

CHEMBIO DIAGNOSTICS, INC.
Form 10-Q
August 04, 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 June 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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer,

Edgar Filing: CHEMBIO DIAGNOSTICS, INC. - Form 10-Q

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. (Check one):

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 3, 2011, the Registrant had 63,303,430 shares outstanding of its \$.01 par value common stock.

Quarterly Report on FORM 10-Q For The Period Ended

June 30, 2011

Table of Contents

Chembio Diagnostics, Inc.

	Page
Part I. FINANCIAL INFORMATION:	
Item 1. Financial Statements:	
Condensed Consolidated Balance Sheets as of June 30, 2011 (unaudited) and December 31, 2010.	2
Condensed Consolidated Statements of Operations (unaudited) for the three and six months ended June 30, 2011 and 2010.	3
Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2011 and 2010.	4
Notes to Condensed Consolidated Financial Statements (unaudited)	5 to 12
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 4. Controls and Procedures	22
Part II. OTHER INFORMATION:	
Item 5. Other Information	22
Exhibits	23
SIGNATURES	24
EXHIBITS	

PART I

Item 1. FINANCIAL STATEMENTS

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

- ASSETS -

	June 30, 2011	December 31, 2010
(UNAUDITED)		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 2,139,329	\$ 2,136,351
Accounts receivable, net of allowance for doubtful accounts of \$20,000 and \$35,000 for 2011 and 2010, respectively	1,642,749	3,946,398
Inventories	2,917,473	1,349,161
Prepaid expenses and other current assets	214,626	204,824
TOTAL CURRENT ASSETS	6,914,177	7,636,734
FIXED ASSETS, net of accumulated depreciation	778,123	813,214
OTHER ASSETS:		
License agreements, net of current portion	550,000	600,000
Deposits on manufacturing equipment	156,536	-
Deposits and other assets	36,226	36,226
TOTAL ASSETS	\$ 8,435,062	\$ 9,086,174

- LIABILITIES AND STOCKHOLDERS' EQUITY -

CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 1,995,746	\$ 2,055,943
Current portion of loans payable	57,214	55,817
Deferred research and development revenue	-	65,000
License fee payable	-	875,000
Current portion of obligations under capital leases	25,716	24,697
TOTAL CURRENT LIABILITIES	2,078,676	3,076,457
OTHER LIABILITIES:		
Loans payable - net of current portion	158,066	186,197

Edgar Filing: CHEMBIO DIAGNOSTICS, INC. - Form 10-Q

Obligations under capital leases - net of current portion	1,631	14,576
TOTAL LIABILITIES	2,238,373	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, 63,303,430 and 62,238,983 shares issued and outstanding for 2011 and 2010, respectively	633,034	622,390
Additional paid-in capital	39,983,176	39,658,617
Accumulated deficit	(34,419,521)	(34,472,063)
TOTAL STOCKHOLDERS' EQUITY	6,196,689	5,808,944
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 8,435,062	\$ 9,086,174

See accompanying notes to condensed consolidated financial statements

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

	For the three months ended		For the six months ended	
	June 30, 2011	June 30, 2010	June 30, 2011	June 30, 2010
REVENUES:				
Net product sales	\$ 2,974,379	\$ 2,335,665	\$ 5,989,442	\$ 4,550,562
License and royalty revenue	71,468	317,472	100,322	338,968
R&D, milestone and grant revenue	568,304	1,096,305	1,160,068	1,643,328
TOTAL REVENUES	3,614,151	3,749,442	7,249,832	6,532,858
Cost of product sales	1,563,873	1,654,476	3,273,212	3,131,518
GROSS MARGIN	2,050,278	2,094,966	3,976,620	3,401,340
OPERATING EXPENSES:				
Research and development expenses	1,164,872	791,596	2,455,014	1,592,354
Selling, general and administrative expenses	688,259	680,014	1,463,630	1,341,862
	1,853,131	1,471,610	3,918,644	2,934,216
NET INCOME FROM OPERATIONS	197,147	623,356	57,976	467,124
OTHER INCOME (EXPENSES):				
Interest income	1,726	618	3,036	1,729
Interest expense	(4,034)	(2,057)	(8,470)	(4,262)
	(2,308)	(1,439)	(5,434)	(2,533)
NET INCOME BEFORE INCOME TAXES	194,839	621,917	52,542	464,591
Provision for income taxes	-	-	-	-
NET INCOME	\$ 194,839	\$ 621,917	\$ 52,542	\$ 464,591
Basic net income per share	\$ 0.00	\$ 0.01	\$ 0.00	\$ 0.01

