

CHEMBIO DIAGNOSTICS, INC.  
Form 10-Q  
August 08, 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 June 30, 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

88-0425691

(State or other jurisdiction of incorporation) (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 x 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 x No \_

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company x

(Do not check if a smaller reporting company)

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

As of August 6, 2013, the Registrant had 9,324,783 shares outstanding of its \$.01 par value common stock.

---

Quarterly Report on FORM 10-Q  
For The Quarterly Period Ended  
June 30, 2013

Table of Contents

Chembio Diagnostics, Inc.

	Page
Part I. FINANCIAL INFORMATION:	
Item 1. Financial Statements:	
Condensed Consolidated Balance Sheets as of June 30, 2013 (unaudited) and December 31, 2012	2
Condensed Consolidated Statements of Operations (unaudited) for the three and six months ended June 30, 2013 and 2012	3
Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2013 and 2012	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	26
Part II. OTHER INFORMATION:	
Item 6. Exhibits	27
SIGNATURES	28
EXHIBITS	

## PART I

## Item 1. FINANCIAL STATEMENTS

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

## - ASSETS -

	June 30, 2013 (Unaudited)	December 31, 2012
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$8,645,392	\$2,951,859
Accounts receivable, net of allowance for doubtful accounts of \$24,000 and \$58,000 at June 30, 2013 and December 31, 2012, respectively	3,894,207	4,821,357
Inventories	3,848,295	2,488,071
Prepaid expenses and other current assets	730,383	747,463
<b>TOTAL CURRENT ASSETS</b>	<b>17,118,277</b>	<b>11,008,750</b>
FIXED ASSETS, net of accumulated depreciation	1,832,570	1,427,646
<b>OTHER ASSETS:</b>		
Deferred tax asset, net of valuation allowance	4,197,113	4,233,194
License agreements, net of current portion	350,000	400,000
Deposits on manufacturing equipment	1,975	223,584
Deposits and other assets	41,976	41,976
<b>TOTAL ASSETS</b>	<b>\$23,541,911</b>	<b>\$17,335,150</b>
<b>- LIABILITIES AND STOCKHOLDERS' EQUITY -</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$3,929,431	\$3,303,923
Current portion of loans payable	-	51,236
Customer deposits	-	23,224
<b>TOTAL CURRENT LIABILITIES</b>	<b>3,929,431</b>	<b>3,378,383</b>
<b>OTHER LIABILITIES:</b>		
Loans payable - net of current portion	-	82,247
<b>TOTAL LIABILITIES</b>	<b>3,929,431</b>	<b>3,460,630</b>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock – 10,000,000 shares authorized, none outstanding	-	-
Common stock - \$.01 par value; 100,000,000 shares authorized, 9,324,783 and 8,036,232 shares issued and outstanding for June 30, 2013 and December 31, 2012, respectively	93,248	80,362
Additional paid-in capital	46,765,088	41,116,149
Accumulated deficit	(27,245,856)	(27,321,991)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>19,612,480</b>	<b>13,874,520</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$23,541,911</b>	<b>\$17,335,150</b>

See accompanying notes to condensed consolidated financial statements

2

---

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

	For the three months ended		For the six months ended	
	June 30, 2013	June 30, 2012	June 30, 2013	June 30, 2012
<b>REVENUES:</b>				
Net product sales	\$5,061,691	\$5,811,190	\$11,374,881	\$12,174,342
License and royalty revenue				
R&D, milestone and grant revenue	331,831	272,701	696,794	562,801
<b>TOTAL REVENUES</b>	<b>5,393,522</b>	<b>6,083,891</b>	<b>12,071,675</b>	<b>12,737,143</b>
Cost of product sales	3,112,347	3,513,267	7,096,610	6,833,656
<b>GROSS MARGIN</b>	<b>2,281,175</b>	<b>2,570,624</b>	<b>4,975,065</b>	<b>5,903,487</b>
<b>OPERATING EXPENSES:</b>				
Research and development expenses	1,500,645	979,044	2,545,904	2,358,174
Selling, general and administrative expenses	1,160,256	1,079,201	2,322,336	2,313,169
	2,660,901	2,058,245	4,868,240	4,671,343
<b>INCOME (LOSS) FROM OPERATIONS</b>	<b>(379,726 )</b>	<b>512,379</b>	<b>106,825</b>	<b>1,232,144</b>
<b>OTHER INCOME (EXPENSE):</b>				
Gain on sale of fixed asset	7,500	-	7,500	-
Interest income	897	1,598	2,235	3,117
Interest expense	-	(2,317 )	(335 )	(4,758 )
	8,397	(719 )	9,400	(1,641 )
<b>INCOME (LOSS) BEFORE INCOME TAXES</b>	<b>(371,329 )</b>	<b>511,660</b>	<b>116,225</b>	<b>1,230,503</b>
Income tax provision (benefit)	(130,340 )	203,130	40,090	488,530
<b>NET (LOSS) INCOME</b>	<b>\$(240,989 )</b>	<b>\$308,530</b>	<b>\$76,135</b>	<b>\$741,973</b>
Basic earnings (loss) per share	\$(0.03 )	\$0.04	\$0.01	\$0.09
Diluted earnings (loss) per share	\$(0.03 )	\$0.04	\$0.01	\$0.09
Weighted average number of shares outstanding, basic	9,259,506	7,987,105	8,664,478	7,960,714
Weighted average number of shares outstanding, diluted	9,259,506	8,525,199	9,230,840	8,512,770

