

CHEMBIO DIAGNOSTICS, INC.
Form 10-Q
May 08, 2012

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

FORM 10 - Q

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

For the quarterly period ended March 31, 2012

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

(State or other jurisdiction of
incorporation)

88-0425691

(IRS Employer Identification
Number)

3661 Horseblock Road

Medford, New York 11763

(Address of principal executive offices including zip code)

(631) 924-1135

(Registrant's telephone number, including area code)

___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 [X]

(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 X

As of May 4, 2012, the Registrant had 63,950,596 shares outstanding of its \$.01 par value common stock.

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

March 31, 2012

Table of Contents

Chembio Diagnostics, Inc.

	Page
Part I. FINANCIAL INFORMATION:	
Item 1. Financial Statements:	
Condensed Consolidated Balance Sheets as of March 31, 2012 (unaudited) and December 31, 2011.	2
Condensed Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2012 and 2011.	3
Condensed Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2012 and 2011.	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	21
Part II. OTHER INFORMATION:	
Item 6. Exhibits	21
SIGNATURES	23
EXHIBITS	

PART I

Item 1. FINANCIAL STATEMENTS

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

- ASSETS -

	March 31, 2012	December 31, 2011
(UNAUDITED)		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 2,954,276	\$ 3,010,954
Accounts receivable, net of allowance for doubtful accounts of \$125,000 and \$30,000 for 2012 and 2011, respectively	3,616,720	2,998,449
Inventories	2,706,676	2,300,286
Prepaid expenses and other current assets	755,082	681,893
TOTAL CURRENT ASSETS	10,032,754	8,991,582
FIXED ASSETS, net of accumulated depreciation	1,118,989	1,062,276
OTHER ASSETS:		
Deferred tax asset, net of valuation allowance	4,492,763	4,749,622
License agreements, net of current portion	475,000	500,000
Deposits on manufacturing equipment	201,846	139,790
Deposits and other assets	38,444	42,474
TOTAL ASSETS	\$ 16,359,796	\$ 15,485,744
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 3,081,694	\$ 2,789,500
Current portion of loans payable	51,705	53,550
Current portion of obligations under capital leases	-	14,576
TOTAL CURRENT LIABILITIES	3,133,399	2,857,626
OTHER LIABILITIES:		
Loans payable - net of current portion	120,937	133,484

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

TOTAL LIABILITIES	3,254,336	2,991,110
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding	-	-
Common stock - \$.01 par value; 100,000,000 shares authorized, 63,675,596 and 63,368,096 shares issued and outstanding for 2012 and 2011, respectively	636,756	633,681
Additional paid-in capital	40,298,533	40,124,225
Accumulated deficit	(27,829,829)	(28,263,272)
TOTAL STOCKHOLDERS' EQUITY	13,105,460	12,494,634
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 16,359,796	\$ 15,485,744

See accompanying notes to condensed consolidated financial statements

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

	March 31, 2012	March 31, 2011
REVENUES:		
Net product sales	\$ 6,363,152	\$ 3,015,063
License and royalty revenue	-	28,854
R&D, milestone and grant revenue	290,100	591,764
TOTAL REVENUES	6,653,252	3,635,681
Cost of product sales	3,320,388	1,709,339
GROSS MARGIN	3,332,864	1,926,342
OPERATING EXPENSES:		
Research and development expenses	1,379,131	1,290,142
Selling, general and administrative expenses	1,233,968	775,371
	2,613,099	2,065,513
INCOME (LOSS) FROM OPERATIONS	719,765	(139,171)
OTHER INCOME (EXPENSES):		
Interest income	1,519	1,310
Interest expense	(2,441)	(4,436)
	(922)	(3,126)
INCOME (LOSS) BEFORE INCOME TAXES	718,843	(142,297)
Income tax provision	285,400	-
NET INCOME (LOSS)	\$ 433,443	\$ (142,297)
Basic net income per share	\$ 0.01	\$ (0.00)
Diluted net income per share	\$ 0.01	\$ (0.00)
Weighted average number of shares outstanding, basic	63,474,580	62,284,772
Weighted average number of shares outstanding, diluted	68,098,858	62,284,772

