share-based compensation expense totaling \$136,000 and \$142,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$12,000 and \$17,000,

respectively), research and development (\$40,000 and \$72,000, respectively) and selling, general and administrative expenses (\$84,000 and \$53,000, respectively). No income tax benefit has been recognized in the statement of operations for share-based compensation arrangements due to the history of pre-2009 operating losses.

Stock option compensation expense for the three- and nine-month periods ended September 30, 2011 and 2010 represents the estimated fair value of options outstanding which is being amortized on a straight-line basis over the requisite service period for each vesting portion of the award, except for those that vested immediately whereby the estimated fair value was expensed immediately.

The following table provides stock option activity for the nine months ended September 30, 2011:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2010	5,530,568	\$ 0.16	2.82 years	\$ 1,497,063
Granted	1,281,250	\$ 0.43		
Exercised	(562,416)	\$ 0.13		
Forfeited/expired/cancelled	(59,334)	\$ 0.34		
Outstanding at September 30, 2011	6,190,068	\$ 0.21	2.85 years	\$ 1,134,600
Exercisable at September 30, 2011	3,643,394	\$ 0.13	2.30 years	\$ 782,931

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2011

(UNAUDITED)

As of September 30, 2011, there was \$338,000 of net unrecognized compensation cost related to stock options that have not vested, which is expected to be recognized over a weighted average period of approximately 1.4 years. The total fair value of stock options vested during the three-month periods ended September 30, 2011 and 2010, was approximately \$49,000 and none, respectively. The total fair value of stock options vested during the nine-month periods ended September 30, 2011 and 2010, was approximately \$149,000 and \$125,000, respectively.

(f) Geographic Information:

U.S. GAAP establishes standards for the manner in which 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 products and services, geographic areas, and major customers.

The Company produces only one group of similar products known collectively as “rapid medical tests”. Management believes that it operates in a single business segment. Net product sales by geographic area are as follows:

	For the three months ended		For the nine months ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
Africa	\$ 456,303	\$ 2,273,872	\$ 1,549,274	\$ 3,591,743
Asia	221,261	28,312	314,884	215,958
Europe	7,286	23,804	49,605	84,436
North America	2,820,017	1,326,186	6,628,629	4,193,957
South America	2,022,016	134,398	2,973,933	251,039
	\$ 5,526,883	\$ 3,786,572	\$ 11,516,325	\$ 8,337,133

(g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

	September 30, 2011	December 31, 2010
Accounts payable – suppliers	\$ 1,309,507	\$ 883,719
Accrued commissions	201,965	114,451
Accrued royalties / license fees	339,437	352,285
Accrued payroll	134,704	162,740
Accrued vacation	162,833	129,732
Accrued bonuses	100,000	140,325
Accrued expenses – other	97,964	272,691
TOTAL	\$ 2,346,410	\$ 2,055,943

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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(UNAUDITED)

(h) Recent Accounting Pronouncements Affecting the Company

Revenue Arrangements with Multiple Deliverables

In October 2009, the FASB issued authoritative guidance that amends existing guidance for identifying separate deliverables in a revenue-generating transaction where multiple deliverables exist, and provides guidance for allocating and recognizing revenue based on those separate deliverables. The guidance is expected to result in more multiple-deliverable arrangements being separable than under current guidance. This guidance became effective for the Company on January 1, 2011. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

NOTE 3 — COLLABORATIVE RESEARCH AND DEVELOPMENT ARRANGEMENTS:

(a) Oswaldo Cruz Foundation/Fiocruz:

During 2008, the Company signed four Agreements with the Bio-Manguinhos unit of the Oswaldo Cruz Foundation of Brazil ("FIOCRUZ") for the supply, license and transfer of certain products and related technologies from the Company to FIOCRUZ. The agreements are for the following rapid test products: i) DPP® HIV 1/2 Screen, ii) DPP® HIV 1/2 Confirmatory, iii) DPP® Leptospirosis and iv) DPP® Leishmaniasis. These Agreements provide for a staged technology transfer collaboration pursuant to which FIOCRUZ will ultimately be able to fully manufacture the applicable product for supply in Brazil provided certain minimum purchases of products and related components have occurred.

In July 2011, FIOCRUZ informed the Company that ANVISA (the Brazilian regulatory agency) had approved the DPP® Leptospirosis assay for use in Brazil. This approval triggered a milestone event of \$100,000. In accordance with guidance, management has concluded the FIOCRUZ event recorded in the third quarter for Leptospirosis met the definition of milestone events. The Company earned \$100,000 for the three months ended September 30, 2011.

Under the Leptospirosis contract, there are additional royalties and purchase commitments due to the Company over the remaining life of the Agreement.

During the three months ended September 30, 2011 and 2010 the Company recognized \$100,000 and \$400,000, respectively in milestone revenues from FIOCRUZ.

During the nine months ended September 30, 2011 and 2010 the Company recognized \$505,000 and \$625,000, respectively in milestone revenues from FIOCRUZ.

(b) Infectious Disease Research Institute (IDRI) Agreement:

In April 2009, Chembio entered into a development agreement for up to approximately \$400,000 in connection with the development and initial supply of a low-cost, rapid point-of-care ("POC") test for infectious diseases. The agreement contemplated a period of approximately two years in which the development activity is to be completed.

As of September 30, 2011, the Company received an aggregate of \$390,000 in research and development payments from this agreement. Future milestone payments of \$10,000 are expected over the next quarter and will be recognized

when the milestones are met.

(c) National Institutes of Health (NIH) Grant:

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. The Company earned, for the three- and nine-month periods ended September 30, 2011, \$159,000 and \$519,000, respectively from this grant. The Company earned an aggregate of \$2,207,000 from this grant from inception through September 30, 2011, of which \$757,000 was paid to sub-contractors.