See accompanying notes to condensed consolidated financial statements

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

	June 30, 2013	June 30, 2012
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Cash received from customers and grants	\$ 12,998,825	\$ 13,520,115
Cash paid to suppliers and employees	(12,197,954)	(11,733,120)
Interest received	2,235	3,117
Interest paid	(335)	(4,758)
Net cash provided by operating activities	802,771	1,785,354
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of and deposits on fixed assets	(415,649)	(447,621)
Net cash used in investing activities	(415,649)	(447,621)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from option and warrant exercises	31,432	84,897
Proceeds from sale of common stock, net	5,512,500	-
Expenses from sale of common stock	(104,038)	-
Payment of loan obligation	(133,483)	(28,967)
Payment of capital lease obligation	-	(14,576)
Net cash provided by financing activities	5,306,411	41,354
<b>INCREASE IN CASH AND CASH EQUIVALENTS</b>		
Cash and cash equivalents - beginning of the period	2,951,859	3,010,954
Cash and cash equivalents - end of the period	\$ 8,645,392	\$ 4,390,041
<b>RECONCILIATION OF NET INCOME TO NET CASH PROVIDED BY OPERATING ACTIVITIES:</b>		
Net Income	\$ 76,135	\$ 741,973
Adjustments:		
Depreciation and amortization	282,334	269,896
Provision for deferred taxes	36,081	439,677
(Recovery of) doubtful accounts	(34,000)	-
Share based compensation	221,931	179,253
Changes in assets and liabilities:		
Accounts receivable	961,150	782,972
Inventories	(1,360,224)	(841,036)
Prepaid expenses and other current assets	17,080	(54,565)
Accounts payable and accrued liabilities	625,508	(149,233)
Customer deposits and deferred revenue	(23,224)	415,919
Net cash provided by operating activities	\$ 802,771	\$ 1,785,354
<b>Supplemental disclosures for non-cash investing and financing activities:</b>		
Deposits on manufacturing equipment transferred to fixed assets	\$ 294,813	\$ 55,794

See accompanying notes to condensed consolidated financial statements

4

---



CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2013  
(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 80 % of the Company's product revenues in the first six months of 2013. The Company's products based on its patented Dual Path Platform (DPP®) platform represented approximately 16 % of the Company's product revenues in the first six months of 2013. The Company also has other rapid tests that together represented approximately 4 % of sales in the first six 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 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.

NOTE 2 — 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 June 30, 2013 and for the six-month periods ended June 30, 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 reverse 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 June 30, 2013, its condensed consolidated results of operations for the three- and six-month periods ended June 30, 2013 and 2012, respectively, and its condensed consolidated cash flows for the six-month periods ended June 30, 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  
JUNE 30, 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 June 30, 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:

	June 30, 2013	December 31, 2012
Raw materials	\$ 1,794,792	\$ 1,418,071
Work in process	902,718	561,530
Finished goods	1,150,785	508,470
	\$ 3,848,295	\$ 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 and six-month periods ended June 30, 2013 and 2012, have been included in the earnings per share computations:

	For the three months ended		For the six months ended	
	June 30, 2013	June 30, 2012	June 30, 2013	June 30, 2012
Basic	9,259,506	7,987,105	8,664,478	7,960,714
Diluted	9,259,506	8,525,199	9,230,840	8,512,770

The following securities, presented on a common share equivalent basis for the three and six-month periods ended June 30, 2013 and 2012, have been included in the diluted per share computations as the exercise prices of these securities were less than the stock price as of June 30, 2013 and 2012, respectively:

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

	For the three months ended		For the six months ended	
	June 30, 2013	June 30, 2012	June 30, 2013	June 30, 2012
1999 and 2008 Plan Stock Options	532,523	538,094	566,362	552,056

6

---

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2013  
(UNAUDITED)

There were 169,662 and 99,594 options outstanding as of June 30, 2013 and 2012, respectively, that were not included in the calculation of diluted per common share equivalent for the three and six months ended June 30, 2013 and 2012, respectively, because the effect would have been anti-dilutive as of June 30, 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 June 30, 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 June 30, 2013, there were 144,220 options exercised, 562,648 options outstanding and 43,132 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- and six-month periods ended June 30, 2013 and 2012 was \$5.39 and \$2.80 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 granted during the periods indicated are as follows (no options issued in the three months ended June 30, 2012):

	For the three months ended		For the six months ended	
	June 30, 2013	June 30, 2012	June 30, 2013	June 30, 2012
Expected term (in years)	3.5	n/a	3	5
Expected volatility	93.80 %	n/a	93.80 % - 101.30 %	115.77 %
Expected dividend yield	0 %	n/a	0 %	0 %
Risk-free interest rate	0.34 %	n/a	0.34 % - 0.40 %	0.36 %

The Company's results for the three-month periods ended June 30, 2013 and 2012 include share-based compensation expense totaling \$84,000 and \$44,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$26,000 and \$5,000, respectively), research and development (\$22,000 and \$9,000, respectively) and selling, general and administrative expenses (\$36,000 and \$30,000, respectively). The results for the six-month periods ended June 30, 2013 and 2012 include share-based compensation expense totaling \$222,000 and \$177,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$56,000 and \$20,000, respectively), research and development (\$62,000 and \$57,000, respectively) and selling, general and administrative expenses (\$104,000 and \$100,000, 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 and six-month periods ended June 30, 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  
JUNE 30, 2013  
(UNAUDITED)

The following table provides stock option activity for the six months ended June 30, 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	\$ 2.23	2.19 years	\$ 3,460,686
Granted	51,360	\$ 5.39		
Exercised	(117,380)	\$ 1.53		
Forfeited/expired/cancelled	(9,228 )	\$ 3.99		
Outstanding at June 30, 2013	656,398	\$ 2.45	2.16 years	\$ 1,698,863
Exercisable at June 30, 2013	446,432	\$ 1.74	1.50 years	\$ 1,535,980

As of June 30, 2013, there was \$282,000 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 2.17 years. The total fair value of stock options vested during the three-month periods ended June 30, 2013 and 2012 was approximately \$174,000 and \$206,000, respectively.

f) Geographic Information:

U.S. GAAP establishes standards for the manner in which business enterprises report information about operating segments in financial statements and requires that those enterprises report selected information. It also establishes standards for related disclosures about products and services, geographic areas, and major customers.

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

	For the three months ended		For the six months ended	
	June 30, 2013	June 30, 2012	June 30, 2013	June 30, 2012
Africa	\$1,009,899	\$442,833	\$1,857,221	\$1,520,569
Asia	31,353	254,003	50,619	266,481
Europe	69,324	7,753	76,929	33,331
North America	2,464,060	2,545,376	5,285,578	5,266,136
South America	1,487,055	2,561,225	4,104,534	5,087,825
	\$5,061,691	\$5,811,190	\$11,374,881	\$12,174,342

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**JUNE 30, 2013**  
**(UNAUDITED)**

## g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

	June 30, 2013	December 31, 2012
Accounts payable – suppliers	\$ 1,992,452	\$ 1,686,431
Accrued commissions	154,119	238,150
Accrued royalties / license fees	761,986	583,923
Accrued payroll	244,821	262,439
Accrued vacation	257,179	181,636
Accrued bonuses	325,500	155,663
Accrued expenses – other	193,374	195,681
<b>TOTAL</b>	<b>\$ 3,929,431</b>	<b>\$ 3,303,923</b>

## 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 0 and \$363,000 for the six-month periods ended June 30, 2013 and 2012, respectively from this grant. The Company earned an aggregate of \$2,756,000 from this grant from inception through June 30, 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 \$331,000 and \$252,000 for the six-month periods ended June 30, 2013 and 2012, respectively from this grant. The Company earned \$2,014,000 from this grant from inception through June 30, 2013 of which \$651,000 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 \$265,000 and 0 for the six-month periods ended June 30, 2013 and 2012, respectively from this agreement. The Company earned \$542,000 from this grant from inception through June 30, 2013.

