

CHEMBIO DIAGNOSTICS, INC.  
Form 10-Q  
August 07, 2014

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, 2014

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)

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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 5, 2014, the Registrant had 9,611,139 shares outstanding of its \$.01 par value common stock.

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Quarterly Report on FORM 10-Q  
For The Quarterly Period Ended  
June 30, 2014

Table of Contents

Chembio Diagnostics, Inc.

	Page
Part I. FINANCIAL INFORMATION:	
Item 1. Financial Statements:	
Condensed Consolidated Balance Sheets as of June 30, 2014 (unaudited) and December 31, 2013	2
Condensed Consolidated Statements of Operations (unaudited) for the three and six months ended June 30, 2014 <sub>3</sub> and 2013	3
Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2014 and 2013	4
Notes to Condensed Consolidated Financial Statements (unaudited)	5
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 4. Controls and Procedures	23
Part II. OTHER INFORMATION:	
Item 6. Exhibits	24
SIGNATURES	25
EXHIBITS	

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## PART I

## Item 1. FINANCIAL STATEMENTS

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

## - ASSETS -

	June 30, 2014 (Unaudited)	December 31, 2013
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$6,835,057	\$9,650,275
Accounts receivable, net of allowance for doubtful accounts of \$24,000 at June 30, 2014 and December 31, 2013, respectively	5,423,418	4,592,121
Inventories	4,079,206	3,188,726
Prepaid expenses and other current assets	1,144,404	1,099,379
<b>TOTAL CURRENT ASSETS</b>	<b>17,482,085</b>	<b>18,530,501</b>
FIXED ASSETS, net of accumulated depreciation	2,126,956	1,978,232
<b>OTHER ASSETS:</b>		
Deferred tax asset, net of valuation allowance	3,816,007	3,590,207
License agreements, net of current portion	273,125	326,875
Deposits on manufacturing equipment	94,506	16,410
Deposits and other assets	264,381	44,367
<b>TOTAL ASSETS</b>	<b>\$24,057,060</b>	<b>\$24,486,592</b>
<b>- LIABILITIES AND STOCKHOLDERS' EQUITY -</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$3,795,872	\$4,309,490
<b>TOTAL LIABILITIES</b>	<b>3,795,872</b>	<b>4,309,490</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; 9,611,139 and 9,324,783 shares issued and outstanding for June 30, 2014 and December 31, 2013, respectively	96,112	93,248
Additional paid-in capital	47,326,969	46,875,027
Accumulated deficit	(27,161,893)	(26,791,173)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>20,261,188</b>	<b>20,177,102</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$24,057,060</b>	<b>\$24,486,592</b>

See accompanying notes to condensed consolidated financial statements



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

	For the three months ended		For the six months ended	
	June 30, 2014	June 30, 2013	June 30, 2014	June 30, 2013
<b>REVENUES:</b>				
Net product sales	\$7,248,470	\$5,061,691	\$12,152,635	\$11,374,881
License and royalty revenue	6,971	-	7,131	-
R&D, milestone and grant revenue	167,156	331,831	1,075,904	696,794
<b>TOTAL REVENUES</b>	<b>7,422,597</b>	<b>5,393,522</b>	<b>13,235,670</b>	<b>12,071,675</b>
Cost of product sales	4,440,046	3,112,347	7,980,508	7,096,610
<b>GROSS MARGIN</b>	<b>2,982,551</b>	<b>2,281,175</b>	<b>5,255,162</b>	<b>4,975,065</b>
<b>OPERATING EXPENSES:</b>				
Research and development expenses	1,268,653	1,500,645	2,466,275	2,545,904
Selling, general and administrative expenses	1,946,763	1,160,256	3,404,491	2,322,336
	3,215,416	2,660,901	5,870,766	4,868,240
<b>(LOSS) INCOME FROM OPERATIONS</b>	<b>(232,865 )</b>	<b>(379,726 )</b>	<b>(615,604 )</b>	<b>106,825</b>
<b>OTHER INCOME (EXPENSE):</b>				
(Loss) Gain on sale of fixed asset	(5,707 )	7,500	(5,707 )	7,500
Interest income	1,561	897	3,391	2,235
Interest expense	-	-	-	(335 )
	(4,146 )	8,397	(2,316 )	9,400
<b>(LOSS) INCOME BEFORE INCOME TAXES</b>	<b>(237,011 )</b>	<b>(371,329 )</b>	<b>(617,920 )</b>	<b>116,225</b>
Income tax (benefit) provision	(91,030 )	(130,340 )	(247,200 )	40,090
<b>NET (LOSS) INCOME</b>	<b>\$(145,981 )</b>	<b>\$(240,989 )</b>	<b>\$(370,720 )</b>	<b>\$76,135</b>
Basic (loss) earnings per share	\$(0.02 )	\$(0.03 )	\$(0.04 )	\$0.01
Diluted (loss) earnings per share	\$(0.02 )	\$(0.03 )	\$(0.04 )	\$0.01
Weighted average number of shares outstanding, basic	9,555,944	9,259,506	9,448,160	8,664,478
Weighted average number of shares outstanding, diluted	9,555,944	9,259,506	9,448,160	9,230,840