Edgar Filing: CHEMBIO DIAGNOSTICS, INC. - Form 10-Q

Diluted net income per share	\$ 0.00	\$ 0.01	\$ 0.00	\$ 0.01
Weighted average number of shares outstanding, basic	63,060,582	62,070,736	62,675,073	62,028,450
Weighted average number of shares outstanding, diluted	69,389,994	69,250,405	69,420,243	69,977,177
See accompanying notes to condensed consolidated financial statements				

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

	June 30, 2011	June 30, 2010
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:		
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	\$ 9,553,481	\$ 6,491,901
Cash paid to suppliers and employees	(8,625,009)	(6,922,455)
Interest received	1,726	1,110
Interest paid	(4,034)	(2,204)
Net cash provided by (used in) operating activities	926,164	(431,648)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of and deposits on fixed assets	(288,402)	(144,345)
Net cash used in investing activities	(288,402)	(144,345)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option and warrant exercises	278,876	20,572
Payment of license obligation	(875,000)	-
(Payment of) and Proceeds from loan obligation, net	(26,734)	244,434
Payment of capital lease obligation	(11,926)	(10,400)
Net cash provided by (used in) financing activities	(634,784)	254,606
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	2,978	(321,387)
Cash and cash equivalents - beginning of the period	2,136,351	1,068,235
Cash and cash equivalents - end of the period	\$ 2,139,329	\$ 746,848
RECONCILIATION OF NET INCOME TO NET CASH PROVIDED BY OPERATING ACTIVITIES:		
Net Income	\$ 52,542	\$ 464,591
Adjustments:		
Depreciation and amortization	216,957	148,052

Edgar Filing: CHEMBIO DIAGNOSTICS, INC. - Form 10-Q

Provision for doubtful accounts	(15,000)	-
Share based compensation	56,327	113,659
Changes in assets and liabilities:		
Accounts receivable	2,318,649	(40,957)
Inventories	(1,568,312)	(293,805)
Prepaid expenses and other current assets	(9,802)	(34,153)
Deposits and other assets	-	52,210
Accounts payable and accrued liabilities	(60,197)	(595,418)
Deferred research and development revenue	(65,000)	(245,827)
Net cash provided by (used in) operating activities	\$ 926,164	\$ (431,648)

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
JUNE 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 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. Lateral flow rapid HIV tests represented approximately 82% of the Company’s net product sales in the six months ended June 30, 2011 compared with nearly 91% for the six months ended June 30, 2010. DPP® rapid tests represented approximately 15% of the Company’s net product sales in the six months ended June 30, 2011 compared with less than 1% for the six months ended June 30, 2010. The Company also has other rapid tests that together represented approximately 2% and 9% of net product sales in the first six 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 a number of 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 June 30, 2011 and for the three- and six-month periods ended June 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 June 30, 2011, its condensed consolidated results of operations for the three- and six-month periods ended June 30, 2011 and 2010 and its cash flows for the six-month periods ended June 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.

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

JUNE 30, 2011
(UNAUDITED)
(c) Inventories:

Inventories consist of the following at:

	June 30, 2011	December 31, 2010
Raw materials	\$ 1,301,630	\$ 785,693
Work in process	595,272	235,548
Finished goods	1,020,571	327,920
	\$ 2,917,473	\$ 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 six-month periods ended June 30, 2011 and 2010, have been included in the diluted per share computations:

	For the three months ended		For the six months ended	
	June 30, 2011	June 30, 2010	June 30, 2011	June 30, 2010
Basic	63,060,582	62,070,736	62,675,073	62,028,450
Diluted	69,389,994	69,250,405	69,420,243	69,977,177

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

	For the three months ended		For the six months ended	
	June 30, 2011	June 30, 2010	June 30, 2011	June 30, 2010
1999 and 2008 Plan Stock Options	4,575,232	5,050,933	4,693,493	5,029,602
Other Stock Options	-	-	-	-
Warrants	1,754,180	2,128,736	2,051,677	2,919,125
	6,329,412	7,179,669	6,745,170	7,948,727

There were 970,700 and 1,363,643 options and warrants outstanding as June 30, 2011 and 2010, respectively that were not included in the calculation of diluted income per share for the six months ended because their effect would have been anti-dilutive. There were 317,358 and 1,363,643 options and warrants outstanding as of June 30, 2011 and 2010, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended June 30, 2011 and 2010, respectively, because their effect would have been anti-dilutive.