## NOTE 4 — LOANS PAYABLE:

On April 30, 2013, the Company entered into a new demand loan agreement ("Demand Note") with HSBC Bank, USA ("HSBC"). 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.





CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2013  
(UNAUDITED)

The Security Agreement, related to the Demand Note, 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.

The Company currently maintains its operating, payroll, and primary cash accounts at HSBC. As of June 30, 2013, nothing had been drawn down on the Demand Note.

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, which is defined below.

Until a Right is exercised, the holder thereof, in his capacity as a holder of Rights, will have no rights as a shareholder of the Company, including, without limitation, the right to vote or to receive dividends.

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

NOTE 6 — COMMON STOCK, WARRANTS AND OPTIONS:

The Company entered into an employment agreement effective May 22, 2013 ("Employment Agreement"), with Ms. Klugewicz to serve as the Company's Chief Operating Officer, which included issuing incentive stock options to purchase 5,000 shares of the Company's common stock. Of these stock options, options to purchase 2,500 shares vest on each of the first two 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 May 22, 2013, which was \$4.50 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2013  
(UNAUDITED)

The Company closed on an underwritten public offering of 1,200,000 shares of its common stock at \$5.00 per share on April 3, 2013. The net proceeds of the offering, after deducting the underwriters' discounts and other estimated offering expenses payable by the Company, was approximately \$5,401,000. The Company intends to use the net proceeds for business expansion and working capital.

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 \$5.44 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 June 30, 2013, the Company had no warrants outstanding to purchase shares of common stock.

NOTE 7 — 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				For the six months ended				Accounts Receivable As of	
	June 30, 2013		June 30, 2012		June 30, 2013		June 30, 2012		June 30, 2013	June 30, 2012
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales		
Customer 1	\$2,305,729	46	\$2,144,051	37	\$4,895,683	43	\$4,592,906	38	\$905,829	\$619,969
Customer 2	650,221	13	2,383,025	41	1,869,096	16	4,899,025	40	712,950	597,984
Customer 3	868,869	17	*	*	2,058,006	18	*	*	856,884	*
Customer 4	664,944	13	*	*	1,127,933	10	*	*	549,263	*

(\*) 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.

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

JUNE 30, 2013

(UNAUDITED)

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		For the six months ended		Accounts Payable	
	June 30, 2013	June 30, 2012	June 30, 2013	June 30, 2012	As of June 30, 2013	June 30, 2012
	Purchases	Purchases	Purchases	Purchases		
	\$	\$	\$	\$		
Vendor 1	\$131,445	\$231,043	\$376,117	\$408,679	\$88,440	\$67,945
Vendor 2	239,539	237,550	565,384	378,204	129,042	29,805

(\* ) 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.

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 three key employees. The contracts call for salaries presently aggregating \$840,000 per year. The Klugewicz contract expires in May 2015, the Esfandiari contract expires in March 2016 and the Siebert employment contract expires in May 2014. In connection with the contract that expires in May 2015, the Company issued, in May 2013, 5,000 options to purchase common stock, with one-half vesting on each of the first and second anniversaries of the grant and 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.

NOTE 8 — 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 \$401, was added to accrued expenses, 35.1 %, or \$40,090, was expensed, and the balance of 31.6 %, or \$39,689, reduced the carrying value of the deferred tax asset for the three months ended June 30, 2013.



## 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 as 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) Antibody Detection and HCV Antigen-Antibody 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 at least capable of identifying antibody response in a more comprehensive manner than the currently available point-of-care test is able to do, and to also, in parallel, engage in efforts to differentiate those patients that are antibody positive from those that have an active infection, as up to 30% of patients that are HCV antibody-positive don't have an active infection.

In July 2012, the U.S. Centers for Disease Control finalized the recommendations for testing all individuals in the United States born between the years of 1945 and 1965 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 of their status. 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. In fact, in May the United States Preventive Services Task Force revised its November 2012 recommendations to more fully endorse the CDC recommendations by giving both hepatitis-C (HCV) screening for at-risk individuals and age-cohort screening a 'B' grade; under the Affordable Care Act, preventive services that have received an 'A' or 'B' grade from the USPSTF must be covered by insurance policies without cost-sharing and be part of the essential health benefits for those individuals eligible for Medicare.

We plan to complete development in mid-2014, and to begin commercialization activities in the US. by the end of 2015 or early 2016.

DPP® HIV Multiplex Antigen-Antibody Test - Development work continues 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, and Alere anticipates near-term approval of its Determine HIV Ag/AB test that we expect will claim earlier detection due to the ability to detect unbound P-24 antigen. 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 or the new Alere Determine test, 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.

Our revised plan for the new HCV and HIV products is to complete development of these products by mid-2014, conduct clinical trials in 2014-2015, and to receive FDA approval by the end of 2015 or early 2016.

International Distribution & Assembly Agreement with Labtest - During the second quarter the Company entered into an international assembly and distribution agreement with Labtest Diagnostica SA (Labtest), a leading diagnostics manufacturer and marketing organization based in Brazil, for products based upon Chembio's patented Dual Path Platform (DPP®) in Brazil and potentially other markets outside the U.S. Pursuant to the agreement, Chembio will manufacture and sell certain specialized test components to Labtest and also will receive a royalty based on sales by Labtest of DPP® products. Labtest will produce certain reagents and perform assembly and packaging operations in a dedicated space at Labtest's manufacturing facilities near Belo Horizonte, Brazil. Chembio will provide Labtest with the training necessary to perform the operations specific to the DPP® products. Labtest will also have responsibility



for marketing, promotion and distribution of the products in Brazil.

