

CHEMBIO DIAGNOSTICS, INC.  
Form 10-Q  
May 09, 2013

---

---

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, 2013

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer”, “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (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 May 8, 2013, the Registrant had 9,286,114 shares outstanding of its \$.01 par value common stock.



Quarterly Report on FORM 10-Q  
For The Quarterly Period Ended  
March 31, 2013

Table of Contents

Chembio Diagnostics, Inc.

	Page
<b>Part I. FINANCIAL INFORMATION:</b>	
<b>Item 1. Financial Statements:</b>	
Condensed Consolidated Balance Sheets as of March 31, 2013 (unaudited) and December 31, 2012.	2
Condensed Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2013 and 2012.	3
Condensed Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2013 and 2012.	4
Notes to Condensed Consolidated Financial Statements (unaudited)	5 to 12
<b>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</b>	<b>13</b>
<b>Item 4. Controls and Procedures</b>	<b>23</b>
<b>Part II. OTHER INFORMATION:</b>	
<b>Item 6. Exhibits</b>	<b>23</b>
<b>SIGNATURES</b>	<b>25</b>
<b>EXHIBITS</b>	



## PART I

## Item 1. FINANCIAL STATEMENTS

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

## - ASSETS -

	March 31, 2013 (Unaudited)	December 31, 2012
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 2,598,745	\$ 2,951,859
Accounts receivable, net of allowance for doubtful accounts of \$24,000 and \$58,000 at March 31, 2013 and December 31, 2012, respectively	5,278,702	4,821,357
Inventories	2,601,489	2,488,071
Prepaid expenses and other current assets	754,648	747,463
<b>TOTAL CURRENT ASSETS</b>	<b>11,233,584</b>	<b>11,008,750</b>
<b>FIXED ASSETS, net of accumulated depreciation</b>		
	1,656,299	1,427,646
<b>OTHER ASSETS:</b>		
Deferred tax asset, net of valuation allowance	4,079,807	4,233,194
License agreements, net of current portion	375,000	400,000
Deposits on manufacturing equipment	86,679	223,584
Deposits and other assets	41,976	41,976
<b>TOTAL ASSETS</b>	<b>\$ 17,473,345</b>	<b>\$ 17,335,150</b>

## - LIABILITIES AND STOCKHOLDERS' EQUITY -

<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 3,189,661	\$ 3,303,923
Current portion of loans payable	-	51,236
Customer deposits	23,224	23,224
<b>TOTAL CURRENT LIABILITIES</b>	<b>3,212,885</b>	<b>3,378,383</b>
<b>OTHER LIABILITIES:</b>		
Loans payable - net of current portion	-	82,247
<b>TOTAL LIABILITIES</b>	<b>3,212,885</b>	<b>3,460,630</b>

COMMITMENTS AND  
CONTINGENCIES

## STOCKHOLDERS' EQUITY:

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

Preferred stock – 10,000,000 shares authorized, none outstanding	-	-
Common stock - \$.01 par value; 100,000,000 shares authorized, 8,086,114 and 8,036,232 shares issued and outstanding for March 31, 2013 and December 31, 2012, respectively	80,861	80,362
Additional paid-in capital	41,184,467	41,116,149
Accumulated deficit	(27,004,868 )	(27,321,991 )
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>14,260,460</b>	<b>13,874,520</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 17,473,345</b>	<b>\$ 17,335,150</b>

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, 2013	March 31, 2012
<b>REVENUES:</b>		
Net product sales	\$ 6,313,190	\$ 6,363,152
R&D, milestone and grant revenue	364,963	290,100
<b>TOTAL REVENUES</b>	<b>6,678,153</b>	<b>6,653,252</b>
Cost of product sales	3,984,263	3,320,388
<b>GROSS MARGIN</b>	<b>2,693,890</b>	<b>3,332,864</b>
<b>OPERATING EXPENSES:</b>		
Research and development expenses	1,045,259	1,379,131
Selling, general and administrative expenses	1,162,080	1,233,968
	2,207,339	2,613,099
<b>INCOME FROM OPERATIONS</b>	<b>486,551</b>	<b>719,765</b>
<b>OTHER INCOME (EXPENSE):</b>		
Interest income	1,337	1,519
Interest expense	(335 )	(2,441 )
	1,002	(922 )
<b>INCOME BEFORE INCOME TAXES</b>	<b>487,553</b>	<b>718,843</b>
Income tax provision	170,430	285,400
<b>NET INCOME</b>	<b>\$ 317,123</b>	<b>\$ 433,443</b>
Basic earnings per share	\$ 0.04	\$ 0.05
Diluted earnings per share	\$ 0.04	\$ 0.05
Weighted average number of shares outstanding, basic	8,062,984	7,934,331
Weighted average number of shares outstanding, diluted	8,699,209	8,512,374
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, 2013	March 31, 2012
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Cash received from customers and grants	\$ 6,220,808	\$ 6,034,981
Cash paid to suppliers and employees	(6,164,372 )	(5,884,833 )
Interest received	1,337	1,519
Interest paid	(335 )	(2,441 )
Net cash provided by operating activities	57,438	149,226
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of and deposits on fixed assets	(207,507 )	(223,716 )
Net cash used in investing activities	(207,507 )	(223,716 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from option and warrant exercises	17,955	42,750
Expenses from sale of common stock	(87,517 )	-
Payment of loan obligation	(133,483 )	(14,392 )
Payment of capital lease obligation	-	(10,546 )
Net cash provided by (used in) financing activities	(203,045 )	17,812
<b>(DECREASE) IN CASH AND CASH EQUIVALENTS</b>		
	(353,114 )	(56,678 )
Cash and cash equivalents - beginning of the period	2,951,859	3,010,954
Cash and cash equivalents - end of the period	\$ 2,598,745	\$ 2,954,276
<b>RECONCILIATION OF NET INCOME TO NET CASH PROVIDED BY OPERATING ACTIVITIES:</b>		
Net Income	\$ 317,123	\$ 433,443
<b>Adjustments:</b>		
Depreciation and amortization	140,759	129,947
Provision for deferred taxes	153,387	256,859
(Recovery of) Provision for doubtful accounts	(34,000 )	95,000