In March 2011, the Company received a \$2.4 million, three-year grant from the United States National Institutes of Health to complete development of a test for Tuberculosis. Grants are invoiced after expenses are incurred. The Company earned, for the three- and nine-month periods ended September 30, 2011, \$97,000 and \$252,000, respectively, from this grant. The Company earned \$280,000 from this grant from inception through September 30, 2011 of which \$27,000 was paid to sub-contractors.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2011

(UNAUDITED)

NOTE 4 — TERM NOTE, REVOLVING DEMAND NOTE, VEHICLE FINANCING AND LICENSE FEE PAYABLE:

In June 2010, the Company entered into three agreements with HSBC Bank, NA (“HSBC”). The three agreements were: 1) a secured term note (“Term Note”) of \$250,000 to be repaid over sixty months; 2) a secured revolving demand note (“Demand Note”) up to \$250,000; and 3) a loan and security agreement (“Security Agreement”).

The Term Note is payable at \$4,775 per month in arrears. The payment was calculated by amortizing the \$250,000 note over 60 months at an interest rate of 5.5% per annum. The Term Note matures June, 2015 and is secured under the terms of the Security Agreement.

The Demand Note allows the Company to draw on the line from time to time an amount up to an aggregate of \$250,000 outstanding at any one time. The accrued interest on the Demand Note is payable monthly at an interest rate equal to one-quarter percent above prime per annum. The Company can repay any or all of the principal balance outstanding at any time. This is a demand note and is subject to annual reviews, as well as a 30-day clean-up, during which there can be no amounts outstanding.

The Security Agreement contains covenants that place restrictions on the Company’s operations, including covenants relating to mergers, debt restrictions, capital expenditures, tangible net worth, net profit, leverage, fixed charge coverage, employee loan restrictions, distribution restrictions (common stock and preferred stock), dividend restrictions, restrictions on lease payments to affiliates, restrictions on changes in business, asset sale restrictions, restrictions on acquisitions and intercompany transactions, restrictions on fundamental changes. The Security Agreement also requires that the Company maintain a minimum tangible net worth at all times of greater than \$3,000,000 and EBITDA to CMLTD plus interest cannot be less than 1.25 to 1.00 for any fiscal year. (EBITDA is earnings before interest, taxes, depreciation and amortization; CMLTD is defined as, for any one-year period, the current scheduled principal payments required to be paid for the applicable period.). The Company was in compliance with all required financial covenants at September 30, 2011.

In July 2011, the Company entered into additional agreements with HSBC Bank, NA (“HSBC”). The agreements were: 1) a secured revolving demand note for equipment (Equipment Note”) up to \$500,000, convertible to a term note after one year; and 2) a loan and security agreement (“Security Agreement”).

The Equipment Note allows the Company to draw on the line from time to time an amount up to an aggregate of \$500,000 outstanding at any one time. The accrued interest on the Equipment Note is payable monthly at an interest rate equal to one-quarter percent above prime per annum. The Company can repay any or all of the principal balance outstanding at any time. The Equipment Note will be converted into a 60-month term note at the end of one year.

The Security Agreement contains covenants that place restrictions on the Company’s operations, including covenants relating to mergers, debt restrictions, capital expenditures, tangible net worth, net profit, leverage, fixed charge coverage, employee loan restrictions, distribution restrictions (common stock and preferred stock), dividend restrictions, restrictions on lease payments to affiliates, restrictions on changes in business, asset sale restrictions, restrictions on acquisitions and intercompany transactions, restrictions on fundamental changes. The Company was in compliance with all required financial covenants at September 30, 2011.

The Company currently maintains its operating, payroll, and primary cash accounts at HSBC. The balance due on the Term Note as of September 30, 2011 was \$194,000 and as of September 30, 2011 nothing was drawn down on the

Demand Note, while \$285,626 was drawn down on the Equipment Note.

Future minimum payments under the Term Note, excluding interest, as of September 30, 2011 were as follows:

Periods ending September 30,

2012	\$47,840
2013	50,538
2014	53,389
2015	42,009
	193,699
Less: current maturities	(47,840)
	\$145,859

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2011

(UNAUDITED)

In June 2009, the Company purchased a vehicle for use by the 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 and carries an interest rate of 2.9% per annum. The balance due on this loan as of September 30, 2011 was \$7,547 and is reflected with the Term Note above on the balance sheet as current portion of loans 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 screening assays that detect HIV-2. In exchange for global non-exclusive rights to these patents, the Agreement initially provided that the Company pay Bio-Rad a \$1,000,000 sublicense fee; \$500,000 payable during 2008, of which \$125,000 was paid and \$375,000 was 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 paid the \$875,000 on January 3, 2011. The Company will also pay Bio-Rad a royalty on net sales in the United States and Canada, if any, of Licensed Products sold under the Company's brands as defined in the Agreement. The Agreement will continue until the expiration of the last-to-expire (in 2017) of the sublicensed patents, unless otherwise terminated at an earlier date by the Company or Bio-Rad.

NOTE 5 — RIGHTS AGREEMENT:

In March 2010, the Company entered into a Rights Agreement dated March 8, 2010 (the "Rights Agreement") between the Company and Action Stock Transfer Corp., as Rights Agent. Pursuant to the Rights Agreement, the Company declared a dividend distribution of one preferred share purchase right (a "Right") for each outstanding share of Common Stock, \$0.01 par value (the "Common Stock"), of the Company. The Board of Directors set the payment date for the distribution of the Rights as March 8, 2010, and the Rights were distributed to the Company's shareholders of record on that date. The description and terms of the Rights are set forth in the Rights Agreement.

Rights Initially Not Exercisable. The Rights are not exercisable until a Distribution Date. Until a Right is exercised, the holder thereof, as such, will have no rights as a shareholder of the Company, including, without limitation, the right to vote or to receive dividends.