See accompanying notes to condensed consolidated financial statements

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

	March 31, 2012	March 31, 2011
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	\$ 6,034,981	\$ 5,855,562
Cash paid to suppliers and employees	(5,884,833)	(4,292,294)
Interest received	1,519	1,310
Interest paid	(2,441)	(4,436)
Net cash provided by operating activities	149,226	1,560,142
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of and deposits on fixed assets	(223,716)	(46,358)
Net cash used in investing activities	(223,716)	(46,358)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option and warrant exercises	42,750	41,521
Payment of license obligation	-	(888,692)
Payment of loan obligation	(14,392)	
Payment of capital lease obligation	(10,546)	(5,861)
Net cash provided by (used in) financing activities	17,812	(853,032)
(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(56,678)	660,752
Cash and cash equivalents - beginning of the period	3,010,954	2,136,351
Cash and cash equivalents - end of the period	\$ 2,954,276	\$ 2,797,103
RECONCILIATION OF NET INCOME (LOSS) TO NET CASH PROVIDED BY OPERATING ACTIVITIES:		
Net Income (Loss)	\$ 433,443	\$ (142,297)
Adjustments:		
Depreciation and amortization	129,947	112,282
Provision for deferred taxes	256,859	-
Provision for doubtful accounts	95,000	(15,000)
Share based compensation	134,633	27,578

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

Changes in assets and liabilities:		
Accounts receivable	(713,271)	2,234,881
Inventories	(406,390)	(242,909)
Prepaid expenses and other current assets	(73,189)	29,010
Accounts payable and accrued liabilities	292,194	(443,403)
Deferred research and development revenue	-	-
Net cash provided by operating activities	\$ 149,226	\$ 1,560,142

Supplemental disclosures for non-cash investing and financing activities:

Deposits on manufacturing equipment transferred to fixed assets	\$ 23,400	\$ -
---	-----------	------

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2012
(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 main products are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA in 2006; the third is sold for export only. Lateral Flow Rapid HIV tests represented nearly 58% of the Company’s product revenues in the first quarter of 2012. The Company’s products based on its patented DPP® platform represented approximately 40% of the Company’s product revenues in the first quarter of 2012. The Company also has other rapid tests that together represented approximately 2% of sales in the first quarter of 2012. The Company’s products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments 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, Inc. (“Alere”), which is the Company’s exclusive marketing partner for its rapid HIV lateral flow test products in the United States. All of the products that are currently being developed by the Company 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.

NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

a) Basis of Presentation:

The following (a) condensed balance sheet as of December 31, 2011, which has been derived from audited financial statements, and (b) the unaudited interim condensed financial statements as of March 31, 2012 and for the three-month periods ended March 31, 2012 and 2011 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, 2011, 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 March 31, 2012, its condensed consolidated results of operations for the three-month periods ended March 31, 2012 and 2011 and its cash flows for the three-month periods ended March 31, 2012 and 2011, 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. As of March 31, 2012 and December 31, 2011, all advanced revenues were earned.

The Company follows Financial Accounting Standards Board (“FASB”) authoritative guidance (“guidance”) prospectively for the recognition of revenue under the milestone method. The Company applies the milestone method of revenue recognition for certain collaborative research projects defining milestones at the inception of the agreement.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2012

(UNAUDITED)

c) Inventories:

Inventories consist of the following at:

	December 31,	
	March 31, 2012	2011
Raw materials	\$ 1,405,229	\$ 1,340,177
Work in process	545,245	390,162
Finished goods	756,202	569,947
	\$ 2,706,676	\$ 2,300,286

d) Earnings Per Share:

Basic earnings per share is computed by dividing net income or loss 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-month periods ended March 31, 2012 and 2011, have been included in the diluted per share computations:

	For the three months ended	
	March 31, 2012	March 31, 2011
Basic	63,474,580	62,284,772
Diluted	68,098,858	62,284,772

The following securities, presented on a common share equivalent basis for the three-month periods ended March 31, 2012 and 2011, have been included in the diluted per share computations as these securities exercise prices were less than the stock price as of March 31, 2012 and 2011, respectively:

	For the three months ended	
	March 31, 2012	March 31, 2011
1999 and 2008 Plan Stock	4,624,278	-
Options	4,624,278	-

There were 1,399,916 and 5,491,003 options and warrants outstanding as of March 31, 2012 and 2011, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended March 31, 2012 and 2011, respectively, because the effect would have been anti-dilutive as of March 31, 2012 and 2011, respectively.

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 March 31, 2012, there were 1,275,500 outstanding options under this SOP. No additional options may be issued under the SOP because it is more than 10 years after its adoption.