(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 June 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. 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 June 30, 2011, there were 73,331 options exercised, 3,831,985 options outstanding and 1,094,684 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 June 30, 2011 and 2010 was .09 and none per share, respectively and for the six-month periods ended June 30, 2011 and 2010 was \$.09 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.

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

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, 2011	June 30, 2010	June 30, 2011	June 30, 2010
Expected term (in years)	3.75	n/a	3.75	5
Expected volatility	92.11 %	n/a	92.11 %	116.82 %
Expected dividend yield	n/a	n/a	n/a	n/a
Risk-free interest rate	1.39 %	n/a	1.39 %	1.43 %

The Company's results for the three-month periods ended June 30, 2011 and 2010 include share-based compensation expense totaling \$29,000 and \$39,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$3,000 and \$5,000, respectively), research and development (\$14,000 and \$17,000, respectively) and selling, general and administrative expenses (\$12,000 and \$17,000, respectively). The results for the six-month periods ended June 30, 2011 and 2010 include share-based compensation expense totaling \$56,000 and \$114,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$6,000 and \$13,000, respectively), research and development (\$26,000 and \$60,000, respectively) and selling, general and administrative expenses (\$24,000 and \$41,000, 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 six-month periods ended June 30, 2011 and 2010 represents the estimated fair value of options outstanding which is being amortized on a straight-line basis over the requisite vesting period of the entire award.

The following table provides stock option activity for the six months ended June 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	500,000	\$ 0.54		
Exercised	(550,749)	\$ 0.13		
Forfeited/expired/cancelled	(59,334)	\$ 0.34		
Outstanding at June 30, 2011	5,420,485	\$ 0.19	2.79 years	\$ 1,455,844
Exercisable at June 30, 2011	3,473,811	\$ 0.12	2.42 years	\$ 1,013,735

As of June 30, 2011, there was \$211,000 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 one year. The total fair value of stock options vested during the three-month periods ended June 30, 2011 and 2010, was approximately

\$100,000 and \$103,000, respectively. The total fair value of stock options vested during the six-month periods ended June 30, 2011 and 2010, was approximately \$100,000 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 six months ended	
	June 30, 2011	June 30, 2010	June 30, 2011	June 30, 2010
Africa	\$ 280,126	\$ 820,980	\$ 1,092,971	\$ 1,317,871
Asia	55,460	33,457	84,415	84,511
Europe	4,260	28,178	42,320	60,632
Middle East	2,046	76,192	9,209	103,135
North America	1,734,475	1,344,134	3,808,612	2,867,771
South America	898,012	32,724	951,915	116,642
	\$ 2,974,379	\$ 2,335,665	\$ 5,989,442	\$ 4,550,562

7

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

(g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

	June 30, 2011	December 31, 2010
Accounts payable – suppliers	\$ 1,125,210	\$ 883,719
Accrued commissions	138,345	114,451
Accrued royalties / license fees	347,877	352,285
Accrued payroll	133,295	162,740
Accrued vacation	172,168	129,732
Accrued bonuses	-	140,325
Accrued expenses – other	78,851	272,691
TOTAL	\$ 1,995,746	\$ 2,055,943

(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:

In November 2010, the Company signed an Agreement 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 agreement is for DPP® Syphilis Screen and Confirm. This Agreement provides 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 accordance with guidance, management has concluded the FIOCRUZ events recorded in the second quarter for Syphilis Screen met the definition of milestone events. The Company earned \$100,000 for the three months ended June 30, 2011.

Under the Syphilis contract, there are additional royalties and purchase commitments due to the Company over the remaining life of the Agreement which will result in a larger revenue stream.