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

Share based compensation	138,379	134,633
Changes in assets and liabilities:		
Accounts receivable	(423,345 )	(713,271 )
Inventories	(113,418 )	(406,390 )
Prepaid expenses and other current assets	(7,185 )	(73,189 )
Accounts payable and accrued liabilities	(114,262 )	292,194
Net cash provided by operating activities	\$ 57,438	\$ 149,226

Supplemental disclosures for non-cash investing and financing activities:

Deposits on manufacturing equipment transferred to fixed assets	\$ 208,134	\$ 23,400
---	------------	-----------

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
March 31, 2013  
(UNAUDITED)

NOTE1 — 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 78% of the Company’s product revenues in the first three months of 2013. The Company’s products based on its patented Dual Path Platform (DPP®) platform represented approximately 18% of the Company’s product revenues in the first three months of 2013. The Company also has other rapid tests that together represented approximately 4% of sales in the first three months of 2013. 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 is 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. These products employ lateral flow technologies that are proprietary and/or licensed to the Company. All of the Company’s products that are currently being developed are based on its patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. In December 2012, the Company received FDA approval for its DPP® HIV 1/2 Assay for the detection of HIV antibodies in saliva, whole blood, serum and plasma samples.

NOTE2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

a) Basis of Presentation:

The preceding (a) condensed consolidated balance sheet as of December 31, 2012, which has been derived from audited financial statements, and (b) the unaudited interim condensed consolidated financial statements as of March 31, 2013 and for the three-month periods ended March 31, 2013 and 2012, respectively, 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, 2012, previously filed with the SEC.

On May 30, 2012, the Company effected a 1-for-8 reverse split of its common stock. This was done to allow the Company to move to the NASDAQ trading market from the QTCQB market, which occurred on June 7, 2012. As a result of the stock split, the outstanding 63,967,263 common shares were reduced to 7,995,918 outstanding common shares on May 30, 2012. The effect of the reverse stock split has been retroactively reflected for all periods in these financial statements.

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, 2013, its condensed

consolidated results of operations for the three-month periods ended March 31, 2013 and 2012, respectively, and its condensed consolidated cash flows for the three-month periods ended March 31, 2013 and 2012, 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.

## CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2013

(UNAUDITED)

## b) Revenue Recognition

The Company recognizes revenue for product sales in accordance with ASC 605, which provides that 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, 2013 and December 31, 2012, 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.

## c) Inventories:

Inventories consist of the following at:

	December 31,	
	March 31, 2013	2012
Raw materials	\$ 1,406,094	\$ 1,418,071
Work in process	762,401	561,530
Finished goods	432,994	508,470
	\$ 2,601,489	\$ 2,488,071

## d) Earnings Per Share:

On May 30, 2012, the Company effected a 1-for-8 reverse split of its common stock. This was done to allow the Company to move to the NASDAQ trading market from the OTCQB market, which occurred on June 7, 2012. As a result of the stock split, the outstanding 63,967,263 common shares were reduced to 7,995,918 outstanding common shares on May 30, 2012. The effect of the reverse stock split has been retroactively reflected for all periods in these financial statements.

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 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, 2013 and 2012, have been included in the earnings per share computations:

	For the three months ended	
	March 31, 2013	March 31, 2012
Basic	8,062,984	7,934,331
Diluted	8,699,209	8,512,374

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

The following securities, presented on a common share equivalent basis for the three- month periods ended March 31, 2013 and 2012, have been included in the diluted per share computations as the exercise process of these securities were less than the stock price as of March 31, 2013 and 2012, respectively:

	For the three months ended	
	March 31, 2013	March 31, 2012
1999 and 2008 Plan Stock Options	636,225	578,043

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
March 31, 2013  
(UNAUDITED)

There were 118,360 and 198,278 options outstanding as of March 31, 2013 and 2012, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended March 31, 2013 and 2012, respectively, because the effect would have been anti-dilutive as of March 31, 2013 and 2012, respectively.

e) Employee Stock Option Plan:

The Company had a 1999 Stock Option Plan (“SOP”). The total number of options available under the SOP was 375,000. As of March 31, 2013, there were 93,750 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 625,000 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 125,000 to 750,000. 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 be 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, 2013, there were 105,551 options exercised, 618,439 options outstanding and 26,010 options or shares 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 March 31, 2013 and 2012 was \$4.08 and \$3.20 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 based on historical information.

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

	For the three months ended			
	March 31, 2013		March 31, 2012	
Expected term (in years)	4.8		5	
Expected volatility	100.91	%	115.77	%
Expected dividend yield	0	%	0	%
Risk-free interest rate	0.57	%	0.36	%

The Company's results for the three-month periods ended March 31, 2013 and 2012 include share-based compensation expense totaling \$138,000 and \$133,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$30,000 and \$15,000, respectively), research and development (\$40,000 and \$48,000, respectively) and selling, general and administrative expenses (\$68,000 and \$70,000, 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, 2013 and 2012 is based on the estimated fair value, at the date of issuance, 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.

7

---

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
March 31, 2013  
(UNAUDITED)

The following table provides stock option activity for the three months ended March 31, 2013:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2012	731,646	\$ 2.12	2.19 years	\$ 3,460,686
Granted	46,360	\$ 5.48		
Exercised	(64,359 )	\$ 1.50		
Forfeited/expired/cancelled	(1,458 )	\$ 1.04		
Outstanding at March 31, 2013	712,189	\$ 2.39	2.34 years	\$ 1,892,082
Exercisable at March 31, 2013	474,867	\$ 1.60	1.61 years	\$ 1,637,100

As of March 31, 2013, there was \$356,000 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 .80 years. The total fair value of stock options vested during the three-month periods ended March 31, 2013 and 2012 was approximately \$90,000 and \$104,000, 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	
	March 31, 2013	March 31, 2012
Africa	\$ 847,322	\$ 1,077,736
Asia	19,266	12,478
Europe	7,605	25,578
North America	2,819,519	2,720,760
South America	2,619,478	2,526,600
	\$ 6,313,190	\$ 6,363,152



CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
March 31, 2013  
(UNAUDITED)

## g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

	March 31, 2013	December 31, 2012
Accounts payable – suppliers	\$ 1,452,610	\$ 1,686,431
Accrued commissions	262,549	238,150
Accrued royalties / license fees	758,047	583,923
Accrued payroll	158,173	262,439
Accrued vacation	217,008	181,636
Accrued bonuses	162,750	155,663
Accrued expenses – other	178,524	195,681
<b>TOTAL</b>	<b>\$ 3,189,661</b>	<b>\$ 3,303,923</b>

## NOTE3 — 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 none and \$155,000 for the three-month periods ended March 31, 2013 and 2012, respectively from this grant. The Company earned an aggregate of \$2,756,000 from this grant from inception through March 31, 2013, of which \$898,000 was paid to sub-contractors.

In March 2011, the Company received a \$2.9 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 \$192,000 and \$125,000 for the three-month periods ended March 31, 2013 and 2012, respectively from this grant. The Company earned \$1,644,000 from this grant from inception through March 31, 2013 of which \$419,000 was paid to sub-contractors.

## b) Battelle/CDC DPP® Influenza Immunity Test:

In July 2012, the Company entered into a follow-on, milestone-based development agreement of up to \$480,000 based on Chembio's previous successful initial development of a multiplex rapid point-of-care ("POC") influenza immunity test utilizing its patented Dual Path Platform (DPP®) technology. The agreement contemplates a period of approximately nine months in which the follow-on development activity is to be completed. The Company earned \$166,000 and none for the three-month periods ended March 31, 2013 and 2012, respectively from this agreement. The Company earned \$444,000 from this grant from inception through March 31, 2013.

NOTE4 — LOANS 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. In January 2013, the Company repaid this Term Note in full without penalty.

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 an annual 30-day clean-up, during which there can be no amounts outstanding.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
March 31, 2013  
(UNAUDITED)

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, and 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, 2013.

The Company currently maintains its operating, payroll, and primary cash accounts at HSBC. There was no balance due on the Term Note as of March 31, 2013, and as of March 31, 2013 nothing had been drawn down on the Demand Note.

NOTE5 — 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, 2013  
(UNAUDITED)

## NOTE6 — COMMON STOCK, WARRANTS AND OPTIONS:

On February 26, 2013, the Company issued 16,360 options to purchase common stock to executives of the Company as part of their 2012 bonus. The options are exercisable immediately at \$5.56 per share, which was the last traded price of the common stock on that day, and they expire five years from the date of issue.

The Company entered into an employment agreement effective March 5, 2013 (“Employment Agreement”), with Mr. Esfandiari to continue as the Company's Senior Vice President of Research and Development which included issuing incentive stock options to purchase 30,000 shares of the Company's common stock. Of these stock options, options to purchase 10,000 shares vest on each of the first three anniversaries of the effective date of the Employment Agreement. The exercise price for these options was to be equal to the last traded price for the Company's common stock on March 5, 2013, which was \$5.56 per share. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the effective date of the grant.

As of March 31, 2013, the Company had no warrants outstanding to purchase shares of common stock.

## NOTE7 — COMMITMENTS, CONTINGENCIES, AND CONCENTRATIONS:

## a) Economic Dependency:

The following table discloses product sales the Company had to each customer that purchased in excess of 10% of the Company's net product sales for the periods indicated:

	For the three months ended				Accounts Receivable As of	
	March 31, 2013		March 31, 2012		March 31, 2013	March 31, 2012
	Sales	% of Sales	Sales	% of Sales		
Customer 1	\$ 2,589,954	41	\$ 2,503,739	39	\$ 1,160,188	\$ 850,482
Customer 2	1,218,875	19	2,516,000	40	1,154,160	1,319,247
Customer 3	1,189,137	19	*	*	1,189,137	*

(\*) Product sales 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 each vendor that sold to the Company in excess of 10% of the Company's total purchases for the periods indicated:

	For the three months ended				Accounts Payable As of	
	March 31, 2013		March 31, 2012		March 31, 2013	March 31, 2012
	Purchases	% of Purc.	Purchases	% of Purc.		

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

Vendor 1	*	*	\$ 177,637	13	*	\$ 32,385
Vendor 2	*	*	140,654	10	*	121,853

(\*) Purchases did not exceed 10% for the period indicated

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

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
March 31, 2013  
(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 \$590,000 per year. The Esfandiari contract expires in March 2016 and as of March 31, 2013, the Siebert employment contract expired in May 2013. On April 19, 2013, the term was extended to May 2014. In connection with the contract that expires in March 2016, the Company issued, in March 2013, 30,000 options to purchase common stock, with one-third vesting on each of the first, second and third anniversaries of the grant.

NOTE8 — INCOME TAXES:

The Company's interim provision for income taxes is measured using an estimated annual effective tax rate of 35.1% based on the 2012 statements. As per IRS rules, only 90% of the taxable income can be offset by NOLs, and therefore 3.5%, or \$17,043, was added to accrued expenses, 35.1%, or \$170,430, was expensed, and the balance of 31.6%, or \$153,387, reduced the carrying value of the deferred tax asset for the three months ended March 31, 2013.

NOTE9 — SUBSEQUENT EVENTS:

The Company closed on an underwritten public offering of 1,200,000 shares of its common stock on April 3, 2013. The price per share of common stock sold in the offering was \$5 per share. The net proceeds of the offering, after deducting the underwriters' discounts and other estimated offering expenses payable by the Company, was approximately \$5,450,000. The Company intends to use the net proceeds for business expansion and working capital.

On April 19, 2013, the Company and its Chief Executive Officer (CEO) agreed to extend the term of the CEO's employment contract from May 2013 to May 2014 with the annual salary remaining the same.