Effective June 3, 2008, the Company's stockholders voted to approve the 2008 Stock Incentive Plan ("SIP"), initially 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 and the number of shares of common stock to covered by each grant. 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 March 31, 2012, there were 134,997 options exercised, 4,754,693 options outstanding and 1,110,310 options or shares still available to be issued under the SIP.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2012
(UNAUDITED)

The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the three-month periods ended March 31, 2012 and 2011 was \$.40 and none 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	
	March 31, 2012	March 31, 2011
Expected term (in years)	5	n/a
Expected volatility	115.77%	n/a
Expected dividend yield	n/a	n/a
Risk-free interest rate	0.36%	n/a

The Company's results for the three-month periods ended March 31, 2012 and 2011 include share-based compensation expense totaling \$133,000 and \$28,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$15,000 and \$4,000, respectively), research and development (\$48,000 and \$12,000, respectively) and selling, general and administrative expenses (\$70,000 and \$12,000, respectively). The income tax benefit has been recognized in the statement of operations for share-based compensation arrangements.

Stock option compensation expense for the three-month periods ended March 31, 2012 and 2011 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 and for which the estimated fair value was expensed immediately.

The following table provides stock option activity for the three months ended March 31, 2012:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2011	6,127,068	\$ 0.21	2.61 years	\$ 1,339,693
Granted	203,125			
Exercised	(300,000)			
Forfeited/expired/cancelled	(36,000)			
Outstanding at March 31, 2012	5,994,193	\$ 0.22	2.57 years	\$ 1,666,687

Exercisable at March 31, 2012	3,517,520	\$	0.17	2.2 years	\$	1,086,928
----------------------------------	-----------	----	------	-----------	----	-----------

As of March 31, 2012, there was \$236,000 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 1.1 years. The total fair value of stock options vested during the three-month periods ended March 31, 2012 and 2011, was approximately \$104,000 and none, respectively.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2012

(UNAUDITED)

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	
	March 31, 2012	March 31, 2011
Africa	\$ 1,077,736	\$ 553,383
Asia	12,478	28,955
Europe	25,578	38,060
Middle East	-	7,163
North America	2,720,760	2,333,600
South America	2,526,600	53,902
	\$ 6,363,152	\$ 3,015,063

g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

	March 31, 2012	December 31, 2011
Accounts payable – suppliers	\$ 1,842,618	\$ 1,258,465
Accrued commissions	238,368	205,588
Accrued royalties / license fees	308,313	480,297
Accrued payroll	134,298	174,398
Accrued vacation	197,330	156,884
Accrued bonuses	144,500	284,375
Accrued expenses – other	216,267	229,493
TOTAL	\$ 3,081,694	\$ 2,789,500

During the first quarter of 2012, the Company received an invoice related to ongoing clinical trials which included the costs associated with certain patients that were seen in 2011. This resulted in an additional \$191,000 research and development charge in the current quarter that should have been recorded in the quarter ended December 31, 2011,

had the Company been aware of the services rendered. In accordance with the Securities and Exchange Commission Staff Accounting Bulletin No. 108 (SAB 108), the Company has determined this error to be immaterial, from both a quantitative and qualitative perspective, and has therefore chosen to record this charge in the first quarter of 2012 and not restate the applicable previously filed financial statements.

NOTE 3 — COLLABORATIVE RESEARCH AND DEVELOPMENT ARRANGEMENTS:

a) National Institutes of Health (NIH) Grant:

In June 2009, the Company received a \$2.8 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 \$155,000 and \$193,000 for the three-month periods ended March 31, 2012 and 2011, respectively from this grant. The Company earned an aggregate of \$2,640,000 from this grant from inception through March 31, 2012, of which \$874,000 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 \$125,000 and \$48,000 for the three-month periods ended March 31, 2012 and 2011, respectively from this grant. The Company earned \$692,000 from this grant from inception through March 31, 2012 of which \$217,000 was paid to sub-contractors.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2012

(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, as defined in the agreement, 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 March 31, 2012.

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 March 31, 2012.

The Company currently maintains its operating, payroll, and primary cash accounts at HSBC. The balance due on the Term Note as of March 31, 2012 was \$170,000 and as of March 31, 2012 nothing had been drawn down on the Demand or Equipment Note.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2012

(UNAUDITED)

Future minimum payments under the Term Note, excluding interest, as of March 31, 2012 were as follows:

Periods ending March 31,

2013	\$49,171
2014	51,944
2015	54,874
2016	14,119
	170,108
Less: current maturities	(49,171)
	\$120,937

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 March 31, 2012 was \$2,534 and is reflected with the Term Note above on the balance sheet as current portion of loans payable.

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").