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

During the six months ended June 30, 2011 and 2010 the Company recognized \$405,000 and \$400,000, 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 June 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.

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

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 six-month periods ended June 30, 2011 \$177,000 and \$370,000, respectively from this grant. The Company earned an aggregate of \$1,939,000 from this grant from inception through June 30, 2011, of which \$660,000 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 six-month periods ended June 30, 2011 \$110,000 and \$158,000 respectively from this grant. The Company earned \$158,000 from this grant from inception through June 30, 2011.

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 annual 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 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 June 30, 2011.

The Company currently maintains its operating, payroll, and primary cash accounts at HSBC. The balance due on the Term Note as of June 30, 2011 was \$205,000 and nothing was drawn down on the Demand Note as of June 30, 2011.

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

Periods ending June 30,

2012	\$47,188
2013	49,850
2014	52,662
2015	55,554
	205,254
Less: current maturities	(47,188)
	\$158,066

9

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
JUNE 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 June 30, 2011 was \$10,026 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").

NOTE6—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 June 30, 2011, the Company had warrants outstanding to purchase 1,248,753 shares of common stock at prices ranging from \$.40 to \$1.00, with a weighted average of \$.475. By October 5, 2011 warrants to purchase 1,173,955 shares of common stock will expire, unless they are exercised prior to that date.

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

NOTE7—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 six months ended				Accounts
	June 30, 2011		June 30, 2010		June 30, 2011		June 30, 2010		Receivable
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	As of June 30, 2011
Customer 1	\$ 1,419,261	48	\$ 1,288,038	55	\$ 3,474,471	58	\$ 2,449,965	54	\$ 26,063
Customer 2	872,734	29	*	*	923,845	15	*	*	860,192
Customer 3	*	*	474,564	20	*	*	474,564	10	37,294

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 six months ended				Accounts
	June 30, 2011		June 30, 2010		June 30, 2011		June 30, 2010		Payable
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	As of June 30, 2011
Vendor 1	\$ *	*	\$ 76,400	15	\$ 258,300	11	\$ 184,063	14	\$ 24,699
Vendor 2	174,952	11	*	*	251,869	11	*	*	134,368

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 for a cash bonus of up to 50% of his base salary for each respective year consisting of (i) a performance-based bonus of up to 20% of his base salary based upon attainment of the Company budget; (ii) a performance-based bonus of up to 15% of his 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 his base salary.

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

NOTE8—SUBSEQUENT EVENTS:

In July 2011, the Company entered into a revolving loan for up to \$500,000 with HSBC Bank, NA (“HSBC”), which will convert into a term loan after a one year period. The loan will be used in the acquisition of fixed assets, such as manufacturing equipment, new computer hardware and other similar assets. The terms of this loan are substantially the same as the one entered into in June 2010 (see Note 4).

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 to the Company which will be recognized in the third quarter of 2011.

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

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 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 six months of 2011, the Company had a total of \$2,455,000 of research and development expenses as compared with \$1,592,000 during the first six months of 2010. Approximately \$594,000 of this \$863,000 increase, or 70% of the increase, is attributable to expenses for clinical trials for its DPP® HIV Screen. 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 75% completed.

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

Oswaldo Cruz Foundation OEM DPP® Agreements - During 2008 we signed four agreements with the Oswaldo Cruz Foundation (FIOCRUZ), which is affiliated with the Ministry of Health in Brazil, relating to products based on our DPP® technology for Leptospirosis, Canine Leishmaniasis, screening for HIV 1/2 with oral fluid and blood samples, and a 5-band multiplex point-of-care confirmation test for HIV 1 and 2. In addition, in 2010 we signed a fifth agreement with FIOCRUZ relating to two DPP® Syphilis rapid tests. We have completed development of all of these products and four products have been approved and two are pending regulatory approval (See REGULATORY ACTIVITIES below).