On April 30, 2013, the Company entered into a new demand loan agreement ("Demand Note") with a commercial bank. The Demand Note allows the Company to draw on the line from time to time an amount up to an aggregate of \$2,000,000 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 for which the bank lender can demand repayment of the entire loan, with accrued interest, at any time. The loan is subject to annual reviews, as well as an annual 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, and restrictions on fundamental changes in the Company and in its business.



## 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 have not changed significantly from December 31, 2012.

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.

All of the Company's future products that are currently being developed are based on its patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. The Company has completed development of several products that employ the DPP® technology, three of which will be marketed under Chembio's label (DPP® HIV 1/2 Screening Assay, DPP® Syphilis Screen & Confirm, and DPP® HIV 1/2 –Syphilis Assay) and several others that have been developed specifically related to private label agreements with The Oswaldo Cruz Foundation ("FIOCRUZ") for the Brazilian public health market, as explained below.

All of the Company's products other than its lateral flow tests are based on the Company's patented Dual Path Platform (DPP®) technology. The Company has had very active research and development programs and has significantly increased its spending on research and development during the last three years. Third-party funding from research and development contracts and grants have offset a significant portion of these increased research and development expenses. The Company has a number of products under development that employ the DPP® technology. The principal product development activities are described below.

DPP® Hepatitis-C (HCV) Multiplex Test – Development work on our DPP® HCV point-of-care rapid test continues. Our development activity has been focused on creating a differentiated product that is capable of identifying active infection versus one that only identifies a simple antibody response, which is all the currently available point-of-care test is able to do. This is because of the fact that up to 30% of patients that are HCV antibody-positive don't have an active infection. We have in fact identified a possible method for doing this in our DPP® point-of-care technology, and we hope to make progress on combining this method with our system during the second and third quarters. If we are able to achieve this then we could complete product development during the first quarter of 2014.

In July 2012, the U.S. Centers for Disease Control finalized the recommendations for testing all individuals in the United States between the ages of 45 and 65 for HCV, which age cohort represents a substantial portion of the estimated over three million individuals in the United States that are infected with HCV infection but unaware. With a number of new anti-retroviral therapies approved, and even more pending approval in the years ahead by the FDA, we believe that over time these new recommendations will be implemented. However, it is unclear how much of these recommendations will be funded by public health programs or under the Affordable Care Act. Regardless if these recommendations are implemented, we believe that they will take time to be funded.

**DPP® HIV Multiplex Antigen-Antibody Test** - We have begun development work on a DPP® HIV multiplex test that is being designed to detect acute (early stage) HIV infection by means of detecting P24 antigen, as well as antibodies, to HIV1/2, in whole blood samples. There are no FDA-approved point-of-care tests that detect acute HIV infection, although there are two FDA approved laboratory tests with such claims. However neither of those products differentiates between P24 antigen and antibodies. We believe that development of such a test in our patented DPP® point-of-care platform may help identify HIV infections that cannot currently be identified by any of the currently FDA-approved rapid HIV tests and thus serve an unmet market need and may help to maintain and potentially grow the already strong position our products have in the U.S. rapid HIV test market.

**Other Potential Products and Collaborations** - We are currently completing development of certain other products for single parameter and multiplex tests, utilizing our patented DPP®. We also are discussing exclusive collaborations for these products, or proprietary components thereof, with certain potential international partners that, if consummated, would provide us with local assembly and distribution, a co-branded DPP® product in the designated market, and a more meaningful stake in the success of the distribution program.

#### Sponsored Research & Development

**Multiplex Influenza Immunity Test** – In July 2012 we entered into a follow-on, milestone-based development agreement of up to \$480,000 based on our previous successful initial development of a multiplex rapid point-of-care (“POC”) influenza immunity test utilizing our patented Dual Path Platform (DPP®) technology. The agreement contemplates a period of approximately six months in which the follow-on development activity is to be completed. In the first quarter of 2013 we completed the requirement of this agreement, and we anticipate an additional development agreement will be entered in 2013.

We entered this agreement with a private contracting organization that is engaged to enter into, implement and provide technical oversight of agreements relating to pandemic preparedness on behalf of its client, the United States Centers for Disease Control and Prevention (“CDC”).

**DPP® Tuberculosis** – In February 2011, we were awarded a three-year \$2.9 million, Small Business Innovative Research (SBIR) Phase II grant from the United States National Institutes of Health (NIH) to continue our successful Phase I grant work to develop a simple, rapid, accurate, and cost-effective serological test for active tuberculosis that can be utilized in resource-limited settings. During 2012, several additional antigens were identified to enhance antibody detection by the DPP® test prototype designed in our Phase I studies. Antigen reagents have been finalized and test prototype evaluation using well-characterized clinical specimens is in progress. Funding for the third and final year of this Phase II grant was confirmed with a reduction of approximately 1%.

In addition to the above-mentioned research and development work sponsored by governmental agencies and/or their contractors for the influenza and tuberculosis projects, we are discussing additional opportunities for sponsored research and development activity. We endeavor to select sponsored research projects where we believe there is an identifiable commercial opportunity and/or where other benefits to the Company are anticipated in connection with these projects.

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 any of them profitably.

## Regulatory Activities

CE Mark for FDA-approved HIV tests – We were audited by our notified body in September and our technical file is being reviewed. We had an additional meeting concerning this in March during which we believe substantial progress was made. We expect a decision on CE Marking of these products soon.

FDA Approval for DPP® HIV 1/2 Screening Assay for Use with oral fluid or blood samples – We received FDA approval of our Pre-Marketing Application (PMA) for this product on December 19, 2012 as we previously announced. We are now working towards a CLIA waiver with the expectation that it will be granted before the end of 2013. As we have reported, we initiated the CLIA study in April, and our plan is still to have the submission into the FDA by July, and to receive a CLIA waiver during the fourth quarter.

### DPP® Syphilis Screen & Confirm -

In late February we received a response from the FDA that will enable us to pursue the regulatory pathway that we outlined in our submission. However there were some questions that we have concerning the FDA response and we intend to have those clarified in a meeting being scheduled in May 2013. While we confirm our intended study approach with the FDA, we are completing our protocol, have identified three clinical sites with the expectation that we will commence the studies, and expect to have an FDA clearance by mid-2014.