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2012

(UNAUDITED)

NOTE 6 — COMMON STOCK, WARRANTS AND OPTIONS:

On March 19, 2012, the Company issued 7,500 shares of common stock to a consultant as part of the consultant's compensation. As long as the consultant continues with the Company, the consultant will receive three more tranches of 7,500 shares every three months for the following nine months. In addition 30,000 options to purchase common stock were issued to the consultant as part of its compensation. The options vest in four equal installments starting three months from the issue date and every three months for the following nine months. These options were valued using a Black-Scholes model at \$8,570, of which \$1,498 was expensed in the three-month period ended March 31, 2012. The options are being accounted for under the variable method as per ITF-96-18 and \$8 of the expense was attributable to this method.

On February 16, 2012, the Company issued 203,125 options to purchase common stock to executives of the Company as part of their 2011 bonus. The options are exercisable immediately at \$.50 per share, which was the last price of stock traded on that day, and they expire five years from date of issue.

As of March 31, 2012, the Company had no warrants outstanding to purchase shares of common.

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				Accounts
	March 31, 2012		March 31, 2011		Receivable
	Sales	% of Sales	Sales	% of Sales	As of
Customer 1	\$ 2,503,739	39	\$ 2,055,210	68	\$ 850,482
Customer 2	2,516,000	40	*	*	1,319,247
Customer 3	601,402	9	*	*	676,596
Customer 4	*	*	459,697	15	*

In the table above, the asterisk (*) indicates that sales to the customer did not exceed 10% for the period indicated. Note that sales include product sales only while accounts receivable reflects the total due from the customer which includes freight.

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		Accounts
	March 31, 2012	March 31, 2011	Payable
			As of

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

	Purchases	% of Purc.	Purchases	% of Purc.	March 31, 2012
Vendor 1	\$ 177,637	13	\$ 108,456	13	\$ 12,700
Vendor 2	140,654	10	*	*	115,294

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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2012

(UNAUDITED)

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, in March 2010, 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.

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, 2011.

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 ("POC") 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 1/2 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 three months of 2012, the Company had a total of \$1,379,131 of research and development expenses as compared with \$1,290,142 during the first three months of 2011. A primary factor for this increase was approximately \$191,000 of clinical trial expenses which, as described in Note 2(g), related to an immaterial error in the accounting for the cost of clinical trials that should have been accrued for in 2011. This had the effect of decreasing operating income during the first three months of 2012 by \$191,000. In addition stock-based compensation increased by \$36,000.

The Company has a number of additional products under development that employ the DPP® technology. In addition, the Company has current and potential collaborations and grant awards that involve or would involve use of the DPP®. These activities are further described below.

DPP® Leptospirosis – Our work under the three-year \$2.8 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 is progressing on schedule and we expect to complete this grant in the second quarter of 2012. The test is being developed with our DPP® technology and utilizes proprietary reagents developed by Yale University and the Oswaldo Cruz Foundation at the Brazilian Ministry of Health. Development of the test has been 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. During 2012 we intend to continue development of a POC test work with DPP technology.

DPP® Syphilis/HIV Combination Test – We have developed a prototype combination Syphilis and HIV test and we are considering various opportunities with respect to this product for the international market. This is an example of the multiplexing capabilities that we expect to drive the Company's revenues and growth.

Other Potential Products and Collaborations - We are currently conducting feasibility studies for three veterinary products and also various pre-natal screening markers that could be used in both single parameter and multiplex tests utilizing our patented DPP®. We also are discussing collaborations for certain of these products which could result in providing Chembio local assembly options in certain markets in South America and Asia. During March we submitted a new preliminary application on behalf of a consortium we would lead related to a multiplex product. In general 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 opportunities in the market and upon whether they can be addressed with our proprietary technology, along with our development and manufacturing capabilities and 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, although there is no assurance that we will be able to obtain or utilize them properly.

We are also in preliminary discussions with a large diversified life sciences company about a potential collaboration for one or more DPP® diagnostic tests for Hepatitis-C. There is no assurance that this collaboration will occur. Given the increasing number and efficacy of treatment options being commercialized for HCV, it is anticipated that if this did occur, it could lead to an increased emphasis on HCV testing. In fact increased testing is already being promoted by several of these companies and related organizations. Revised testing recommendations for HCV are reportedly forthcoming by the CDC, which if issued would likely result in an increase in testing for this condition much like the revised testing recommendations for HIV did when the CDC issued its revised recommendations for HIV testing in 2006. If these new testing recommendations for HCV are issued, we would be more likely to move forward on such a development program on our own.