Separation and Distribution of Rights. The Rights will be evidenced by the certificates for shares of Common Stock registered in the names of the holders thereof, and not by separate rights certificates until the earlier to occur of (i) the close of business on the tenth business day following a public announcement that an Acquiring Person (as defined in the Rights Agreement) acquired a Combined Ownership (as defined in the Rights Agreement) of 15% or more of the outstanding shares of the Common Stock (the "Shares Acquisition Date") or (ii) the later of (A) the close of business on the tenth business day (or such later date as may be determined by action of the Board of Directors prior to such time as any person or group of affiliated or associated persons becomes an Acquiring Person) after the date that a tender or exchange offer or intention to commence a tender or exchange offer by any person is first published, announced, sent or given within the meaning of Rule 14d-4(A) under the Securities Exchange Act of 1934, as amended, the consummation of which would result in any person having Combined Ownership of 15% or more of the outstanding shares of the Common Stock, or (B) if such a tender or exchange offer has been published, announced, sent or given before the date of the Rights Agreement, then the close of business on the tenth business day after the date the Rights Agreement was entered into (or such later date as may be determined by action of the Board of Directors prior to such time as any person becomes an Acquiring Person); (the earlier of such dates referred to in (i)

and (ii), which date may include any such date that is after the date of the Rights Agreement but prior to the issuance of the Rights, being called the "Distribution Date").

NOTE 6 — WARRANTS

On April 26, 2011, warrants to purchase 513,698 shares of common stock were exercised at \$.40 per share. The Company received \$205,479 for this exercise.

As of September 30, 2011, the Company had warrants outstanding to purchase 1,218,915 shares of common stock at prices ranging from \$.40 to \$1.00, with a weighted average of \$.468. On October 5, 2011 warrants to purchase 1,144,117 shares of common stock expired.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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(UNAUDITED)

NOTE 7 — COMMITMENTS, CONTINGENCIES, AND CONCENTRATIONS:

(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 nine months ended				Accounts
	September 30, 2011		September 30, 2010		September 30, 2011		September 30, 2010		Receivable
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	As of September 30, 2011
Customer 1	\$ 1,912,199	35	\$ 1,090,599	29	\$ 5,386,670	47	\$ 3,540,525	42	\$ 714,974
Customer 2	2,012,425	36	*	*	2,936,270	25	*	*	762,121
Customer 3	573,957	10	*	*	*	*	1,763,895	21	468,165
Customer 4	*	*	1,289,184	34	*	*	*	*	91,814
Customer 5	*	*	735,750	19	*	*	*	*	80,196

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 a vendor in excess of 10% of total purchases for the periods indicated:

	For the three months ended				For the nine months ended				Accounts
	September 30, 2011		September 30, 2010		September 30, 2011		September 30, 2010		Payable
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	As of September 30, 2011
Vendor 1	\$ 174,278	13	\$ 250,754	23	\$ 432,577	11	\$ 434,817	18	\$ 17,845
Vendor 2	160,218	12	-	-	412,086	11	-	-	111,643

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 United States Food and Drug Administration, United States 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) Employment Agreement:

The Company has employment contracts with two key employees. The contracts call for salaries presently aggregating \$545,000 per year. One contract expires in May 2013 and one contract expires in March 2013. In connection with the contract that expires in March 2013, the Company issued 300,000 options to purchase common stock with one-third vesting immediately and one-third vesting on each of the second and third anniversaries of the grant.

On June 24, 2011, the cash bonus portion of the contract expiring March 2013 was amended in its entirety to provide the following to the key employee: cash bonus of up to 50% of base salary for each respective year consisting of (i) a performance-based bonus of up to 20% of base salary based upon attainment of the Company budget; (ii) a performance-based bonus of up to 15% of base salary based upon attainment of specified and agreed-upon goals and objectives within the Research & Development Department; and (iii) a discretionary bonus of up to 15% of base salary.

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

The terms "Chembio", "Company," "we", "us", and "our" refer to Chembio Diagnostics, Inc. and its subsidiary a consolidated entity, unless the context suggests otherwise.

Overview

This discussion and analysis should be read in conjunction with the accompanying Condensed Consolidated Financial Statements and related notes. The 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 generally accepted accounting principles in the United States ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP 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 are 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 other than as stated in Note 2 (b), have not changed significantly from December 31, 2010.

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 are 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 discussion and analysis relates to the business of the Company, which consists of the development, manufacture and marketing of rapid diagnostic tests that detect infectious diseases. All of the Company's future products that are currently being developed are based on our patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. The Company has completed development of five 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 three that have been developed specifically related to technology transfer, supply and license agreements with The Oswaldo Cruz Foundation ("FIOCRUZ") for the Brazilian public health market, as explained below. The DPP® HIV Screening Assay

will be manufactured as an OEM product only for the Brazilian market pursuant to one of our agreements with FIOCRUZ.

During the first nine months of 2011, the Company had a total of \$3,697,000 of research and development expenses as compared with \$2,822,000 during the first nine months of 2010. A primary factor for this increase was approximately \$661,000 attributable to expenses for clinical trials. Because of the Company's strong operating cash flow during 2010 and 2011 year-to-date, including but not limited to its receipt of \$1.467 million of Qualified Therapeutic Discovery Project grants ("QTDP") under Section 48D of the Internal Revenue Code, as enacted under the Patient Protection and Affordable Care Act of 2010, the Company has been able to accelerate the pace of these clinical trials, which are now over 90% completed.

The Company has a number of additional products under development that employ the DPP® technology. These product development activities are further described below.