DPP® HIV-Syphilis – We have submitted this product for evaluation by the CDC, and the WHO has accepted this product to be evaluated for pre-qualification in its global procurement scheme. Other international registrations are pending. We have received very encouraging results thus far. We recently submitted a guidance request to the FDA for determining the pathways for getting this multiplex combination product approved/cleared by the FDA. We plan to initiate the syphilis studies (the HIV component of this test is already approved pursuant to the PMA approval received in December 2012), upon receiving feedback from the FDA on our study design protocols.

SURE CHECK® HIV OTC Study - We completed the self-testing study to meet the requirements for submitting an IDE (“Investigational Device Exemption”) application in order to commence clinical trials for this product in 2013. The IDE application can be filed now and we plan to do this soon. Thereafter, assuming the IDE is granted, the Phase II observed user clinical trials could be commenced during 2013 and the pivotal trial could be completed during 2014. This would enable a PMA approval by late-2015.

However, we believe that the development of this market will take time, and that its development will likely require OraSure to invest significantly in its development, as it is now. Orasure’s first two quarters of results for this product did nothing to change this expectation. Although we still believe that Chembio is the only other company that for all practical purposes has a product that can participate in this new market, we have serious reservations about the size of the opportunity, particularly in relation to the significant investment of funds required in order to achieve regulatory approval and then commercialize the product. Nevertheless, because OraSure’s product was approved with lower sensitivity than was previously expected by the FDA, this provides an opportunity for Chembio’s product(s) to achieve improved performance – either with its blood and/or oral fluid HIV tests. We believe it is critical to go to this market with a substantially improved sensitivity and comparable specificity to OraSure’s product, and a lower price (which would include lower packaging and distribution costs as compared with Orasure), and our current efforts are focused in this direction.

There can be no assurance that any of the aforementioned Research & Development and/or Regulatory products or activities will result in any product approvals or commercialization, 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.

## Recent Events

In April of 2013, the Company closed an underwritten public offering of 1,200,000 shares of its common stock. The price per share of common stock sold in the offering was \$5 per share. The net proceeds of the offering, after deducting the underwriters' discounts and other estimated offering expenses payable by the Company, was approximately \$5,450,000.

On April 19, 2013, the Company and its Chief Executive Officer (CEO) agreed to extend the term of the CEO's employment contract from May 2013 to May 2014 with the annual salary remaining the same.

On April 30, 2013, the Company entered into a new demand loan agreement (“Demand Note”) with a commercial bank. The Demand Note allows the Company to draw on the line from time to time an amount up to an aggregate of \$2,000,000 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 for which the bank lender can demand repayment of the entire loan, with accrued interest, at any time. The loan is subject to annual reviews, as well as an annual 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, and restrictions on fundamental changes in the Company and in its business.

#### 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, 2012, see our Annual Report on Form 10-K for the twelve months ended December 31, 2012, which was filed with the SEC on March 7, 2013.

## RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2013 AS COMPARED WITH THE THREE MONTHS ENDED MARCH 31, 2012

## Income:

Income before income taxes for the three months ended March 31, 2013 decreased to \$488,000 from \$719,000 for the three months ended March 31, 2012. Net Income decreased from \$433,000 for 2012 to \$317,000 for 2013. The decrease in net income is primarily attributable to increased cost of products sold. In 2013, as a result of a .79% decrease in Net Product sales and a 25.8% increase in non-product revenues along with a 20% increase in cost of products sold, the Company had a \$639,000, or 19%, decrease in its gross margin, to \$2,694,000. This decreased gross margin was partially offset by decreased operating expenses, the most significant of which was a decrease in clinical trial expenses of \$386,000 as well as a decrease in commissions of \$130,000, due to the decreased sales in Brazil.

## Revenues:

## Selected Product

## Categories:

	For the three months ended		\$ Change	% Change	
	March 31, 2013	March 31, 2012			
Lateral Flow HIV Tests and Components	\$ 4,934,154	\$ 3,675,022	\$ 1,259,132		34.26 %
DPP Tests and Components	1,142,835	2,518,913	(1,376,078 )		-54.63 %
Other	236,201	169,217	66,984		39.58 %
Net Product Sales	6,313,190	6,363,152	(49,962 )		-0.79 %
License and royalty revenue	-	-	-		100.00 %
R&D, milestone and grant revenue	364,963	290,100	74,863		25.81 %
Total Revenues	\$ 6,678,153	\$ 6,653,252	\$ 24,901		0.37 %

Revenues for our lateral flow HIV tests and related components during the three months ended March 31, 2013 increased by approximately \$1,259,000 from the same period in 2012. This was attributable to increased sales to South America, excluding Brazil, of \$1,388,000 and increased sales to Alere from \$2,504,000 during the three months ended March 31, 2012 to \$2,590,000 during the three months ended March 31, 2013, these increases were partially offset by decreased sales to Africa of \$230,000. Revenues for our DPP® products during the three months ended March 31, 2013 decreased by approximately \$1,376,000 over the same period in 2012, a decrease of 55%, which decrease is attributable to the delayed launch of programs in Brazil for our DPP® products. The increase in R&D, milestone and grant revenue was due to revenue from certain development projects granted in the fourth quarter of 2012. R&D revenues include funds, recognized on an “as expenses are incurred” basis, from a Phase II NIH grant for Leptospirosis, which was effective as of June 1, 2009, and from a Phase II grant for Tuberculosis which was effective March 1, 2011 as well as a development contract with Battelle entered into in the fourth quarter of 2012.