There can be no assurance that any of the aforementioned activities will result in any funding awards to the Company, nor that any of the existing research and development activities, or any new potential development programs or collaborations will materialize 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, which we have been pursuing for some time, were submitted to our notified body during October 2011. However, due to the length of time it has taken to achieve this regulatory approval, and the additional fees requested by our notified body (NB) to review our file again with the supplemental data requested, we decided to reassess the justification of this. During this reassessment we also became aware of a new submissions strategy, as well as potential new marketing opportunities for rapid HIV testing in certain markets in Europe. As a result we had discussions with respect to this new submission strategy during the first quarter which has resulted in our committing to this new strategy. We now expect to have the review completed 3Q12 and the inspection by the NB to completed shortly thereafter, with the anticipation of CE marking by 4Q12.

FDA Approval for DPP® HIV 1/2 Screening Assay - We began submitting the PMA (Pre-Marketing Approval) application to the FDA 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 2011. As reported, we completed enrollment in the 3,000 patient clinical trial and we believe they support product performance that will meet or exceed the requirement for a PMA approval on oral fluid, finger-stick whole blood, venous whole blood, serum and plasma samples. We expect to submit Module III to the FDA during June and we would anticipate an FDA approval at least on an approvable PMA decision before year-end. We would then immediately apply for CLIA waiver, which is expected to take approximately three months to be granted.

DPP® Syphilis - As a result of our having received a CE Mark for the product in Q3'11 and our business development efforts during Q4'11, we are establishing European distribution for this product. Product evaluations are being completed in France and the UK. In the U.S. we have determined that even with a reader, our test does not compare sufficiently with the reference test that is the only "predicate device" available for establishing "substantial equivalence" under the 510(K) clearance guidelines established by FDA. Therefore we are in the process of having studies performed to substantiate that the Chembio DPP® Syphilis Screen & Confirm test detects primary infections and that certain positive results on the reference test for the non-treponemal marker, Rapid Plasma Reagin ("RPR"), do not represent primary infections (that the United States Preventive Services Task Force (USPSTF) estimates sensitivity of RPR/VDRL for primary infection to be 78-86%). We already are manufacturing large volumes of a visually read, treponemal-only test for Brazil with outstanding performance. This product would be an alternative pathway to bringing a syphilis POC test to the U.S. market. However such a test, like the laboratory treponemal tests, would not differentiate between active and previous infections, which are a preferred feature at least for testing in higher prevalence and risk groups. Assuming we can successfully complete these studies by the end of the third quarter, we believe we can complete the clinical trials and make the 510(k) / De Novo submission to the FDA for this product during the first half of 2013. Therefore FDA 510(k) clearance could be during 2013 followed by commercial launch in the U.S.

Sure Check® HIV OTC Study - We have made progress toward completing the requirements for submitting an IDE ("Investigational Device Exemption") application. This exemption must be granted in order to begin clinical studies that would be necessary to gain FDA approval of this product, which approval could take two or three years from the time that we initiate such clinical studies. We believe that this year (2012) there will be external events that will help us to better define the market opportunity. This principally includes a meeting of the FDA's Blood Products Advisory Committee on May 15 that is likely to result in a final recommendation concerning the application by Orasure Technologies for OTC use of its oral fluid HIV test. Assuming it is recommended, and the product is actually launched, we will be able to assess the market approach and its reception by their targeted consumers. This information will help us before we commit additional significant sums to this program. We can do this knowing that we are the only company other than this competitor that has a device that is qualified to begin the studies necessary to gain OTC approval.

We have completed the "instructional manual" for home-testing using the Flesch-Kincaid readability tests. The initial validation on the comprehension of the manual was recently completed and we have received a detailed report containing the findings. We are encouraged by the results.

In addition to making progress towards the regulatory path for commercialization, we are actively working with public health agencies to begin studies in 2012. The objective of these studies is to understand the barriers and facilitators to increased home testing and other strategies that can be employed to prevention and care of certain demographics at risk to HIV infection. These studies, while providing invaluable health care strategies, can provide feedback to Chembio to improve upon or validate the design of the product to assure it remains safe and effective in a non-professional laboratory setting.

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 have not changed from December 31, 2011, see our Annual Report on Form 10-K for the twelve months ended December 31, 2011, which was filed with the SEC on March 8, 2012.