DPP® Leptospirosis – We have approximately nine months left of the three-year \$3 million Small Business Innovative Research (SBIR) Phase II grant we were awarded in 2009 by the United States National Institutes of Health (NIH) to fully develop, validate, and commercialize a rapid diagnostic test for Leptospirosis for general use worldwide. Our work pursuant to this grant is progressing on schedule. The test will be developed with our DPP® technology and will utilize proprietary reagents developed by Yale 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, Yale University in New Haven, CT and the Oswaldo Cruz Foundation, the largest biomedical research institution in Latin America.

DPP® Tuberculosis – As reported in February 2011, we were awarded a three-year \$2.9 million, subsequently reduced to \$2.4 million, Small Business Innovative Research (SBIR) Phase II grant from the United States National Institutes of Health (NIH) to continue development of a simple, rapid, accurate, and cost-effective serological test for active tuberculosis that can be utilized in resource-limited settings.

Battelle/CDC DPP® Influenza Immunity Test – Our prototypes were evaluated by Battelle/CDC and this resulted in a request for additional development work during the summer. Subsequently, in October, we recently entered into an amendment of this contract, beginning November 1, 2011, to continue additional development work for this product in the fourth quarter of 2011 and the first quarter of 2012. This development work will be funded by approximately \$250,000 in periodic milestone payments to be received by the Company during this period upon attainment of such milestones.

Other Research & Development Activities - We are considering certain new DPP® product opportunities, either as OEM development projects and/or as Chembio-branded products. These products are being identified based upon our assessment of unique opportunities in the market and how they can be uniquely addressed by our proprietary technology, as well as by our development and manufacturing experience. We are also identifying and assessing additional technologies that we believe could provide us with additional products, and capabilities, and thereby provide additional revenue streams. Chembio continues to work with commercial, governmental and private organizations in order to obtain R&D contracts and grant 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 have also served in creating important collaborative relationships.

On November 1, 2010, the Company was notified by the IRS that it received awards in the total amount of \$1.467 million relating to six "Qualifying Therapeutic Discovery Projects" under the U.S. Patient Protection and Affordable Care Act of 2010 (P.L. 111-148), a program that was created as part of the major United States federal health care reform legislation enacted earlier this year.

Under the award guidelines, qualified therapeutic discovery projects had to show a reasonable potential to result in new therapies to treat areas of unmet medical need or prevent, detect or treat chronic or acute diseases and conditions, reduce the long-term growth of health care costs in the United States, or significantly advance the goal of curing cancer within 30 years. Chembio's projects that received awards include products based on the Company's patented DPP® point-of-care diagnostic platform that are in various stages of its development pipeline such as its products for the rapid diagnosis of HIV, Hepatitis-C, and Syphilis.

We also have some smaller research and development agreements and grants in place, and applications for others that are pending.

There can be no assurance that any of these grant applications will result in any funding awards to the Company, nor that any of the existing research and development contracts or grants will continue or that they will meet regulatory or any other technical requirements and specifications, and/or that if continued, will result in completed products, or that such products, if they are successfully completed, can or will be successfully commercialized.

Regulatory Activities

CE Mark for FDA approved HIV tests – The final studies for the CE Marking requirements are complete and we submitted this data during October.

Regulatory Approvals in Brazil through the Oswaldo Cruz Foundation (FIOCRUZ) – During 2010 we received notification from FIOCRUZ that our DPP® HIV 1/2 screening test and our DPP® HIV confirmatory test were each approved by Brazil's National Health Surveillance Agency (ANVISA). During 2011 our DPP® visceral canine

leishmania ("VL") rapid test was approved by Brazil's Ministry of Agriculture, Livestock and Food Supply ("MAPA"). This is the first diagnostic product that FIOCRUZ has successfully submitted for approval to MAPA in Brazil. In addition, FIOCRUZ received the required approval from ANVISA for the DPP® Syphilis-Treponemal test and the DPP®-Leptospirosis test. The submission for the DPP® multiplex Syphilis Treponemal-Non-Treponemal has not yet occurred.

FDA Approval for DPP® HIV 1/2 Screening Assay - We began submitting the PMA (Pre-Marketing Approval) application using the Modular PMA option, and we have thus far submitted Module I containing manufacturing information and Module II containing non-clinical data, which was submitted in the beginning of October. We have experienced some delays in completing the clinical trials, which are the main component for the final Module III. We now expect to finish the clinical trials during the fourth quarter. As of October 31 we have completed approximately 90% of the 3,000-patient clinical trial. We believe that the results of the clinical trial thus far indicate that the sensitivity and specificity of this product on all matrices meets or exceeds the performance requirements for FDA approval. However the trials are not complete and there can be no assurance that the FDA will agree with our assessment.

DPP® Syphilis Screen & Confirm - We are engaged in a number of activities oriented to commercializing this product. We have commenced testing at the first of three sites in support of our planned 510(K) clearance of this product, we are ready to begin testing at the remaining two sites, and we anticipate the trials to be substantially completed during the first quarter of 2012. Based on these factors, we anticipate the Company will apply for FDA 510(K) clearance during the first quarter of 2012.

During October 2011 we received CE Marking for this product, and which is allowing us to start commercializing this product outside the United States.

Sure Check HIV for Consumer Self-Testing – In September 2011, the Company received clarification from the Food and Drug Administration for the regulatory requirements for the Sure Check® HIV 1/2 rapid test for sale over-the-counter (OTC). Additional studies are required for submission of an Investigational Device Exemption (IDE) as the first step toward product approval. We believe these studies can be completed by the end of the first quarter of 2012 at which time we would submit our IDE to the FDA.

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 and income taxes. For a summary of our significant accounting policies, which other than stated in Note 2 (b), have not changed from December 31, 2010, see our Annual Report on Form 10-K for the twelve months ended December 31, 2010, which was filed with the SEC on March 3, 2011.