## Gross Margin:

## Gross Margin related to Net Product Sales:

	For the three months ended		\$ Change	% Change	
	March 31, 2013	March 31, 2012			



Gross Margin per Statement of Operations	\$	2,693,890	\$	3,332,864	\$	(638,974 )	-19.17	%
Less: R&D, milestone, grant, license and royalties		364,963		290,100		74,863	25.81	%
Gross Margin from Net Product Sales	\$	2,328,927	\$	3,042,764	\$	(713,837 )	-23.46	%
Product Gross Margin %		36.89	%	47.82	%			

The gross margin dollar decrease of \$639,000 included a 23.5% decrease in gross margin from product sales, partially offsetting a 25.8% increase in non-product revenues. The 11% decrease in our product gross margin percentage, from 47.82% in 2012 to 36.89% in 2013, was primarily due to increased costs in our operations support group, incoming freight, overhead costs related to adding additional shifts (such as additional supervision, QC, etc.) and other costs together with a change in the product sales mix. Some of the product mix change was due to the decreased sales to Brazil as a percentage of overall sales from 39.6% to 18%. Partially offsetting these increased costs was a decrease in our scrap expenses as we focused on this area after the higher scrap experienced at the end of 2012.

## Research and Development:

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

## Selected expense

lines:

	For the three months ended		\$ Change	% Change	
	March 31, 2013	March 31, 2012			
<b>Clinical and Regulatory Affairs:</b>					
Wages and related costs					
	\$ 105,491	\$ 123,725	\$ (18,234 )	-14.74	%
Consulting	17,726	4,250	13,476	317.08	%
Stock-based compensation					
	11,605	15,424	(3,819 )	-24.76	%
Clinical trials	97,776	483,689	(385,913 )	-79.79	%
Other	4,349	13,201	(8,852 )	-67.06	%
<b>Total Regulatory</b>	<b>236,947</b>	<b>640,289</b>	<b>(403,342 )</b>	<b>-62.99</b>	<b>%</b>
<b>R&amp;D Other than Regulatory:</b>					
Wages and related costs					
	507,795	471,925	35,870	7.60	%
Consulting	9,837	5,000	4,837	96.74	%
Stock-based compensation					
	28,307	33,166	(4,859 )	-14.65	%
Materials and supplies	181,184	155,208	25,976	16.74	%
Other	81,189	73,543	7,646	10.40	%
<b>Total other than Regulatory</b>	<b>808,312</b>	<b>738,842</b>	<b>69,470</b>	<b>9.40</b>	<b>%</b>
<b>Total Research and Development</b>	<b>\$ 1,045,259</b>	<b>\$ 1,379,131</b>	<b>\$ (333,872 )</b>	<b>-24.21</b>	<b>%</b>

Expenses for Clinical & Regulatory Affairs for the three months ended March 31, 2013 decreased by \$403,000 as compared to the same period in 2012. This was primarily due to the reduction of \$386,000 in clinical trial expenses which were mostly associated with clinical studies for our DPP® HIV 1/2 Assay. These studies were completed during the first half of 2012.

R&D expenses other than Clinical & Regulatory Affairs increased by \$69,000 in the three months ended March 31, 2013, as compared with the same period in 2012, and were primarily related to an increase in wages and related costs and in material and supplies, partially offset by an increase in stock-based compensation.

## Selling, General and Administrative Expenses:

Selected expense lines: For the three months ended

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

	March 31, 2013	March 31, 2012	\$ Change	% Change	
Wages and related costs	\$ 441,472	\$ 356,669	\$ 84,803	23.78	%
Consulting	6,200	63,569	(57,369 )	-90.25	%
Commissions	159,908	289,494	(129,586 )	-44.76	%
Stock-based compensation	68,666	70,043	(1,377 )	-1.97	%
Marketing materials	6,963	10,457	(3,494 )	-33.41	%
Investor relations/investment bankers	74,863	46,510	28,353	60.96	%
Legal, accounting and compliance	240,057	158,177	81,880	51.76	%
Travel, entertainment and trade shows	27,751	27,077	674	2.49	%
Bad debt allowance (recovery)	(33,450 )	95,000	(128,450 )	-135.21	%
Other	169,650	116,972	52,678	45.03	%
Total S, G & A	\$ 1,162,080	\$ 1,233,968	\$ (71,888 )	-5.83	%

Selling, general and administrative expenses for the three months ended March 31, 2013, decreased by \$72,000 as compared with the same period in 2012. The primary factor of this decrease was a \$130,000 decrease in commissions due to decreased sales to Brazil along with a decrease in bad debt allowance of \$128,000 and consulting expenses of \$57,000. The following expense categories experienced an increase of greater than \$30,000, which partially offset the decreases: wages and related expenses, professional fees, investor relations and other expenses which primarily include excise tax expense related to the health care act.

## Other Income and (Expense):

	For the three months ended			
	March 31, 2013	March 31, 2012	\$ Change	% Change
Interest income	\$ 1,337	\$ 1,519	\$ (182 )	-11.98 %
Interest expense	(335 )	(2,441 )	2,106	-86.28 %
Total Other Income and (Expense)	\$ 1,002	\$ (922 )	\$ 1,924	-208.68 %

Other income for the three months ended March 31, 2013 increased approximately \$2,000, to \$1,000 from an expense of \$1,000 as compared with the same period in 2012, primarily as a result of a decrease in interest expense due on the term loan with HSBC.

## Income tax (benefit) provision:

For the three months ended March 31, 2013 the Company charged \$170,000 to income tax expense and reduced its deferred tax assets by \$153,000. The Company still maintains a full valuation allowance on research and development tax credits.

## MATERIAL CHANGES IN FINANCIAL CONDITION

## Selected Changes in Financial Condition

	As of			
	March 31, 2013	December 31, 2012	\$ Change	% Change
Cash and cash equivalents	\$ 2,598,745	\$ 2,951,859	\$ (353,114 )	-11.96 %
Accounts receivable, net of allowance for doubtful accounts of \$24,000 and \$58,000 at March 31, 2013 and December 31, 2012, respectively	5,278,702	4,821,357	457,345	9.49 %
Inventories	2,601,489	2,488,071	113,418	4.56 %
Fixed assets, net of accumulated depreciation	1,656,299	1,427,646	228,653	16.02 %
Deposits on manufacturing equipment	86,679	223,584	(136,905 )	-61.23 %
Deferred tax asset, net of valuation allowance	4,079,807	4,233,194	(153,387 )	-3.62 %
Accounts payable and accrued liabilities	3,189,661	3,303,923	(114,262 )	-3.46 %

Cash decreased by \$353,000 from December 31, 2012, primarily due to an increase in accounts receivable of \$457,000, net fixed assets of \$229,000 and inventories of \$113,000, partially offset by net income, net of non-cash items, of \$57,000, together with the decrease of deposits on fixed assets by \$137,000, a decrease in deferred tax asset of \$153,000, and an increase in accrued expenses and payables of \$114,000.