All products will be marketed under brand names that will include Chembio's DPP® trademark together with trade names selected by Labtest, and each test kit will state that Chembio Diagnostic Systems, Inc. is the licensor of the DPP® trademark and technology. The products selected for inclusion in this agreement will address both private as well as public health markets, and will enable Chembio to participate in significant market opportunities in Brazil. This agreement addresses market opportunities that are independent of those addressed by Chembio's ongoing collaboration with the Oswaldo Cruz Foundation.

Chembio and Labtest will immediately begin product registration activities for an initial group of infectious disease products with sales expected to commence by early 2014. The agreement contemplates additional products and territories to be added by mutual agreement. In addition, the agreement offers the possibility for Labtest to assemble products for other global Chembio customers as a contract manufacturer.

14

---

## 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 contemplated a period of approximately six months in which the follow-on development activity was to be completed. In the first quarter of 2013 we completed the requirements of this agreement.

During the second quarter we reported that the Company had entered into a follow-on, milestone-based development agreement with the private contracting organization that is engaged to enter into, implement and provide technical oversight of agreements relating to pandemic influenza preparedness on behalf of its client, the United States Centers for Disease Control and Prevention (CDC), for a multiplex, rapid, POC influenza immunity test utilizing Chembio's patented Dual Path Platform (DPP®) technology. The follow-on agreement is for up to approximately \$472,000 and contemplates a period of approximately six months, or May through October of 2013, in which the follow-on development activity is to be completed.

The early prototype development work for this product was successfully completed by Chembio in 2010 through 2013 pursuant to previous contracts with the same organization totaling approximately \$1.4 million. The objective of this follow-on project is to further develop a rapid influenza immunity test that can determine a person's influenza immunity status in the field or in an outpatient setting, while incorporating certain additional subunits of influenza virus proteins.

As a result of pandemic planning activities, the United States Department of Health and Human Services and the CDC have identified POC and high-throughput testing as a gap in influenza diagnostics. Rapid responses in the field — such as the vaccination, prophylactic treatment or isolation of patients — require POC diagnostic tests for influenza infection and immunity. Ideally, these tests should be fast, portable, self-contained and non-technical. Development of this test is especially critical for the military, as evidenced by previous influenza outbreaks that spread rapidly through densely populated barracks and killed thousands of soldiers.

**DPP® Febrile Illness Multiplex test** – During the second quarter we entered into a cooperative research project agreement with a U.S. government agency for up to \$750,000 for an eight-month development project. The project is to develop a rapid POC diagnostic test for five infectious diseases associated with febrile illness and to multiplex them into one assay. The project also contemplates that the test would be optimized for use with a mobile reader that incorporates cell phone technology to enable the results to be recorded, transmitted and monitored remotely via a cloud system, in real-time. This research project supports our efforts in developing multiplex products using our proprietary DPP® technology. Our DPP® technology, when combined with the mobile reader being used in the project, will enable real time data collection and monitoring capabilities. As these infectious diseases can all exhibit similar clinical symptoms, a rapid multiplex test that could distinguish them would be very useful, particularly in field conditions, so that correct diagnosis and treatment could be provided on a timely basis.

**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%.

Chembio's work to finalize DPP assay design using various fusion proteins has been completed and production of an evaluation lot is in progress; these tests will be used for verification studies, internal and external evaluations at the

selected collaborative sites (see below), QC protocol validation, and accelerated stability study. The target sensitivity is 80% and specificity is 95%. Study sites for external evaluations of DPP assay include Bangladesh, Brazil, China, Haiti, Peru, Venezuela, and South Africa.

In addition to the above-mentioned research and development work sponsored by governmental agencies and/or their contractors for the influenza, febrile illnesses, 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.

15

---

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 – The Company's SURE CHECK® HIV 1/2 Assay has received CE Mark approval from European regulators and is therefore now cleared for commercialization within the European Union (EU) for rapid, point-of-care detection of HIV. Chembio is currently working with commercialization partners in Europe. We anticipate that our HIV 1/2 STAT PAK® lateral flow HIV test and our DPP® HIV 1/2 test will receive CE Mark approval in the fall.

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, however we now expect that it will not be granted before the end of 2013. As we had reported, we initiated the CLIA study in April, and our plan was to have the submission into the FDA by July, and to receive a CLIA waiver during the fourth quarter. However, start up of certain sites was delayed, so that completion of the trial is also delayed. As of July 31, 2013, approximately 50% of the enrollment criteria had been completed, and the results are in accordance with expected requirements. At this rate, enrollment will be completed by September 2013, as compared with the original expectation of July. Therefore the CLIA waiver is not likely to be submitted until during the fourth quarter and therefore the CLIA waiver grant is now expected to be received in the first quarter of 2014.

DPP® HIV-Syphilis – We have developed this product for international and US marketing; Although initial international registrations and approvals are anticipated before the end of 2013, we expect the US FDA approval process to be lengthier (see below). Globally, far more pregnant women are estimated to have syphilis than HIV, and untreated maternal syphilis always results in an adverse pregnancy outcome such as fetal death, stillbirth, premature birth, low birth weight or congenital syphilis infection. As syphilis commonly co-exists in patients with HIV (prevalence is 14-36%), a dual rapid test for HIV and syphilis could greatly strengthen pregnant mother-to-child testing, or PMTCT, of syphilis. This is particularly true, because there are already well financed programs for the PMTCT of HIV.

For the international market we have submitted this product both for evaluation by the CDC, acting on behalf of the United States Agency of International Development, and the WHO, which has accepted this product to be evaluated for pre-qualification in its global procurement scheme. Other international registrations are pending. During the second quarter we announced receipt of an evaluation report from Mexico's Institute of Epidemiological Diagnosis and Reference (InDRE) regarding the Company's DPP® HIV-Syphilis multiplex test, which showed the Company's assay performed with 100% agreement for both markers on all 941 samples tested. In evaluating the sensitivity and specificity of the Chembio DPP® HIV-Syphilis product, 527 biological samples were tested on the HIV line, of which 158 were true negative and 369 were true positive, and 414 were tested on the Syphilis line, of which 108 were true negative and 306 were true positive. The Chembio DPP® HIV-Syphilis test performed with 100% sensitivity and 100% specificity on all samples.

The FDA review timeline for this product, which we originally anticipated would be in mid-2014, has now been shifted to late 2014, with CLIA waiver now anticipated in early 2015. This development is due to this product being characterized by FDA as a PMA, not a 510(K), as the syphilis component performance will be compared to actual patient infection status, as compared to a predicate device allowed in 510(K). This change will be more time

consuming due to the increased statutory review time, and potentially more costly.