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2011 AS COMPARED WITH THE THREE MONTHS ENDED SEPTEMBER 30, 2010

Revenues:

Selected Product

Categories:

	For the three months ended		\$ Change	% Change
	September 30, 2011	September 30, 2010		
HIV	\$ 3,777,682	\$ 3,589,417	\$ 188,265	5.25 %
DPP	1,705,150	920	1,704,230	185242.39 %
Other	44,051	196,235	(152,184)	-77.55 %
Net Product Sales	5,526,883	3,786,572	1,740,311	45.96 %
License and royalty revenue	25,000	61,789	(36,789)	-59.54 %
R&D, milestone and grant revenue	369,904	656,642	(286,738)	-43.67 %
Total Revenues	\$ 5,921,787	\$ 4,505,003	\$ 1,416,784	31.45 %

Revenues for our lateral flow HIV tests and related components during the three months ended September 30, 2011 increased by approximately \$188,000 over the same period in 2010. This was primarily attributable to increased sales to Alere from \$1,091,000 during the first three months of 2010 to \$1,912,000 during the three months ended September 30, 2011, an increase of \$821,000, or 75%, increased sales to Mexico of \$728,000, Brazil of \$166,000 and Asia of \$180,000, partially offset by decreased sales to Africa of \$1,818,000. Revenues for our DPP® products during the three months ended September 30, 2011 increased by approximately \$1,700,000 over the same period in 2010 which is attributable to the launch of four of our five DPP® products that have been approved in Brazil during 2010 and 2011. The decrease in R&D, milestone and grant revenue was due to revenue from milestones and certain development projects that were not repeated, which was partially offset by revenue generated from our recent grants from NIH for Human Tuberculosis, which were effective as of March 1, 2011 and a milestone event of \$100,000 from FIOCRUZ on the approval of the Company's DPP® Leptospirosis rapid test. License and royalty revenue primarily includes royalties from Brazil under our 2004 technology transfer and license agreement; and the 2010 period includes a license fee earned from Bio-Rad Laboratories N.A.

Gross Margin:

Gross Margin related to Net

Product Sales:

	For the three months ended		\$ Change	% Change
	September 30, 2011	September 30, 2010		
Gross Margin per Statement of Operations	\$ 2,670,733	\$ 2,208,501	\$ 462,232	20.93 %
Less: R&D, milestone, grant, license and royalties	394,904	718,431	(323,527)	-45.03 %
Gross Margin from Net Product Sales	\$ 2,275,829	\$ 1,490,070	\$ 785,759	52.73 %
Gross Margin %	41.18 %	39.35 %		

The increase in our gross margin percentage was primarily due to an increase in our DPP® product sold in Brazil as well as sales to Alere which are at higher margin than products sold in Africa. Alere sales represented approximately

35% of sales in the three months ended September 30, 2011 as compared to approximately 29% in the three months ended September 30, 2010.

Research and Development:

Research and development expenses include costs incurred for product development, regulatory approvals, clinical trials, and product evaluations.

Selected expense lines:

	For the three months ended		\$ Change	% Change
	September 30, 2011	September 30, 2010		
Clinical and Regulatory Affairs:				
Wages and related costs	\$ 111,452	\$ 108,722	\$ 2,730	2.51 %
Consulting	4,065	23,170	(19,105)	-82.46 %
Share-based compensation	6,011	2,122	3,889	183.27 %
Clinical trials	320,516	259,574	60,942	23.48 %
Other	18,904	38,716	(19,812)	-51.17 %
Total Regulatory	460,948	432,304	28,644	6.63 %
R&D Other than Regulatory:				
Wages and related costs	508,424	477,726	30,698	6.43 %
Consulting	12,726	4,052	8,674	214.07 %
Share-based compensation	8,181	10,950	(2,769)	-25.29 %
Materials and supplies	185,567	243,332	(57,765)	-23.74 %
Other	66,449	61,736	4,713	7.63 %
Total other than Regulatory	\$ 781,347	797,796	(16,449)	-2.06 %
Total Research and Development	\$ 1,242,295	\$ 1,230,100	\$ 12,195	0.99 %

Expenses for Clinical & Regulatory Affairs for the three months ended September 30, 2011 increased by \$29,000 as compared to the same period in 2010. This was primarily due to expenses we incurred in 2011 for clinical trials primarily conducted for our DPP® HIV Screen Assay as well as Pre-IDE market and flex studies that were conducted related to our Sure Check HIV for consumer self-testing, which together accounted for an increase of approximately \$61,000 over the 2010 period, which was partially offset by decreases in consulting and other expenses.

R&D expenses other than Clinical & Regulatory Affairs decreased by \$16,000 in the three months ended September 30, 2011 as compared with the same period in 2010 and were primarily related to a decrease in materials and supplies partially offset by an increase in wages and related costs due to new hires and consulting.

Selling, General and Administrative Expenses:

Selected expense lines:

	For the three months ended		\$ Change	% Change
	September 30, 2011	September 30, 2010		
Wages and related costs	\$ 323,789	\$ 264,509	\$ 59,280	22.41 %
Consulting	50,347	74,393	(24,046)	-32.32 %
Commissions	221,128	32,653	188,475	577.21 %
Share-based compensation	59,921	11,543	48,378	419.11 %
Marketing materials	19,571	3,942	15,629	396.47 %
Investor relations/investment bankers	40,408	61,420	(21,012)	-34.21 %
Legal, accounting and SOX 404 compliance	92,240	167,708	(75,468)	-45.00 %

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Travel, entertainment and trade shows	13,849	19,036	(5,187)	-27.25	%
Bad Debt Allowance	-		-	100.00	%
Other	127,984	166,650	(38,666)	-23.20	%
Total S, G &A	\$ 949,237	\$ 801,854	\$ 147,383	18.38	%

Selling, general and administrative expenses for the three months ended September 30, increased by \$147,000 as compared with the same period in 2010. The following expense categories experienced a decrease; consulting, investor relations and professional fees. The following expense categories experienced an increase: commissions as a result of the milestone payment and an increase in sales to Brazil, wages and related expenses and share-based compensation (primarily from options issued to new board members).