Bio-Rad Laboratories OEM DPP® Agreement – During 2010 we completed work on a two-year development contract with Bio-Rad Laboratories, Inc. of a six band multiplex product on our DPP® platform after a two-year development phase, which was then followed by a technology transfer phase. After the product development was successfully completed in 2010, Chembio earned a license fee from Bio-Rad and Bio-Rad exercised its option to have the manufacture of the product transferred to Bio-Rad. Chembio will therefore participate in the commercialization of this product through the license agreement that it executed with Bio-Rad, which agreement provides for royalties payable to Chembio at the rate of 7% of Net Sales of licensed products as defined in that agreement. We believe the regulatory submissions by Bio-Rad will commence as soon as practicable. There can be no assurance that Bio-Rad will submit this product for regulatory approval, that the product if submitted will be approved, and if approved will be successfully commercialized and produce royalty income to Chembio.

Battelle/CDC DPP® Influenza Immunity Test – We have completed the development work associated with this project and our initial prototypes are being evaluated by Battelle/CDC. During the second quarter of 2011 we shipped 5,000 additional prototypes to Battelle. We recently submitted a new proposal to Battelle related to additional research and development activities they requested us to prepare to further this development work.

DPP® Hepatitis C and DPP® Hepatitis C/HIV Tests – Various prototypes of these products are being developed and evaluated internally and externally, including a study that was organized by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) at the CDC. However we are further assessing the economic justification for an HCV rapid test in the United States, so this development program is on hold.

DPP® Influenza – We have made significant progress on our multiplex test for FLU A/B Antigen Detection and we are completing validation in order to be ready to commence the 510(K) process. However recent revisions in FDA guidance on obtaining FDA clearance and CLIA waiver for this type of test will require us to make significant modifications to this product. Until we can determine the feasibility of implementing these modifications we cannot make a reasonable estimate as to the timetable for this product.

DPP® Leptospirosis – We have approximately one year 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.

Other Research & Development Activities - 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 will be submitting this data during the third quarter of 2011.

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 the first quarter of 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; we believe the remaining DPP® product approval that FIOCRUZ has pending with ANVISA, which is for the DPP® Leptospirosis test, will be granted soon. The submission for the 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. We have now completed all studies required for the non-clinical data which is required for our submitting Module II, and we therefore anticipate filing this module during the third quarter. 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. We have completed approximately 75% 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 blood matrices will exceed 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. We further believe that the performance of this product thus far in the clinical trial on oral fluid samples may or may not meet FDA approval requirements. Alternatively, additional studies may need to be performed in order to achieve the oral fluid claim. FDA approval of an oral fluid claim from the current or additional clinical trials will ultimately depend on several factors including but not limited to the product performance in the remainder of the clinical trial, the assessment by the FDA of such clinical trial data, and the product performance and procedural claims that the Company is seeking versus those that the FDA determines in its sole discretion are supported by the data.

DPP® Syphilis Screen & Confirm - We are engaged in a number of activities oriented to commercializing this product. The site contract IRB approval, and training are now complete for our first clinical site to commence the testing in support of our planned 510(K) clearance of this product. We anticipate the trials to be substantially completed during 2011 and for the Company to received FDA 510(K) clearance and CLIA waiver to begin marketing this product during 2012. We are submitting a CE Mark application to our notified body for this product, and anticipate receiving the CE Mark in September, 2011. This will facilitate our efforts to start commercializing this product outside the United States.

Sure Check HIV for Consumer Self-Testing – As announced in June 2011, the Company has initiated studies required for submission of an Investigational Device Exemption (IDE) to the Food and Drug Administration for its Sure Check® HIV 1/2 rapid test as the first step toward over-the-counter (OTC) product approval. Chembio believes that a market study of the intended users and an additional "Flex" Study are required to complete the IDE submission. Both of these studies have been initiated and Chembio plans to complete both of these studies and submit an IDE to the FDA during the latter part of this year. Chembio has requested a meeting with the FDA to confirm and further clarify the process prior to submitting an IDE.

Recent Events

In July 2011, the Company entered into a revolving loan of up to \$500,000 with HSBC Bank, NA ("HSBC"), which will convert into a term loan after a one-year draw down period. The loan will be used in the acquisition of fixed assets, such as manufacturing equipment, new computer hardware and other similar assets. The terms of this loan are substantially the same as the one entered into in June 2010 (see Note 4 of the financial statements).

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 to the Company.