**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. While we confirmed our intended study approach with the FDA, we have encountered problems with the supply of one of the key raw materials used in this test. Until we are able to resolve those problems, this project is on hold.

16

---

SURE CHECK® HIV OTC Study – We completed the self-testing study required for submitting an IDE ("Investigational Device Exemption") application in order to commence clinical trials for this product. However due to the results reported to date by Orasure, which show significant marketing expenditures without meaningful revenues, let alone the costs of the clinical trials and other costs associated with FDA approval, we will keep this project on hold though we will continue to monitor this market opportunity closely.

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.

#### 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 JUNE 30, 2013 AS COMPARED WITH THE THREE MONTHS ENDED JUNE 30, 2012

Income:

For the three months ended June 30, 2013 loss before income taxes was (\$371,000) compared to income before taxes of \$512,000 for the three months ended June 30, 2012. Net income for the 2012 period was \$309,000 as compared to a net loss of (\$241,000) for 2013. The decrease in net income is primarily attributable to a combination of increased operating expenses, especially increased clinical trial expenses attributable to our ongoing CLIA waiver studies, and to decreased product sales. In the three months ended 2013, as a result of a 12.9% decrease in Net Product Sales and a 21.7% increase in non-product revenues along with a 11.4% decrease in cost of products sold, the Company had a \$289,000, or 11.3%, decrease in its gross margin, to \$2,281,000. This decreased gross margin also included increased operating expenses, the most significant of which was an increase in clinical trial expenses of \$350,000, partially offset by a decrease in commissions of \$184,000, due to the decreased sales in Brazil account for most of the change from a net income to a net loss.

Revenues:

Selected Product Categories:	For the three months ended			
	June 30, 2013	June 30, 2012	\$ Change	% Change
Lateral Flow HIV Tests and Components	\$4,158,354	\$3,159,657	\$998,697	31.61 %
DPP Tests and Components	694,816	2,226,200	(1,531,384)	-68.79 %
Other	208,521	425,333	(216,812)	-50.97 %
Net Product Sales	5,061,691	5,811,190	(749,499)	-12.90 %
License and royalty revenue	-	-	-	100.00 %
R&D, milestone and grant revenue	331,831	272,701	59,130	21.68 %
Total Revenues	\$5,393,522	\$6,083,891	\$(690,369)	-11.35 %

Revenues for our lateral flow HIV tests and related components during the three months ended June 30, 2013 increased by approximately \$999,000 from the same period in 2012. This was attributable to increased sales to South America, excluding Brazil, of approximately \$654,000, increased sales to Africa of \$567,000, and increased sales to Alere from \$2,144,000 during the three months ended June 30, 2012 to \$2,306,000 during the three months ended June 30, 2013. These increases were partially offset by decreased sales to Brazil of \$201,000 and decreased sales to Asia of \$223,000. Revenues for our DPP® products during the three months ended June 30, 2013 decreased by approximately \$1,531,000 over the same period in 2012, a decrease of 69%, which decrease is attributable to a reduction in sales to the Oswaldo Cruz Foundation. 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			
	June 30, 2013	June 30, 2012	\$ Change	% Change

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

Gross Margin per Statement of Operations	\$2,281,175	\$2,570,624	\$(289,449)	-11.26 %
Less: R&D, milestone, grant, license and royalties	331,831	272,701	59,130	21.68 %
Gross Margin from Net Product Sales	\$1,949,344	\$2,297,923	\$(348,579)	-15.17 %
Product Gross Margin %	38.51	%	39.54	%

The gross margin dollar decrease of \$289,000 included a \$349,000 decrease in gross margin from product sales, partially offset by a \$59,000 increase in non-product revenues. The decrease in product gross margin is primarily attributable to the lower product sales compared to 2012 period of \$296,000. The 1% decrease in our product gross margin percentage, from 39.5% in 2012 to 38.5% in 2013, accounted for the \$53,000 balance and was primarily due to increased costs in products overhead application, 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 38.3% to 13.7%.

Partially offsetting these increased costs was a decrease in our scrap expenses as we focused on this area after the higher scrap experienced during 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			
	June 30, 2013	June 30, 2012	\$ Change	% Change
<b>Clinical and Regulatory Affairs:</b>				
Wages and related costs	\$ 108,466	\$ 125,956	\$(17,490 )	-13.89 %
Consulting	7,463	5,081	2,382	46.88 %
Stock-based compensation	3,027	5,268	(2,241 )	-42.54 %
Clinical trials	421,768	71,845	349,923	487.05 %
Other	24,466	19,517	4,949	25.36 %
Total Regulatory	565,190	227,667	337,523	148.25 %
<b>R&amp;D Other than Regulatory:</b>				
Wages and related costs	538,789	467,570	71,219	15.23 %
Consulting	42,326	43,362	(1,036 )	-2.39 %
Stock-based compensation	19,334	3,080	16,254	527.73 %
Materials and supplies	251,716	161,305	90,411	56.05 %
Other	83,290	76,060	7,230	9.51 %
Total other than Regulatory	935,455	751,377	184,078	24.50 %
Total Research and Development	\$ 1,500,645	\$ 979,044	\$ 521,601	53.28 %

Expenses for Clinical & Regulatory Affairs for the three months ended June 30, 2013 increased by \$338,000 as compared to the same period in 2012. This was primarily due to an increase of \$350,000 in clinical trial expenses which are mostly associated with CLIA waiver studies for our DPP® HIV 1/2 Assay.

R&D expenses other than Clinical & Regulatory Affairs increased by \$184,000 in the three months ended June 30, 2013, as compared with the same period in 2012. The increases were primarily related to an increase in wages and related costs and in material and supplies to support our sponsored research and internal development programs.

Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended			
	June 30, 2013	June 30, 2012	\$ Change	% Change
Wages and related costs	\$ 452,103	\$ 358,167	\$ 93,936	26.23 %
Consulting	100,061	105,432	(5,371 )	-5.09 %
Commissions	92,002	275,745	(183,743)	-66.64 %
Stock-based compensation	34,867	30,078	4,789	15.92 %
Marketing materials	22,294	15,710	6,584	41.91 %
Investor relations/investment bankers	39,023	73,769	(34,746 )	-47.10 %
Legal, accounting and compliance	73,587	133,523	(59,936 )	-44.89 %
Travel, entertainment and trade shows	69,554	37,213	32,341	86.91 %
Bad debt allowance (recovery)	-	(95,000 )	95,000	-100.00%
Other	276,765	144,564	132,201	91.45 %
Total S, G & A	\$ 1,160,256	\$ 1,079,201	\$ 81,055	7.51 %

Selling, general and administrative expenses for the three months ended June 30, 2013, increased by \$81,000 as compared with the same period in 2012, a 7.5% increase. Significant increases in wages and related costs, travel, entertainment and trade shows and non-recurrence of a bad debt recovery in 2012 were partially offset by a \$184,000 decrease in commissions due to decreased sales to Brazil along with a decrease in investor relations/investment bankers of \$35,000 and professional expenses of \$60,000.