Other Income and (Expense):

	For the three months ended		\$ Change	% Change	
	September 30, 2011	September 30, 2010			
Other income (expense)	\$ -	\$ (3,923)	\$ 3,923	-100.00	%
Interest income	1,278	1,018	260	25.54	%
Interest expense	(4,874)	(5,666)	792	-13.98	%
Total Other Income and (Expense)	\$ (3,596)	\$ (8,571)	\$ 4,975	-58.04	%

Other income and (expense) for the three months ended September 30, 2011 decreased approximately \$5,000 as compared with the same period in 2010, primarily as a result of a decrease in other expense and a decrease in interest expense due to the term loan with HSBC as well as an increase in interest income due to an increase in cash in interest-bearing accounts.

RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2011 AS COMPARED WITH THE NINE MONTHS ENDED SEPTEMBER 30, 2010

Revenues:

Selected Product
Categories:

	For the nine months ended			
	September 30, 2011	September 30, 2010	\$ Change	% Change
HIV	\$ 8,712,985	\$ 7,732,462	\$ 980,523	12.68 %
DPP	2,604,185	6,521	2,597,664	39835.36 %
Other	199,155	598,150	(398,995)	-66.70 %
Net Product Sales	11,516,325	8,337,133	3,179,192	38.13 %
License and royalty revenue	125,322	400,758	(275,436)	-68.73 %
R&D, milestone and grant revenue	1,529,972	2,299,970	(769,998)	-33.48 %
Total Revenues	\$ 13,171,619	\$ 11,037,861	\$ 2,133,758	19.33 %

Revenues for our HIV tests and related components during the nine months ended September 30, 2011 increased by approximately \$981,000 over the same period in 2010. This was primarily attributable to increased sales to Alere from \$3,540,000 during the first nine months of 2010 to \$5,387,000 during the nine months ended September 30, 2011, an increase of \$1,846,000, or 52% as well as increased sales to Mexico of \$724,000 and Asia of \$180,000, partially offset by decreased sales to Africa of \$2,001,000. Revenues for our DPP® products during the nine months ended September 30, 2011 increased by approximately \$2,600,000 over the same period in 2010, which is attributable to the launch of four of our five DPP® products that have been approved in Brazil during 2010 and 2011. The decrease in R&D, milestone and grant revenue was due to revenue from milestones and certain development projects that were not repeated partially offset by revenue generated from our recent grants from NIH for Human Tuberculosis, which was effective as of March 1, 2011, a milestone event of \$305,000 from FIOCRUZ on the approval of the Company's DPP® Leishmaniasis rapid test, \$100,000 from FIOCRUZ on the approval of the Company's DPP® Leptospirosis rapid test and \$100,000 from FIOCRUZ on the approval of the Company's DPP® Syphilis rapid test. License and royalty revenue primarily includes royalties from Brazil under our 2004 technology transfer and license agreement.

Gross Margin:

Gross Margin related to Net
Product Sales:

	For the nine months ended			
	September 30, 2011	September 30, 2010	\$ Change	% Change
Gross Margin per Statement of Operations	\$ 6,647,353	\$ 5,609,841	\$ 1,037,512	18.49 %
Less: R&D, milestone, grant, license and royalties	1,655,294	2,700,728	(1,045,434)	-38.71 %
Gross Margin from Net Product Sales	\$ 4,992,059	\$ 2,909,113	\$ 2,082,946	71.60 %
Gross Margin %	43.35 %	34.89 %		

The increase in our gross margin percentage was primarily due to an increase in our sales of DPP® product sold in Brazil as well as products sold to Alere which are at higher margin than products sold in Africa. This gross margin

increase was after, and partially offset by, approximately \$200,000 in an unusually high scrap expense that was incurred as a result of a product non-conformance detected during quality control in a production batch. Alere sales represented approximately 42% of sales in the nine months ended September 30, 2010 as compared to approximately 47% in the nine months ended September 30, 2011.

Research and Development:

Research and development expenses include costs incurred for product development, regulatory approvals, clinical trials, and product evaluations.

Selected expense lines:	For the nine months ended			
	September 30, 2011	September 30, 2010	\$ Change	% Change
Clinical and Regulatory Affairs:				
Wages and related costs	\$ 336,120	\$ 278,773	\$ 57,347	20.57 %
Consulting	4,065	37,975	(33,910)	-89.30 %
Share-based compensation	12,847	9,759	3,088	31.64 %
Clinical trials	1,054,684	393,342	661,342	168.13 %
Other	46,091	68,409	(22,318)	-32.62 %
Total Regulatory	1,453,807	788,258	665,549	84.43 %
R&D Other than Regulatory:				
Wages and related costs	1,485,766	1,306,417	179,349	13.73 %
Consulting	61,034	19,190	41,844	218.05 %
Share-based compensation	27,603	62,706	(35,103)	-55.98 %
Materials and supplies	478,603	477,870	733	0.15 %
Other	190,496	168,014	22,483	13.38 %
Total other than Regulatory	\$ 2,243,502	2,034,197	209,305	10.29 %
Total Research and Development	\$ 3,697,309	\$ 2,822,455	\$ 874,854	31.00 %

Expenses for Clinical & Regulatory Affairs for the nine months ended September 30, 2011 increased by \$666,000 as compared to the same period in 2010. This was primarily due to expenses we incurred in 2011 for clinical trials conducted for our DPP® HIV Screen Assay, which increased approximately \$661,000 over the 2010 period.

R&D expenses other than Clinical & Regulatory Affairs increased by \$209,000 in the nine months ended September 30, 2011 as compared with the same period in 2010 and were primarily related to wages and related costs due primarily to new hires, both related to additional products being developed utilizing our patented DPP® technology, partially offset by decreases in share-based compensation.