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 JUNE 30, 2011 AS COMPARED WITH THE THREE MONTHS ENDED JUNE 30, 2010

Revenues:

Selected Product

Categories:

	For the three months ended			
	June 30, 2011	June 30, 2010	\$ Change	% Change
HIV	\$ 2,044,223	\$ 2,135,711	\$ (91,488)	-4.28 %
DPP	848,035	5,601	842,434	15040.78 %
Other	82,121	194,353	(112,232)	-57.75 %
Net Product Sales	2,974,379	2,335,665	638,714	27.35 %
License and royalty revenue	71,468	317,472	(246,004)	-77.49 %
R&D, milestone and grant revenue	568,304	1,096,305	(528,001)	-48.16 %
Total Revenues	\$ 3,614,151	\$ 3,749,442	\$ (135,291)	-3.61 %

Revenues for our HIV tests and related components during the three months ended June 30, 2011 decreased by approximately \$91,000 over the same period in 2010. This was primarily attributable to decreased sales to Africa of \$541,000 partially offset by increased sales to Mexico of \$283,000 and increased sales to Alere from \$1,288,000 during the first three months of 2010 to \$1,419,000 during the three months ended June 30, 2011, an increase of \$131,000, or 10%. 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 our recent grants from NIH for Human Tuberculosis, which was effective as of March 1, 2011 and a milestone event of \$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; and the 2010 period includes a license fee earned from Bio-Rad Laboratories N.A.

Gross Margin:

Gross Margin related to	For the three months ended			
	June 30, 2011	June 30, 2010	\$ Change	% Change
Net Product Sales:				
Gross Margin per Statement of Operations	\$ 2,050,278	\$ 2,094,966	\$ (44,688)	-2.13 %
Less: R&D, milestone, grant, license and royalties	639,772	1,413,777	(774,005)	-54.75 %
Gross Margin from Net Product Sales	\$ 1,410,506	\$ 681,189	\$ 729,317	107.07 %
Gross Margin %	47.42 %	29.16 %		

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. This gross margin increase was after, and partially offset by, approximately \$80,000 in an unusually high scrap expense. Alere sales represented

approximately 55% of sales in the three months ended June 30, 2010 as compared to approximately 48% in the three months ended June 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 three months ended			
	June 30, 2011	June 30, 2010	\$ Change	% Change
Clinical and Regulatory Affairs:				
Wages and related costs	\$ 111,648	\$ 88,580	\$ 23,068	26.04 %
Consulting	-	-	-	100.00 %
Share-based compensation	4,715	2,970	1,745	58.75 %
Clinical trials	282,104	77,018	205,086	266.28 %
Other	8,322	20,419	(12,097)	-59.24 %
Total Regulatory	406,789	188,987	217,802	115.25 %
R&D Other than Regulatory:				
Wages and related costs	502,066	404,098	97,968	24.24 %
Consulting	47,808	5,156	42,652	827.23 %
Share-based compensation	9,104	13,496	(4,392)	-32.54 %
Materials and supplies	134,187	127,279	6,908	5.43 %
Other	64,918	52,580	12,338	23.47 %
Total other than Regulatory	\$ 758,083	602,609	155,474	25.80 %
Total Research and Development	\$ 1,164,872	\$ 791,596	\$ 373,276	47.15 %

Expenses for Clinical & Regulatory Affairs for the three months ended June 30, 2011 increased by \$218,000 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 \$205,000 over the 2010 period.

R&D expenses other than Clinical & Regulatory Affairs increased by \$155,000 in the three months ended June 30, 2011 as compared with the same period in 2010 and were primarily related to an increase in wages and related costs due to new hires, consulting and material and supplies, both related to additional products being developed utilizing our patented DPP® technology.

Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended			
	June 30, 2011	June 30, 2010	\$ Change	% Change
Wages and related costs	\$ 251,041	\$ 238,658	\$ 12,383	5.19 %
Consulting	54,600	41,745	12,855	30.79 %
Commissions	119,574	16,020	103,554	646.40 %
Share-based compensation	12,219	17,015	(4,796)	-28.19 %
Marketing materials	14,738	8,422	6,316	74.99 %
	44,083	61,949	(17,866)	-28.84 %

Investor relations/investment bankers					
Legal, accounting and SOX 404 compliance	56,769	96,893	(40,124)	-41.41	%
Travel, entertainment and trade shows	11,502	14,804	(3,302)	-22.30	%
Bad Debt Allowance	-		-	100.00	%
Other	123,733	184,508	(60,775)	-32.94	%
Total S, G &A	\$ 688,259	\$ 680,014	\$ 8,245	1.21	%

Selling, general and administrative expenses for the three months ended June 30, 2011 remained substantially steady as compared with the same period in 2010, however the mix of expenses were different. The following expense categories experienced a decrease; Investor relations, professional fees and other (This was primarily due to a decrease in expenses incurred in 2011 for the recording of \$27,000 in Brazilian tax withholdings on the milestone payments compared to \$61,000 in 2010). 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.