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2012 AS COMPARED WITH THE THREE MONTHS ENDED MARCH 31, 2011

Revenues:

Selected Product Categories:	For the three months ended			
	March 31, 2012	March 31, 2011	\$ Change	% Change
Lateral Flow HIV Tests and Components	\$ 3,675,022	\$ 2,891,079	\$ 783,943	27.12 %
DPP Tests and Components	2,518,913	51,000	2,467,913	4839.05 %
Other	169,217	72,984	96,233	131.85 %
Net Product Sales	6,363,152	3,015,063	3,348,089	111.05 %
License and royalty revenue	-	28,854	(28,854)	-100.00 %
R&D, milestone and grant revenue	290,100	591,764	(301,664)	-50.98 %
Total Revenues	\$ 6,653,252	\$ 3,635,681	\$ 3,017,571	83.00 %

Revenues for our lateral flow HIV tests and related components during the three months ended March 31, 2012 increased by approximately \$784,000 over the same period in 2011. This was primarily attributable to increased sales to Alere from \$2,055,000 during the first three months of 2011 to \$2,504,000 during the three months ended March 31, 2012, an increase of \$449,000, or 22%, and increased sales to Africa of \$524,000, which were partially offset by decreased sales to North America (other than Alere) of \$198,000. Revenues for our DPP® products during the three months ended March 31, 2012 increased by approximately \$2,468,000 over the same period in 2011 which is attributable to the launch of our 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 in the 2011 first quarter that were not repeated. License and royalty revenue in 2011 is from royalties from Brazil under our 2004 technology transfer and license agreement, which has ended.

Gross Margin:

Gross Margin related to Net Product Sales:	For the three months ended			
	March 31, 2012	March 31, 2011	\$ Change	% Change
Gross Margin per Statement of Operations	\$ 3,332,864	\$ 1,926,342	\$ 1,406,522	73.02 %
Less: R&D, milestone, grant, license and royalties	290,100	620,618	(330,518)	-53.26 %
Gross Margin from Net Product Sales	\$ 3,042,764	\$ 1,305,724	\$ 1,737,040	133.03 %
Gross Margin %	47.82 %	43.31 %		

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 other products we sell, as well as a result of increased utilization of our facility. DPP sales represented approximately 40% of sales in the three months ended March 31, 2012 as compared to approximately 2% in the three months ended March 31, 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			
	March 31, 2012	March 31, 2011	\$ Change	% Change
Clinical and Regulatory Affairs:				
Wages and related costs	\$ 123,725	\$ 113,020	\$ 10,705	9.47 %
Consulting	4,250	-	4,250	100.00 %
Stock-based compensation	15,424	2,122	13,302	626.86 %
Clinical trials	483,689	452,064	31,625	7.00 %
Other	13,201	18,896	(5,695)	-30.14 %
Total Regulatory	640,289	586,102	54,187	9.25 %
R&D Other than Regulatory:				
Wages and related costs	471,925	475,277	(3,352)	-0.71 %
Consulting	5,000	500	4,500	900.00 %
Stock-based compensation	33,166	10,318	22,848	221.44 %
Materials and supplies	155,208	158,848	(3,640)	-2.29 %
Other	73,543	59,097	14,446	24.44 %
Total other than Regulatory	\$ 738,842	704,040	34,802	4.94 %
Total Research and Development	\$ 1,379,131	\$ 1,290,142	\$ 88,989	6.90 %

Expenses for Clinical & Regulatory Affairs for the three months ended March 31, 2012 increased by \$54,000 as compared to the same period in 2011. This was primarily due to approximately \$428,000 of expenses in 2012 for clinical trials primarily conducted for our DPP® HIV Screen Assay (Clinical trial expenses before the correction were approximately \$294,000 - please see note 2(g) of our 10-Q for further explanation) as well as Pre-IDE market studies that were conducted related to our Sure Check HIV and that are required prior to initiating clinical trials for a potential submission of this product to the FDA for approval for consumer self-testing. These expenses together accounted for an increase of approximately \$32,000 over the 2011 period, as did increased stock-based compensation of approximately \$13,000, which was partially offset by decreases in other expenses.

R&D expenses other than Clinical & Regulatory Affairs increased by \$35,000 in the three months ended March 31, 2012 as compared with the same period in 2011 and were primarily related to an increase in stock-based compensation partially offset by a decrease in wages and related costs and material and supplies.

Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended			
	March 31, 2012	March 31, 2011	\$ Change	% Change
Wages and related costs	\$ 356,669	\$ 269,398	\$ 87,271	32.39 %
Consulting	63,569	37,571	25,998	69.20 %
Commissions	289,494	65,652	223,842	340.95 %

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

Stock-based compensation	70,043	11,549	58,494	506.49	%
Marketing materials	10,457	734	9,723	1324.66	%
Investor relations/investment bankers	46,510	51,029	(4,519)	-8.86	%
Legal, accounting and SOX 404 compliance	158,177	182,900	(24,723)	-13.52	%
Travel, entertainment and trade shows	27,077	12,444	14,633	117.59	%
Bad Debt Allowance	95,000	(15,000)	110,000	-733.33	%
Other	116,972	159,094	(42,122)	-26.48	%
Total S, G &A	\$ 1,233,968	\$ 775,371	\$ 458,597	59.15	%