19

---

Other Income and (Expense):

	For the three months ended		\$	%	
	June 30, 2013	June 30, 2012			
Other income (expense)	\$7,500	\$-	\$ 7,500	100.00	%
Interest income	897	1,598	(701 )	-43.87	%
Interest expense	-	(2,317)	2,317	-100.00	%
Total Other Income and (Expense)	\$8,397	\$(719 )	\$ 9,116	-1267.87	%

Other income for the three months ended June 30, 2013 increased approximately \$9,000, to an income of \$8,000 from an expense of \$1,000 in the same period in 2012, primarily as a result of a gain on the sale of a fixed asset and a decrease in interest expense due on the term loan with HSBC.

**RESULTS OF OPERATIONS FOR THE SIX MONTHS ENDED JUNE 30, 2013 AS COMPARED WITH THE SIX MONTHS ENDED JUNE 30, 2012**

Income:

Income before income taxes for the six months ended June 30, 2013 decreased to \$116,000 from \$1,231,000 for the six months ended June 30, 2012. Net Income decreased from \$742,000 for 2012 to \$76,000 for 2013. The decrease is primarily attributable to a decrease in Net Product Sales. In 2013, as a result of a 6.6% decrease in Net Product sales and a 23.8% increase in non-product revenues along with a 3.8% decrease in cost of products sold, the Company had a \$928,000, or 16%, decrease in its gross margin, to \$4,975,000. This decreased gross margin along with increased operating expenses, accounted for most of the decrease in net income.

Revenues:

Selected Product Categories:	For the six months ended		\$ Change	%	Change
	June 30, 2013	June 30, 2012			
Lateral Flow HIV Tests and Components	\$9,095,215	\$6,927,593	\$2,167,622	31.29	%
DPP Tests and Components	1,837,651	4,652,200	(2,814,549)	-60.50	%
Other	442,015	594,549	(152,534 )	-25.66	%
Net Product Sales	11,374,881	12,174,342	(799,461 )	-6.57	%
License and royalty revenue	-	-	-	100.00	%
R&D, milestone and grant revenue	696,794	562,801	133,993	23.81	%
Total Revenues	\$12,071,675	\$12,737,143	\$(665,468 )	-5.22	%

Revenues for our lateral flow HIV tests and related components during the six months ended June 30, 2013 increased by approximately \$2,168,000 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 \$4,896,000 during the six months ended June 30, 2012 to \$4,593,000 during the six months ended June 30, 2013. These increases were partially offset by decreased sales to Africa of \$230,000. Revenues for our DPP® products during the six months ended June 30, 2013 decreased by approximately \$2,815,000 over the same period in 2012, a decrease of 60.5%, which decrease is attributable to a reduction in sales to the Oswaldo Cruz Foundation. 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.

20

---

Gross Margin:

Gross Margin related to Net Product Sales:	For the six months ended			
	June 30, 2013	June 30, 2012	\$ Change	% Change
Gross Margin per Statement of Operations	\$4,975,065	\$5,903,487	\$(928,422 )	-15.73 %
Less: R&D, milestone, grant, license and royalties	696,794	562,801	133,993	23.81 %
Gross Margin from Net Product Sales	\$4,278,271	\$5,340,686	\$(1,062,415 )	-19.89 %
Product Gross Margin %	37.61 %	43.87 %		

The gross margin dollar decrease of \$928,000 included a \$1,062,000 decrease in gross margin from product sales, partially offset by a \$134,000 increase in non-product revenues. The 6.4% decrease in our product gross margin percentage, from 43.9% in 2012 to 37.6% in 2013, was primarily due to increased costs in our operations support group, incoming freight, overhead costs, together with a change in the product sales mix. Some of the product mix change was due to the decreased sales of DPP as a percentage of overall sales from 38.2% to 16.2%. 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 six months ended			
	June 30, 2013	June 30, 2012	\$ Change	% Change
<b>Clinical and Regulatory Affairs:</b>				
Wages and related costs	\$213,957	\$249,681	\$(35,724 )	-14.31 %
Consulting	25,189	9,331	15,858	169.95 %
Stock-based compensation	14,632	20,692	(6,060 )	-29.29 %
Clinical trials	519,544	555,534	(35,990 )	-6.48 %
Other	28,544	32,718	(4,174 )	-12.76 %
Total Regulatory	801,866	867,956	(66,090 )	-7.61 %
<b>R&amp;D Other than Regulatory:</b>				
Wages and related costs	1,046,583	939,495	107,088	11.40 %
Consulting	52,163	48,362	3,801	7.86 %
Stock-based compensation	47,641	36,247	11,394	31.43 %
Materials and supplies	432,896	316,513	116,383	36.77 %
Other	164,755	149,601	15,154	10.13 %
Total other than Regulatory	1,744,038	1,490,218	253,820	17.03 %
<b>Total Research and Development</b>	<b>\$2,545,904</b>	<b>\$2,358,174</b>	<b>\$187,730</b>	<b>7.96 %</b>

Expenses for Clinical & Regulatory Affairs for the six months ended June 30, 2013 decreased by \$66,000 as compared to the same period in 2012. This was primarily due to the reduction of \$36,000 in clinical trial expenses which were mostly associated with clinical studies for our DPP® HIV 1/2 Assay along with a \$36,000 decrease in wages and related costs. The clinical studies for this product were completed during the first half of 2012, while 2013 primarily reflects the CLIA waiver study costs related to this product.

R&D expenses other than Clinical & Regulatory Affairs increased by \$254,000 in the six months ended June 30, 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, as well as an increase in stock-based compensation.