Other Income and (Expense):

	For the three months ended			
	June 30, 2011	June 30, 2010	\$ Change	% Change
Interest income	\$ 1,726	\$ 618	\$ 1,108	179.29 %
Interest expense	(4,034)	(2,057)	(1,977)	96.11 %
	-	-	-	100.00 %
Total Other Income and (Expense)	\$ (2,308)	\$ (1,439)	\$ (869)	60.39 %

Other income and (expense) for the three months ended June 30, 2011 decreased approximately \$900 as compared with the same period in 2010, primarily as a result of an increase in interest expense due to the term loan with HSBC, and partially offset by an increase in interest income due to an increase in cash in interest-bearing accounts.

RESULTS OF OPERATIONS FOR THE SIX MONTHS ENDED JUNE 30, 2011 AS COMPARED WITH THE SIX MONTHS ENDED JUNE 30, 2010

Revenues:

Selected Product Categories:

	For the six months ended			
	June 30, 2011	June 30, 2010	\$ Change	% Change
HIV	\$ 4,935,302	\$ 4,143,044	\$ 792,258	19.12 %
DPP	899,035	5,601	893,434	15951.33 %
Other	155,105	401,917	(246,812)	-61.41 %
Net Product Sales	5,989,442	4,550,562	1,438,880	31.62 %
License and royalty revenue	100,322	338,968	(238,646)	-70.40 %
R&D, milestone and grant revenue	1,160,068	1,643,328	(483,260)	-29.41 %
Total Revenues	\$ 7,249,832	\$ 6,532,858	\$ 716,974	10.97 %

Revenues for our HIV tests and related components during the six months ended June 30, 2011 increased by approximately \$792,000 over the same period in 2010. This was primarily attributable to increased sales to Alere from \$2,450,000 during the first six months of 2010 to \$3,474,000 during the six months ended June 30, 2011, an increase of \$1,024,000, or 42% partially offset by decreased sales to Africa of \$225,000. 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 our recent grants from NIH for Human Tuberculosis, which was effective as of March 1, 2011 and a milestone event of \$305,000 from FIOCRUZ on the approval of the Company's DPP® Leishmaniasis 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 For the six months ended

Edgar Filing: CHEMBIO DIAGNOSTICS, INC. - Form 10-Q

Net Product Sales:	June 30, 2011	June 30, 2010	\$ Change	% Change
Gross Margin per Statement of Operations	\$ 3,976,620	\$ 3,401,340	\$ 575,280	16.91 %
Less: R&D, milestone, grant, license and royalties	1,260,390	1,982,296	(721,906)	-36.42 %
Gross Margin from Net Product Sales	\$ 2,716,230	\$ 1,419,044	\$ 1,297,186	91.41 %

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 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 54% of sales in the six months ended June 30, 2010 as compared to approximately 58% in the six months ended June 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 six months ended			
	June 30, 2011	June 30, 2010	\$ Change	% Change
Clinical and Regulatory Affairs:				
Wages and related costs	\$ 224,668	\$ 170,051	\$ 54,617	32.12 %
Consulting	-	14,805	(14,805)	-100.00 %
Share-based compensation	6,836	7,638	(802)	-10.50 %
Clinical trials	734,168	133,768	600,400	448.84 %
Other	27,218	29,693	(2,475)	-8.34 %
Total Regulatory	992,890	355,955	636,935	178.94 %
R&D Other than Regulatory:				
Wages and related costs	977,343	828,691	148,652	17.94 %
Consulting	48,308	15,139	33,169	219.10 %
Share-based compensation	19,422	51,756	(32,334)	-62.47 %
Materials and supplies	293,036	234,538	58,498	24.94 %
Other	124,015	106,275	17,741	16.69 %
Total other than Regulatory	\$ 1,462,124	1,236,399	225,725	18.26 %
Total Research and Development	\$ 2,455,014	\$ 1,592,354	\$ 862,660	54.18 %

Expenses for Clinical & Regulatory Affairs for the six months ended June 30, 2011 increased by \$637,000 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 \$600,000 over the 2010 period.