Selling, general and administrative expenses for the three months ended March 31, 2012, increased by \$459,000 as compared with the same period in 2011. The primary factor of this increase was commissions of \$224,000 due to increased sales to Brazil as well as an increase in bad debt allowance of \$110,000 due to uncertainty of collectability from a customer. In addition, the following expense categories experienced a decrease: investor relations, professional fees and other expenses. The following expense categories experienced an increase of greater than \$50,000: wages and related expenses (partially as a result of accruing year-end bonuses on a quarterly basis) and share-based compensation (primarily from options issued to executives).

Other Income and (Expense):

	For the three months ended		\$ Change	% Change
	March 31, 2012	March 31, 2011		
Other income (expense)				
Interest income	1,519	1,310	209	15.95 %
Interest expense	(2,441)	(4,436)	1,995	-44.97 %
Total Other Income and (Expense)	\$ (922)	\$ (3,126)	\$ 2,204	-70.51 %

Other expense for the three months ended March 31, 2012 decreased approximately \$2,000, to \$922 from \$3,126 as compared with the same period in 2011, primarily as a result of 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.

Income Taxes:

During 2011, the Company reversed its valuation allowance, in regard to net operating loss (NOL) carryforwards, previously recorded against its deferred tax assets. As such the Company now records an income tax expense (benefit) for income (loss) for periods starting after December 31, 2011. The Company uses the rate reconciliation calculated from its 2011 note 10 of 39.7% (after removing the change in valuation benefit). As per IRS rules only 90% of the loss can be offset by NOLs and therefore 39.7%, or \$285,400 was expensed 3.97%, or \$28,500 was added to accrued expenses and the balance of 35.73%, or \$256,900, reduced the carrying value of the deferred tax asset.

MATERIAL CHANGES IN FINANCIAL CONDITION

Selected Changes in Financial Condition	As of		\$ Change	% Change
	March 31, 2012	December 31, 2011		
Cash and cash equivalents	\$ 2,954,276	\$ 3,010,954	\$ (56,678)	-1.88 %
Accounts receivable, net of allowance for doubtful accounts of \$125,000 and \$30,000 for 2012 and 2011, respectively	3,616,720	2,998,449	618,271	20.62 %
Inventories	2,706,676	2,300,286	406,390	17.67 %
Prepaid expenses and other current assets	755,082	681,893	73,189	10.73 %
Deposits on manufacturing equipment	201,846	139,790	62,056	44.39 %
Accounts payable and accrued liabilities	3,081,694	2,789,500	292,194	10.47 %

Cash decreased by \$57,000 from December 31, 2011, primarily due to the increase of accounts receivable by \$713,000 along with an increase in inventories of \$406,000, an increase in fixed assets and deposits of \$224,000 (see table below) and an increase in prepaid assets of \$73,000, which was partially offset by net income, net of noncash items, of \$1,050,000, an increase in taxes payable of \$29,000 (not in table above) and an increase in accounts payable

of \$292,000.

The increase in accounts receivable was primarily attributable to a large amount of credit sales at the end of March 2012, which have been collected in April 2012. 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 second quarter of 2012.

LIQUIDITY AND CAPITAL RESOURCES

	For the three months ended		\$ Change	% Change
	March 31, 2012	March 31, 2011		
Net cash provided by operating activities	\$ 149,226	\$ 1,560,142	\$ (1,410,916)	-90.44 %
Net cash used in investing activities	(223,716)	(46,358)	(177,358)	382.59 %
Net cash provided by (used in) financing activities	17,812	(853,032)	870,844	-102.09 %
(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	\$ (56,678)	\$ 660,752	\$ (717,430)	-108.58 %

The Company's cash decreased for the three months ended March 31, 2012 by \$57,000 as compared to an increase in cash for the same period in 2011 of \$661,000. The decrease in the 2012 period is enumerated above under Material Changes in Financial Condition. The increase during the 2011 period are primarily attributable to the change in receivables of \$2.23 million, along with non-cash expenses aggregating \$125,000 and a decrease in other assets of \$29,000 partially offset by an increase in accruals and payables of \$443,000 and an increase in inventories of \$243,000. The increase in the 2012 period includes noncash items from the change in deferred tax assets of \$257,000. The Company's non-cash expenses totaled \$616,000, which consisted of \$130,000 from depreciation and amortization expense, \$257,000 in deferred tax assets, \$95,000 in provision for doubtful accounts and \$135,000 in share-based compensation expense.