Selling, General and Administrative Expenses:

Selected expense lines:	For the six months ended			
	June 30, 2013	June 30, 2012	\$ Change	% Change
Wages and related costs	\$893,575	\$714,836	\$178,739	25.00 %
Consulting	106,261	169,001	(62,740 )	-37.12 %
Commissions	251,910	565,239	(313,329)	-55.43 %
Stock-based compensation	103,533	100,383	3,150	3.14 %
Marketing materials	29,257	26,168	3,089	11.80 %
Investor relations/investment bankers	113,886	120,017	(6,131 )	-5.11 %
Legal, accounting and compliance	313,644	291,700	21,944	7.52 %
Travel, entertainment and trade shows	97,305	64,289	33,016	51.36 %
Bad debt allowance (recovery)	(33,450 )	-	(33,450 )	100.00 %
Other	446,415	261,536	184,879	70.69 %
Total S, G &A	\$2,322,336	\$2,313,169	\$9,167	0.40 %

Selling, general and administrative expenses for the six months ended June 30, 2013, increased by \$9,000 as compared with the same period in 2012. The primary factor of this decrease was a \$313,000 decrease in commissions due to decreased sales to Brazil along with decreases in consulting fees of \$63,000 and in bad debt allowance of \$33,000. The following expense categories experienced an increase of greater than \$30,000, which partially offset the decreases: wages and related expenses, travel, entertainment and trade shows, and other expenses which primarily include excise tax expense related to the health care act.

Other Income and (Expense):

	For the six months ended			
	June 30, 2013	June 30, 2012	\$ Change	% Change
Other income (expense)	\$7,500	\$-	\$7,500	100.00 %
Interest income	2,235	3,117	(882 )	-28.30 %
Interest expense	(335 )	(4,758)	4,423	-92.96 %
Total Other Income and (Expense)	\$9,400	\$(1,641)	\$11,041	-672.82 %

Other income for the six months ended June 30, 2013 increased approximately \$11,000, due to an income of \$9,000 from an expense of \$2,000 in the same period in 2012, primarily as a result of a gain on the sale of fixed assets and a decrease in interest expense due on the term loan with HSBC.

Income tax (benefit) provision:

For the six months ended June 30, 2013 the Company charged \$40,000 to income tax expense and reduced its deferred tax assets by \$36,000. The Company maintains a full valuation allowance on research and development tax credits.

## MATERIAL CHANGES IN FINANCIAL CONDITION

## Selected Changes in Financial Condition

Selected Changes in Financial Condition	As of		\$ Change	% Change	
	June 30, 2013	December 31, 2012			
Cash and cash equivalents	\$8,645,392	\$2,951,859	\$5,693,533	192.88	%
Accounts receivable, net of allowance for doubtful accounts of \$24,000 and \$58,000 at June 30, 2013 and December 31, 2012, respectively	3,894,207	4,821,357	(927,150 )	-19.23	%
Inventories	3,848,295	2,488,071	1,360,224	54.67	%
Fixed assets, net of accumulated depreciation	1,832,570	1,427,646	404,924	28.36	%
Deposits on manufacturing equipment	1,975	223,584	(221,609 )	-99.12	%
Deferred tax asset, net of valuation allowance	4,197,113	4,233,194	(36,081 )	-0.85	%
Accounts payable and accrued liabilities	\$3,929,431	\$3,303,923	\$625,508	18.93	%

Cash increased by \$5,694,000 from December 31, 2012, primarily due to the common stock funding completed in April 2013 which added \$5,409,000. Excluding the financing, the increase in cash was \$285,000. In addition there were decreases in accounts receivable, net of allowance, of \$927,000, deposits on manufacturing equipment of \$222,000 and deferred tax asset of \$36,000. We experienced increases in inventories of \$1,360,000, fixed assets of \$405,000 and accounts payable and accrued expenses of \$626,000.

The decrease in accounts receivable was primarily attributable to a larger amount of credit sales at the end of December of 2012 versus June of 2013. The increase in inventories is due to production for orders received to be shipped in the third quarter of 2013, which partially explains the increase in accounts payable and other accrued expenses. The increase in fixed assets is due in part to delivery of equipment for which we had made deposits, this equipment included vial filing equipment, a reel-to-reel printer for R&D, some leasehold improvements, and other pieces of equipment. Deferred tax asset decrease is related to the provision for income tax expense.

## LIQUIDITY AND CAPITAL RESOURCES

	For the six months ended			
	June 30, 2013	June 30, 2012	\$ Change	% Change
Net cash provided by operating activities	\$802,771	\$1,785,354	\$(982,583 )	-55.04 %
Net cash used in investing activities	(415,649 )	(447,621 )	31,972	-7.14 %
Net cash provided by financing activities	5,306,411	41,354	5,265,057	12731.68 %
<b>INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>\$5,693,533</b>	<b>\$1,379,087</b>	<b>\$4,314,446</b>	<b>312.85 %</b>

The Company's cash increased by \$5,694,000 from December 31, 2012, primarily due to the common stock funding completed in April 2013 which added \$5,409,000 and was partially offset by other uses of cash from financing activities, compared to an increase in cash of \$1,379,000 in the 2012 period.

The cash provided from operations in 2013 was \$803,000, primarily due to a reduction in accounts receivable of \$961,000 along with an increase of \$626,000 in accounts payable and other accrued liabilities and net income net of non-cash items of \$588,000 which were partially offset by an increase of \$1,360,000 in inventory. Net income net of non-cash items includes net income of \$76,000, \$282,000 in depreciation and amortization, \$222,000 in share-based compensation as well as other items aggregating \$19,000. The use of cash from investing activities is primarily the purchase of fixed assets.

The increase in cash from operations in 2012 was \$1,785,000, primarily due to net income net of non-cash items of \$1,631,000 a reduction in accounts receivable of \$783,000 along with an increase of \$416,000 in customer deposits, which were partially offset by a decrease of \$149,000 in accounts payable and accrued liabilities, an increase of \$841,000 in inventory and other items aggregating \$54,000. Net income net of non-cash items includes net income of \$742,000, \$270,000 in depreciation and amortization, \$179,000 in share-based compensation, \$440,000 in provision for deferred taxes. The use of cash from investing activities is primarily the purchase of fixed assets.

## Fixed Asset Commitments



As of June 30, 2013, the Company had paid deposits on various pieces of equipment aggregating \$1,975, which is reflected in deposits on manufacturing equipment on the balance sheet. The Company has no further commits for additional equipment purchase obligations.