R&D expenses other than Clinical & Regulatory Affairs increased by \$226,000 in the six months ended June 30, 2011 as compared with the same period in 2010 and were primarily related to an increase in material and supplies along with an increase in wages and related costs due 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 six months ended			
	June 30, 2011	June 30, 2010	\$ Change	% Change
Wages and related costs	\$ 520,439	\$ 479,113	\$ 41,326	8.63 %
Consulting	92,171	97,621	(5,450)	-5.58 %
Commissions	185,226	33,569	151,657	451.78 %
Share-based compensation	23,768	41,338	(17,570)	-42.50 %
Marketing materials	15,472	9,768	5,704	58.39 %

Investor relations/investment bankers	95,113	99,352	(4,239)	-4.27	%
Legal, accounting and SOX 404 compliance	239,669	272,352	(32,683)	-12.00	%
Travel, entertainment and trade shows	23,945	30,291	(6,346)	-20.95	%
Bad Debt Allowance	(15,000)	-	(15,000)	100.00	%
Other	282,827	278,458	4,369	1.57	%
Total S, G &A	\$ 1,463,630	\$ 1,341,862	\$ 121,768	9.07	%

Selling, general and administrative expenses for the six months ended June 30, 2011 increased by 9% 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 share-based compensation expenses.

Other Income and (Expense):

	For the six months ended			
	June 30, 2011	June 30, 2010	\$ Change	% Change
Interest income	\$ 3,036	\$ 1,729	\$ 1,307	75.59 %
Interest expense	(8,470)	(4,262)	(4,208)	98.73 %
				100.00 %
Total Other Income and (Expense)	\$ (5,434)	\$ (2,533)	\$ (2,901)	114.53 %

Other income and (expense) for the six months ended June 30, 2011 decreased approximately \$3,000 as compared with the same period in 2010, primarily as a result of an increase in interest expense due to the term loan with HSBC, and partially offset by an increase in interest income due to an increase in cash in interest-bearing accounts.

MATERIAL CHANGES IN FINANCIAL CONDITION

Selected Changes in Financial Condition

	As of			
	June 30, 2011	December 31, 2010	\$ Change	% Change
Cash and cash equivalents	\$ 2,139,329	\$ 2,136,351	\$ 2,978	0.14 %
Accounts receivable, net of allowance for doubtful accounts of \$20,000 and \$35,000 for 2011 and 2010, respectively	1,642,749	3,946,398	(2,303,649)	-58.37 %
Inventories	2,917,473	1,349,161	1,568,312	116.24 %
Accounts payable and accrued liabilities	1,995,746	2,055,943	(60,197)	-2.93 %
License fee payable	-	875,000	(875,000)	-100.00 %
Deferred research and development revenue	-	65,000	(65,000)	-100.00 %

Cash increased by \$3,000 from December 31, 2010, primarily due to the collection of accounts receivable which decreased by \$2.30 million, which was partially offset by the payment to Bio-Rad of \$875,000 (see reduction in license fee payable), an increase in inventory of \$1.57 million, a reduction of deferred revenue of \$65,000 and a \$68,000 reduction of accounts payable.

LIQUIDITY AND CAPITAL RESOURCES

	For the six months ended			
	June 30, 2011	June 30, 2010	\$ Change	% Change
Net cash provided by (used in) operating activities	\$ 926,164	\$ (431,648)	\$ 1,357,812	-314.56 %
Net cash used in investing activities	(338,402)	(144,345)	(194,057)	134.44 %
	(634,784)	254,606	(889,390)	-349.32 %

Net cash provided by
(used in) financing
activities

INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	\$ (47,022)	\$ (321,387)	\$ 274,365	-85.37	%
---	--------------	---------------	------------	--------	---

The Company's cash increased for the six months ended June 30, 2011 as compared to a de