Selling, General and Administrative Expenses:

Selected expense lines:	For the nine months ended			
	September 30, 2011	September 30, 2010	\$ Change	% Change
Wages and related costs	\$ 844,228	\$ 743,623	\$ 100,605	13.53 %
Consulting	142,518	172,014	(29,496)	-17.15 %
Commissions	406,354	100,236	306,118	305.40 %
Share-based compensation	83,689	52,881	30,808	58.26 %
Marketing materials	35,044	13,710	21,334	155.61 %
Investor relations/investment bankers	135,520	160,771	(25,251)	-15.71 %
	331,909	440,229	(108,320)	-24.61 %

Legal, accounting and SOX 404 compliance					
Travel, entertainment and trade shows	37,794	49,327	(11,533)	-23.38	%
Bad Debt Allowance	(15,000)	-	(15,000)	100.00	%
Other	410,811	410,924	(113)	-0.03	%
Total S, G &A	\$ 2,412,867	\$ 2,143,715	\$ 269,152	12.56	%

Selling, general and administrative expenses for the nine months ended September 30, 2011 increased by 12.6% as compared with the same period in 2010. This was primarily due to an increase in commissions as a result of higher sales to Brazil and an increase in wages and related expenses, partially offset by a decrease in professional fees, consulting and investor relation expenses.

Other Income and (Expense):

	For the nine months ended				
	September 30, 2011	September 30, 2010	\$ Change	% Change	
Other income (expense)	\$ -	\$ (3,923)	\$ 3,923	-100.00	%
Interest income	4,315	2,747	1,568	57.08	%
Interest expense	(13,345)	(9,927)	(3,418)	34.43	%
Total Other Income and (Expense)	\$ (9,030)	\$ (11,103)	\$ 2,073	-18.67	%

Other income and (expense) for the nine months ended September 30, 2011 decreased approximately \$2,000 as compared with the same period in 2010, primarily as a result of a decrease in other expense and an increase in interest income due to an increase in cash in interest-bearing accounts, and partially offset by an increase in interest expense due to the term loan with HSBC.

MATERIAL CHANGES IN FINANCIAL CONDITION

Selected Changes in Financial Condition	As of		\$ Change	% Change	
	September 30, 2011	December 31, 2010			
Cash and cash equivalents	\$ 3,045,348	\$ 2,136,351	\$ 908,997	42.55	%
Accounts receivable, net of allowance for doubtful accounts of \$20,000 and \$35,000 for 2011 and 2010, respectively	2,657,781	3,946,398	(1,288,617)	-32.65	%
Inventories	2,588,225	1,349,161	1,239,064	91.84	%
Current portion of loans payable	341,013	55,817	285,196	510.95	%
Accounts payable and accrued liabilities	2,346,410	2,055,943	290,467	14.13	%
License fee payable	-	875,000	(875,000)	-100.00	%
Deferred revenue	490,522	65,000	425,522	654.65	%

Cash increased by \$909,000 from December 31, 2010, primarily due to the collection of accounts receivable which decreased by \$1.29 million along with an increase in deferred revenue of \$426,000, an increase in loans from HSBC on the revolver for equipment purchases and a \$290,000 increase in accounts payable, which was partially offset by the payment to Bio-Rad of \$875,000 (see reduction in license fee payable) and an increase in inventory of \$1.24 million.

The decrease in accounts receivable was primarily attributable to a large amount of credit sales in December of 2010 which were collected in 2011 compared to a large amount of September 2011 sales, some of which were prepaid and some early September shipments which were paid by the end of September. The increase in accounts payable and in inventories were both primarily due to a larger amount of materials ordered and manufactured for orders due to ship in the fourth quarter of 2011.

LIQUIDITY AND CAPITAL RESOURCES

	For the nine months ended		\$ Change	% Change	
	September 30, 2011	September 30, 2010			
Net cash provided by operating activities	\$ 1,559,123	\$ 213,731	\$ 1,345,392	629.48	%
Net cash used in investing activities	(282,175)	(188,193)	(93,982)	49.94	%
Net cash (used in) provided by financing activities	(367,951)	242,210	(610,161)	-251.91	%
INCREASE IN CASH AND CASH EQUIVALENTS	\$ 908,997	\$ 267,748	\$ 641,249	239.50	%

The Company's cash increased for the nine months ended September 30, 2011 by \$909,000 as compared to an increase in cash for the same period in 2010 of \$268,000. The increases during the 2011 and 2010 periods are primarily attributable to cash provided by operations. The increase in the 2011 period includes cash received from the change in receivables of \$1.29 million, an increase in deferred revenue of \$426,000, an increase in loans from HSBC on the revolver for equipment purchases and a \$290,000 increase in accounts payables partially offset by an increase in

inventories of \$1.24 million. In addition the Company received \$205,000 from the exercise of warrants. The increased cash from operations in 2011 was also attributable to non-cash expenses aggregating \$458,000 and an increase in other assets of \$16,000. The Company's non-cash expenses totaled \$458,000, which consisted of \$322,000 from depreciation and amortization expense and \$136,000 in share-based compensation expense, partially offset by a decrease in accounts receivable allowance of \$15,000.

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

In the quarter ended September 30, 2011, Chembio experienced record product sales and gross margin as compared both with the directly comparable period of the third quarter of 2010 as well as with the record fourth quarter of 2010. The record product revenues were based on exceptionally strong shipments of four of the five DPP® products now approved for distribution by our OEM partner in Brazil, FIOCRUZ, as well as on substantial growth in our product revenues from Alere, and increased sales to Mexico and Asia.