The increase in accounts receivable was primarily attributable to a larger amount of credit sales at the end of March 2013 versus December of 2012.

## LIQUIDITY AND CAPITAL RESOURCES

	For the three months ended			
	March 31, 2013	March 31, 2012	\$ Change	% Change
Net cash provided by operating activities	\$ 57,438	\$ 149,226	\$ (91,788 )	-61.51 %
Net cash used in investing activities	(207,507 )	(223,716 )	16,209	-7.25 %
Net cash provided by (used in) financing activities	(203,045 )	17,812	(220,857 )	-1239.93 %
(DECREASE) IN CASH AND CASH EQUIVALENTS	\$ (353,114 )	\$ (56,678 )	\$ (296,436 )	523.02 %

The Company's cash decreased by \$353,000 from December 31, 2012, primarily due to increases in accounts receivable, net fixed assets, and inventories, and partially offset by net income, net of non-cash items, of \$57,000 as compared to a decrease in cash for the same period in 2012 of \$57,000. The decrease in the 2013 period is enumerated above under Material Changes in Financial Condition. The decrease in the 2013 period includes non-cash items from the change in deferred tax assets of \$153,000. The Company's other non-cash expenses totaled \$245,000, which consisted of \$141,000 from depreciation and amortization expense and \$138,000 in share-based compensation expense offset by a decrease in accounts receivable allowance of \$34,000. The decrease during the 2012 period is primarily attributable to the acquisition of fixed assets of \$224,000 along with a decrease in receivables of \$713,000, inventories of \$406,000, and prepaid expenses of \$73,000, which were partially offset by a decrease in accounts payable and accruals of \$292,000, along with non-cash expenses aggregating \$616,000.

## Fixed Asset Commitments

As of March 31, 2013, the Company had paid deposits on various pieces of equipment aggregating \$86,679, which is reflected in deposits on manufacturing equipment on the balance sheet. The Company has no further commits for additional equipment-purchase obligations.

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

We are optimistic for continued growth of our FDA-approved lateral flow HIV tests in 2013, which are marketed by Alere under their Clearview® label as Clearview® HIV 1/2 STAT-PAK® and Clearview® Complete® HIV 1/2. The final recommendations issued on April 30, 2013 by the United States Preventive Services Task Force, which fully embrace the routine testing for HIV which the United States Centers for Disease Control has been recommending since 2006, should help drive demand for testing, especially as the Affordable Care Act is implemented. In particular, there will be no co-pay required for this preventive service, given the "A" rating that has been indicated.

As we reported in March 2013, we anticipate that our revenues from FIOCRUZ in Brazil will be lower in 2013 than they were in 2012. Revenues from FIOCRUZ in 2012 were over \$10 million, and were \$1.2MM in the first quarter of 2013. Beginning 2011 which is when revenues under these contracts commenced, through the first quarter 2013, approximately \$15.8 million of DPP® products have been shipped under the agreements with FIOCRUZ. Under these agreements, which are actually five separate agreements, minimum purchases of the subject product are required in each case in order to trigger a technology transfer for such product. Such aggregate minimum purchases required under these agreements are approximately \$23 million, and through the first quarter of 2013 we have shipped approximately \$14 million against these minimum purchases, leaving approximately \$9 million of potential purchases if only the purchase minimums, as described, are to be met. The totals sold to FIOCRUZ on certain agreements have already exceeded minimum purchases, while under other agreements they have not. We believe, based on a revised estimated forecast that we received from FIOCRUZ in early May 2013, that we will derive approximately \$6 million of revenue during the course of 2013, including the first quarter revenues. In addition, based on the minimum purchase requirements which have not been exceeded, we could receive up to another \$9 million in revenue from FIOCRUZ in 2014. However, none of the contracts requires FIOCRUZ to purchase the minimum amounts unless it wants to trigger the technology transfer for that product.

We are working on developing a number of new revenue opportunities in a number of international markets, including but not limited to Brazil, with current and new international distribution partners, for our DPP® HIV-Syphilis, for which we are getting strong interest in a number of international markets, as well as for our lateral flow product lines. We are increasingly optimistic that these new revenue opportunities will at least offset the reduced 2013 FIOCRUZ sales, and hope to report on these opportunities as developments warrant.

Having received, in December 2012, FDA approval of our Pre-Marketing Application for our DPP® HIV 1/2 Assay (DPP® HIV) for use with oral fluid or blood samples, we are now focused on completing the requirements for a Clinical Laboratory Improvement Act (CLIA) waiver for this product in order to enable the product to be sold in the point-of-care market segments where these tests are primarily used. We anticipate the CLIA waiver studies to be completed within the next few months and for the CLIA waiver application to be submitted to the FDA in July 2013.

With the above-mentioned anticipated increase in routine testing for HIV being increasingly funded by private insurance, and with more individuals having such insurance, we believe the availability of an alternative oral fluid HIV rapid test, which test also performs very well on all blood matrices, will enable Chembio to participate in market segments not currently addressed by the blood POCT products sold through Alere.

We will plan to address the public health market for the DPP® HIV product through a small direct sales organization and the hospital and physician office market through distribution relationships. We are increasingly optimistic that this sales organization will be able to market, by mid-2014, our DPP® Syphilis Screen & Confirm test and DPP® HIV-Syphilis multiplex test, and, in 2015, our Hepatitis- C (HCV) test. However each of these products has substantial development or regulatory steps ahead before it can be commercialized, even though significant progress is being made. Nevertheless, we are making significant progress toward commercializing these products and have begun to invest in our commercialization activities, although there can be no assurance.