23

---

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

The operating loss in the second quarter is because of a combination of increased operating expenses, especially an increase in clinical trial expenses attributable to our DPP® HIV 1/2 Assay CLIA waiver studies, and decreased product sales. Also, we made the decision to add significant manufacturing personnel in the second quarter in order to meet significantly larger unit volumes that were anticipated for the balance of this year. Although this level of cost would not be justified based on the second quarter revenues, it was critical in order to meet current demand; based on our current backlog and anticipated orders, these staffing increases were necessary. We anticipate completing shipment of the \$5.3MM order we received in June in the third quarter. Also, as reported, an increased level of sponsored research and development contracts with U.S. government agencies or their contractors, as compared with the second half of 2012, will subsidize our research and development activities, extend our development capabilities and know-how, potentially result in new product opportunities, and also have a positive impact on our operating results net of the costs incurred related to these projects.

We believe that there are a number of international procurement opportunities for our HIV, syphilis, and other products and we are vigorously pursuing such opportunities. It is difficult to predict whether or when we are going to be successful in these opportunities, and they typically result in significant variations to our quarterly results; however we believe we can continue to grow our international business with our high quality products.

Our ongoing efforts to improve our gross margins are beginning to yield results, as our production efficiencies have improved during the first half of 2013. This, combined with a very high equipment capacity utilization and an improved sales mix, should result in higher gross margins during the second half of 2013. These efforts, which began last year, have also been more recently impacted by organizational changes that included the appointment of Sharon Klugewicz as our Chief Operating Officer and related changes to our operating team. In addition to an increased focus on material usage, supply management, and automation, including reorganizing certain manufacturing support teams, the Company is implementing a short-term plan to expand its available production capacity by leasing adjacent space that can be used for new packaging and related equipment that has been ordered. This capacity is anticipated to be available for use before the end of 2013. Also we continue to explore various options relating to a longer-term facility expansion or relocation.

We have made good progress in our development programs, particularly in our CLIA waiver studies for our DPP® HIV 1/2 Assay and in our having established with the FDA the pathway to regulatory approval for our unique DPP® HIV-Syphilis assay.

On the DPP® HIV 1/2 Assay CLIA waiver study, we are now well on our way to completing the study. However enrollment is slower than planned which, when combined with startup delays will delay when we can file our CLIA waiver application until the fourth quarter. This means therefore that we would not reasonably expect to receive a CLIA waiver decision until early 2014. While disappointing, we believe this kind of delay is not unusual in these circumstances.

On the DPP® HIV-Syphilis product we have made excellent progress with this product in terms of international evaluations and registrations, and we believe that this will result in revenues in the near term. However, the FDA review timeline for this product, which we originally anticipated would be in mid-2014, has now been shifted to late 2014, with CLIA waiver now anticipated in early 2015. This development is due to this product being characterized by the FDA as a PMA, not a 510(K). This change will be more time consuming due to the increased statutory review time, and potentially more costly.

Although there are some challenges in public health budgets due to sequestration, our U.S. product revenues have remained strong. We are ever more optimistic that routine HIV testing will be expanded in the U.S. as a result of the recent full and final endorsement by the U.S. Preventive Services Task Force (USPSTF), with an "A" rating, of the

CDC HIV testing recommendations. This is an important development as we near full implementation of the Affordable Care Act. Also, the USPSTF's recently issued final recommendation on HCV testing validates our HCV rapid test development program, which is proceeding for this product, as more efficacious therapies are expected to come to market, causing an anticipated scale-up in testing, both in the laboratory and at the point of care.

Our plans to directly market our DPP® HIV 1/2 Assay, and future FDA approved products, under Chembio brands, are also expected to enable us to enjoy increased gross margins, but there will be an offsetting cost of supporting this effort from establishing a direct sales and customer and distributor support team, which we are beginning now with some key hires. If we are able to achieve our plan to bring the additional products in our pipeline through this organization, these costs will be distributed over a larger revenue base. This strategy allows Chembio to build a brand in the United States.

24

---

We now also have the opportunity, if we choose to do so, to re-brand our FDA- approved lateral flow HIV rapid tests, which are currently sold by Alere under its Clearview brand, and sell them directly to the market or through distributors, under Chembio brands. This opportunity has come about due to Alere's decision, as anticipated, to introduce a competitive rapid HIV test in the United States, which decision triggered a provision in our agreements with Alere. That provision in our agreement gives Chembio the option, at any time, to terminate Alere's rights to market the cassette agreement and/or to make Alere non-exclusive on the barrel product, although the agreements terminate in 2016 in any case. We are in discussions with Alere concerning alternatives that we believe could be mutually beneficial.

Notwithstanding Alere's decision to compete, we believe that Alere has every interest in continuing to successfully market and promote our lateral flow products for so long as it is in their best interest to do so.

The Company has also been evaluating a number of new technologies that could be the basis for new products. Our opportunities to sell our products under our own brand, expand and improve our facility, and identify new technologies all come at a time when we are looking forward to completing our fifth straight year of top line growth and profitability, with our strongest balance sheet position ever.

ITEM 4. CONTROLS AND PROCEDURES

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,

- (a) 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 six 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)(11)
  - 10.2\* Employment Agreement dated March 5, 2013 with Javan Esfandiari (10).
  - 10.3\* Employment Agreement dated May 22, 2013 with Sharon Klugewicz
  - 10.4 HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Alere and StatSure. (8)
  - 10.5 HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (8)
  - 10.6 Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (8)
  - 10.7 Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (8)
  - 10.8 Secured Revolving Demand Note, dated as of April 30, 2013, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA
  - 10.9 Loan and Security Agreement, dated as of April 30, 2013, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA
  - 14.1 Ethics Policy (9)
  - 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.SCHXBRL Taxonomy Extension Schema Document
  - 101.CALXBRL Taxonomy Extension Calculation Linkbase Document
  - 101.DEF XBRL Taxonomy Definition Linkbase Document
  - 101.LABXBRL 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.
  - 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 Annual Report on Form 10-KSB filed with the Commission on March 30, 2006.
- 10 Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Commission on March 7, 2013.
- 11 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 report.

27

---

SIGNATURES

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

Chembio Diagnostics, Inc.

Date: August 8, 2013 By: /s/ Lawrence A. Siebert  
Lawrence A. Siebert  
Chief Executive Officer  
(Principal Executive Officer)

Date: August 8, 2013 By: /s / Richard J. Larkin  
Richard J. Larkin  
Chief Financial Officer  
(Principal Financial and Accounting Officer)