More specifically, the record revenue performance was attributable to \$1.70 million in revenues from shipments of our DPP® HIV 1-2 screening, DPP® HIV 1-2 Confirmatory, DPP® Syphilis Treponemal, and DPP® Canine Leishmaniasis to FIOCRUZ, (versus almost none in the comparable 2010 period) and a 75% increase in sales to Alere of our two FDA-approved rapid HIV tests, from \$1.09 million in the comparable 2010 period, to \$1.91 million. These increases more than offset decreased sales to Africa, which are generally lower margin sales.

Based on the purchase orders and forecasts we have from Alere, FIOCRUZ, and other key current and potential new customers, we believe that Chembio will finish 2011 with record product sales and gross margin. The extent of our revenue and gross margin growth, and the cost and timing of our research and development, regulatory and clinical programs, will be the primary determinants of whether, and to what extent, we will generate profits after these expenses. We do believe these clinical, regulatory and research and development expenses will be significantly increased as compared with the comparable periods in 2010, as is evident in our year-to-date 2011 results. Nevertheless we believe that the anticipated increased product revenues together with the cash on hand, which we believe will increase, augmented by our recently expanded bank facility, will enable us to fund all of our budgeted clinical and development programs for our Chembio-branded DPP® products for the next twelve months.

In addition to the reduced non-product revenue for the nine months ended September 30, 2011, which we anticipate will continue in 2011, we also anticipate the non-recurrence of the QTDP grants which, notwithstanding the use of the word "grant" by this program, was recognized under GAAP in our 2010 audited financial statements as a \$1.467 million reduction in our 2010 research and development expenses. Accordingly, our comparisons of our 2011 results to the results of 2010 will be after adjusting for the \$1.467 million of QTDP "grants" recognized in (the fourth quarter of) 2010. On the other hand, our comparisons will also be after accounting for \$275,000 in non-recurring expenses in 2010 (which we assume will not recur in 2011 or the foreseeable future, although there can be no assurance of this) that we incurred during the second half of 2010 related to potential strategic opportunities.

We believe that our investment in clinical trial expenses during 2011 will be approximately \$1.7 million, of which we have incurred \$1.05 million this year to date. This is due to the overlap of the commencement of the DPP® Syphilis Screen & Confirm clinical trials during the fourth quarter of 2011 with the completion of the DPP HIV Screening Assay during this same period.

Our inventory, which had increased significantly during the second quarter, has begun to decrease in the third quarter and we believe that this will be reduced even further during the fourth quarter, which will improve our liquidity.

During the third quarter, as we reported, we received a CE Marking for our DPP® Syphilis Screen & Confirm Assay. We are therefore now in the process of identifying those markets where we believe there is a significant opportunity for this assay and establishing distributors and/or representatives to begin commercializing this product. We expect to begin to see initial commercial sales from these efforts in the beginning of 2012.

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 first 2011 fiscal nine months that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

EXHIBITS – See next page.

EXHIBITS INDEX

Number	Description
3.1	Articles of Incorporation, as amended. (1)
3.2	Amended and Restated Bylaws. (2)
4.1	Form of Warrant, dated June 29, 2006, issued pursuant to Company and purchasers of the Company's Secured Debentures. (3)
4.2	Registration Rights Agreement, dated June 29, 2006. (4)
4.3	Registration Rights Agreement, dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (5)
4.4	Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated September 29, 2006 (5).
4.5	Amended Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated October 5, 2006. (5)
4.6	Amended Form of Common Stock Warrant issued to Placement Agents pursuant to the October 5, 2005 Securities Purchase Agreement(6)
4.7*	Form of Employee Option Agreement. (13)
4.8	1999 Equity Incentive Plan. (7)
4.9	2008 Stock Incentive Plan. (8)
4.1	Rights Agreement, dated March 8, 2010 (9)
4.11	Form of Warrant (to be filed by amendment)
10.1*	Employment Agreement dated June 15, 2006 with Lawrence A. Siebert. (10)
10.2*	Employment Agreement dated March 5, 2010 with Javan Esfandiari. (11)
10.3	Security Purchase Agreement, dated June 29, 2006, among the Company and purchasers of the Company's Secured Debentures. (4)
10.4	Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (5)
10.5	Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (5)
10.6	Letter of Amendment to Securities Purchase Agreements dated as of September 29, 2006 by and among the Registrant and the Purchasers listed therein. (5)
10.7	HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Alere and StatSure. (5)
10.8	HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (5)
10.9	Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (5)
10.10	Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (5)
10.11	Secured Term Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc.and HSBC Bank, NA(12)
10.12	Secured Revolving Demand Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc.and HSBC Bank, NA(12)
10.13	Loan and Security Agreement, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (12)
10.14	Revolving Term Note, dated as of July 22, 2011, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (13)
10.15	Loan and Security Agreement, dated as of July 22, 2011, by and among the Registrant, Chembio Diagnostics Systems, Inc.and HSBC Bank, NA(13)
10.16*	Amendment to Employment Agreement dated March 5, 2010 with Javan Esfandiari
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.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

1 Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 31, 2005.

2 Incorporated by reference to the Registrant's registration statement on Form SB-2 (File No. 333-85787) 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.

3 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on January 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 October 5, 2006.

6 Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 12, 2008.

7 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on May 11, 2005.

8 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on April 14, 2008.

9 Incorporated by reference to the Registrant's registration statement on Form 8-A (File No. 000-30379) filed with the Commission on March 11, 2010.

10 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 21, 2006.

11 Incorporated by reference to the Registrant's registration statement on Form S-1/A (File No.333-138266) filed with the Commission on March 11, 2010.

12 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on July 29, 2010.

13 Filed herewith

(*) 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: November 3, By: /s/ Lawrence A. Siebert
2011

Lawrence A. Siebert
Chief Executive Officer
(Principal Executive Officer)

Date: November 3, By: /s / Richard J. Larkin
2011

Richard J. Larkin
Chief Financial Officer
(Principal Financial and Accounting Officer)