Our gross margin percentage, which was substantially lower in the first quarter of 2013 versus 2012 (but was marginally better than the fourth quarter of 2012), reflects lower DPP® product sales to Brazil, which are at higher average gross margins, and increased overhead rates adopted as of 2013 related to additional personnel costs in 2012 to manage and fulfill the higher production volumes. If we are successful in our international business development activities, where we are investing significant management effort, then unit volumes will continue to be at a relatively high level but they will likely be at lower average selling prices compared to our 2012 results. The greater volume of units produced will therefore allow fixed overhead costs to be spread over a larger number of items, thereby resulting in a lower overhead rate. Until we begin generating revenues from the U.S. market, where we anticipate higher average selling prices, product gross margins as a percentage of revenues are likely to remain relatively low, even if revenues and nominal product gross margins are higher. To address the lower margins in the short term, we may need to increase capacity with capital expenditures, rather than adding shifts, overtime and temporary labor to lower costs, and this may involve a substantial commitment of capital, which we have available if needed. We believe that our ability to manufacture high quality and yet competitively priced products that serve the United States, other developed markets, and developing world markets as well, all from our New York-based FDA-approved production facility, is a significant competitive advantage that we uniquely enjoy.

Also, our overall gross margins are impacted by non-product revenues, which are largely comprised of research and development contracts and grants. We are working on completing new research and development contract agreements which, if awarded, will favorably impact gross margins as they have in previous periods.

The Company has a number of new product and technology opportunities in addition to the aforementioned tests. We are completing the application to the FDA for an Investigational Device Exemption for our Sure Check HIV 1/2 for home use so that we can begin clinical trials to pursue FDA approval for home use if and when we determine the investment is warranted. Our development work on our multiplex HIV test, as well as the above-mentioned Hepatitis-C test, continues. Each of these products is being designed to detect acute infection. We are pursuing the incorporation of one or more patented detection enhancement technologies, and other features, that could facilitate these development efforts. In certain cases the incorporation of these technologies may involve completing license agreements.

We were also pleased to learn recently that Bio-Rad Laboratories, Inc. has received a CE Marking for the HIV 1/2 Confirmatory test which Chembio developed for and licensed to Bio-Rad, and for which Bio-Rad exercised the option to manufacture in its facility. The Bio-Rad product incorporates Chembio's patented DPP® technology, and Chembio will receive royalty on Bio-Rad's net sales of this product. This product was launched in Europe in April 2013, and we believe that Bio-Rad is also pursuing FDA approval of this product. As advertised, the product greatly simplifies and improves the accuracy of confirmatory testing for HIV infection, historically done using western blot technology which is less accurate, time consuming, labor intensive and complex. We believe our DPP® technology is strongly suited for such multiplex applications, and given the success of that project, we are pursuing other new opportunities that we believe offer additional potential success to Chembio.

The needs we are likely to have to improve and expand our production capacity, as well as those needs that we may have to commercialize our products and/or to license new technologies, were the principal reasons the Company's Board of Directors authorized the \$6 million public offering of common stock in April.



Also, our overall gross margins are impacted by non-product revenues, which are largely comprised of research and development contracts and grants. We are working on completing new research and development contract agreements which, if awarded, will favorably impact gross margins as they have in previous periods.

The Company has a number of new product and technology opportunities in addition to the aforementioned tests. We are completing the application to the FDA for an Investigational Device Exemption for our Sure Check HIV 1/2 for home use so that we can begin clinical trials to pursue FDA approval for home use if and when we determine the investment is warranted. Our development work on our multiplex HIV test, as well as the above-mentioned Hepatitis-C test, continues. Each of these products is being designed to detect acute infection. We are pursuing the incorporation of one or more patented detection enhancement technologies, and other features, that could facilitate these development efforts. In certain cases the incorporation of these technologies may involve completing license agreements. In order to obtain the use of certain patented detection enhancement technologies.

We were also pleased to learn recently that Bio-Rad Laboratories, Inc. has received a CE Marking for its HIV 1/2 Confirmatory test which Chembio developed for and licensed to Bio-Rad, and for which Bio-Rad exercised the option to manufacture in its facility. The Bio-Rad product incorporates Chembio's patented DPP® technology, and Chembio will receive royalty on Bio-Rad's net sales of this product. This product was launched in Europe in April 2013, and we believe that Bio-Rad is also pursuing FDA approval. As advertised, the product greatly simplifies and improves the accuracy of confirmatory testing for HIV infection, historically done using an archaic western blot technology. We believe our DPP® technology is strongly suited for such multiplex applications, and given the success of that project, we are pursuing other new opportunities that we believe offer additional potential success to Chembio.

The needs we are likely to have to improve and expand our production capacity, the investment needed to enhance our ability to successfully commercialize our products, and the opportunity to license the aforementioned detection enhancement and/or other technologies, were the principal reasons the Company's Board of Directors authorized the \$6 million public offering of common stock in April.

#### 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 three months of fiscal 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II. OTHER INFORMATION

#### ITEM 6. EXHIBITS

## 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, as extended. (7)(13)
10.2*	Employment Agreement dated March 5, 2013 with Javan Esfandiari (12).
10.3	HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Alere and StatSure. (8)
10.4	HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (8)
10.5	Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (8)
10.6	Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (8)
10.7	Secured Term Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (9)
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 (9)
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 (9)
10.10	Revolving Term Note, dated as of July 22, 2011, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (10)
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 (10)
14.1	Ethics Policy (11)
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.
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.

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

- 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 Current Report on Form 8-K filed with the Commission on October 5, 2006.
  - 9 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on July 29, 2010.
  - 10 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on November 3, 2011.
  - 11 Incorporated by reference to the Registrant's Annual Report on Form 10-KSB filed with the Commission on March 30, 2006.
  - 12 Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Commission on March 7, 2013.
  - 13 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on April 25, 2013.
- (\*) 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 registration statement.

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: M a y By: /s/ Lawrence A.  
9 , Siebert  
2013

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

Date: M a y By: /s / Richard J.  
9 , Larkin  
2013

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