Fixed Asset Commitments

As of March 31, 2012, the Company had paid deposits on various pieces of equipment aggregating \$201,846, which is reflected in Other Assets on the balance sheet. The Company is further committed to additional equipment-purchase obligation of \$224,834 as various milestones are achieved by the various vendors.

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

In the quarter ended March 31, 2012, Chembio experienced record product sales and gross margin as compared both with the directly comparable period of the first quarter of 2011 as well as with the record fourth quarter of 2011. 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.

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 2011 period) and a 22% increase in sales to Alere of our two FDA-approved rapid HIV tests, from \$2.05 million in the comparable 2011 period, to \$2.50 million. The 3,000 patient study we commenced in 2010 in support of a Pre-Marketing Application approval for our DPP® HIV Screening Assay for use with oral fluid or blood samples is complete. We expect to submit the third and final module of the PMA to the FDA in June. Within 180 days we expect that the FDA will respond to our PMA application. The intent of the modular submission is to increase the possibility that we will receive such response sooner than the 180 day statutory period though this is not required and cannot be assured. Nevertheless, we believe that we will submit and get this response well within the 2012 calendar year.

As a result of our having received a CE Mark for our Syphilis Screen & Confirm product in the third quarter of 2011 and our business development efforts during the fourth quarter of 2011, we are establishing European distributors for this product. Product evaluations are ongoing in France and the UK. We are initiating studies to determine the regulatory pathway in the U.S. market.

The Company has a number of new product opportunities and new product features that could result in new revenue streams in future periods. In each case these would utilize our patented DPP® platform to develop proprietary products, and could also combine additional proprietary features such as biomarkers in collaboration with others or other features we may add to our platform technology. These products will be developed either under the Chembio DPP® brand or the brands of potential OEM customers that incorporate our DPP® trademark. We are working on a number of new potential projects in this regard and in some cases conducting feasibility studies. These include potential products with application to the areas of women's health, veterinary diagnostics, and blood viruses. We believe that these projects can ultimately result in potential new revenue streams in future periods, although there can be no assurance of this.

In the meantime, based on substantially increased revenues that are anticipated this year from our DPP® OEM products with FIOCRUZ in Brazil, combined with even modest growth in the U.S. rapid HIV test market and/or our market share with our FDA-approved rapid HIV tests marketed by Alere, as well as possible gains from existing and/or new international distributors for our lateral flow and DPP® products, we anticipate strong improvements to our revenues and net income in 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 2012 fiscal three months that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 6. 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 Employee Option Agreement. (3)
4.2	1999 Equity Incentive Plan. (4)
4.3	2008 Stock Incentive Plan. (5)
4.4	Rights Agreement, dated March 8, 2010 (6)
4.5	Form of Warrant (to be filed by amendment) [to be revised]
10.1*	Employment Agreement dated June 15, 2006 with Lawrence A. Siebert. (7)
10.2*	Employment Agreement dated March 5, 2010 with Javan Esfandiari. (8)
10.3	HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Alere and StatSure. (9)
10.4	HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (9)
10.5	Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (9)
10.6	Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (9)
10.7	Secured Term Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (10)
10.8	Secured Revolving Demand Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (10)
10.9	Loan and Security Agreement, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (10)
10.10	Revolving Term Note, dated as of July 22, 2011, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (11)
10.11	Loan and Security Agreement, dated as of July 22, 2011, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (11)
14.1	Ethics Policy (12)
21	List of Subsidiaries
23.1	Consent of BDO USA, LLP, Independent Registered Public Accountants.
23.2	Consent of ParenteBeard LLC, Independent Registered Public Accountants.
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.DEF	XBRL Taxonomy Definition Linkbase Document
101.LAB	XBRL Taxonomy Label Linkbase Document
101.PRE	XBRL Taxonomy 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.

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

- 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 annual report on Form 10-KSB filed with the Commission on March 12, 2008.
- 4 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on May 11, 2005.
- 5 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on April 14, 2008.
- 6 Incorporated by reference to the Registrant's registration statement on Form 8-A filed with the Commission on March 11, 2010.
- 7 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 21, 2006.
- 8 Incorporated by reference to the Registrant's registration statement on Form S-1/A filed with the Commission on March 11, 2010.
- 9 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.
- 10 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on July 29, 2010.
- 11 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on November 3, 2011.
- 12 Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 30, 2006.
- (*) 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 document.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Chembio Diagnostics, Inc.

Date: May 8, By: /s/ Lawrence A. Siebert
2012

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

Date: May 8, By: /s / Richard J. Larkin
2012

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