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, 2014	June 30, 2013
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Cash received from customers and grants	\$12,404,373	\$12,998,825
Cash paid to suppliers and employees	(14,943,293)	(12,197,954)
Interest received	3,391	2,235
Interest paid	-	(335 )
Net cash (used in) provided by operating activities	(2,535,529 )	802,771
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of and deposits on fixed assets	(516,869 )	(415,649 )
Net cash used in investing activities	(516,869 )	(415,649 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from option exercises	237,180	31,432
Proceeds from sale of common stock, net	-	5,512,500
Expenses from sale of common stock	-	(104,038 )
Payment of loan obligation	-	(133,483 )
Net cash provided by financing activities	237,180	5,306,411
<b>(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(2,815,218 )</b>	<b>5,693,533</b>
Cash and cash equivalents - beginning of the period	9,650,275	2,951,859
Cash and cash equivalents - end of the period	\$6,835,057	\$8,645,392
<b>RECONCILIATION OF NET (LOSS) INCOME TO NET CASH (USED IN) PROVIDED BY OPERATING ACTIVITIES:</b>		
Net (Loss) Income	\$(370,720 )	\$76,135
Adjustments:		
Depreciation and amortization	343,799	282,334
Deferred taxes	(225,800 )	36,081
(Recovery of) doubtful accounts	-	(34,000 )
Share based compensation	217,626	221,931
Changes in assets and liabilities:		
Accounts receivable	(831,297 )	961,150
Inventories	(890,480 )	(1,360,224 )
Prepaid expenses and other current assets	(45,025 )	17,080
Deposits and other assets	(220,014 )	-
Accounts payable and accrued liabilities	(513,618 )	625,508
Customer deposits and deferred revenue	-	(23,224 )
Net cash (used in) provided by operating activities	\$(2,535,529 )	\$802,771
<b>Supplemental disclosures for non-cash investing and financing activities:</b>		
Deposits on manufacturing equipment transferred to fixed assets	\$59,798	\$294,813

See accompanying notes to condensed consolidated financial statements

4

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2014  
(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 45 % of the Company's product revenues in the first six months of 2014. The Company's products based on its patented Dual Path Platform (DPP®) platform represented approximately 52 % of the Company's product revenues in the first six months of 2014. The Company also has other rapid tests that together represented approximately 3 % of sales in the first six months of 2014. 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. 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.

NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

a) Basis of Presentation:

The preceding (a) condensed consolidated balance sheet as of December 31, 2013, which has been derived from audited financial statements, and (b) the unaudited interim condensed consolidated financial statements as of June 30, 2014 and for the three- and six-month periods ended June 30, 2014 and 2013, 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, 2013, previously filed with the SEC.

In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present a fair statement of the Company's condensed consolidated financial position as of June 30, 2014, its condensed consolidated results of operations for the three- and six-month periods ended June 30, 2014 and 2013, respectively, and its condensed consolidated cash flows for the six-month periods ended June 30, 2014 and 2013, as applicable, have been made. The interim results of operations are not necessarily indicative of the operating results for the full fiscal year or any future periods.

b) Revenue Recognition

The Company recognizes revenue for product sales in accordance with 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 payments 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, 2014 and December 31, 2013, respectively, all advanced revenues had been earned.

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

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2014  
(UNAUDITED)

## c) Inventories:

Inventories consist of the following at:

	June 30, 2014	December 31, 2013
Raw materials	\$2,087,691	\$1,710,627
Work in process	709,290	464,481
Finished goods	1,282,225	1,013,618
	\$4,079,206	\$3,188,726

## d) Earnings Per Share:

Basic earnings per share is computed by dividing net income or loss by the weighted-average number of common shares outstanding for the period. Diluted income 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, 2014 and 2013, have been included in the earnings per share computations:

	For the three months ended		For the six months ended	
	June 30, 2014	June 30, 2013	June 30, 2014	June 30, 2013
Basic	9,555,944	9,259,506	9,448,160	8,664,478
Diluted	9,555,944	9,259,506	9,448,160	9,230,840

The following securities, presented on a common share equivalent basis for the three and six-month periods ended June 30, 2014 and 2013, 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, 2014 and 2013, respectively:

	For the three months ended		For the six months ended	
	June 30, 2014	June 30, 2013	June 30, 2014	June 30, 2013
1999, 2008 and 2014 Plan Stock Options	-	532,523	-	566,362

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There were 737,183 and 167,458 options outstanding as of June 30, 2014 and 2013, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended June 30, 2014 and 2013, respectively. There were 858,769 and 169,662 options outstanding as of June 30, 2014 and 2013, respectively, that were not included in the calculation of diluted per common share equivalent for the six months ended June 30, 2014 and 2013, respectively, because the effect would have been anti-dilutive as of June 30, 2014 and 2013, 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, 2014, there were no 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 at the time of the initial stock option grant. As of June 30, 2014, there were 336,826 options exercised and 355,877 options outstanding under the SIP.

On March 13, 2014, the Company issued 206,868 stock options to its new CEO under a NASDAQ Rule, which allows for the issuance of options outside of a plan for newly hired employees. These options are still outstanding as of June 30, 2014 and reflected in the stock option activity table below.

Effective June 19, 2014, the Company's stockholders voted to approve the 2014 Stock Incentive Plan ("2014-SIP"), with 800,000 shares of Common Stock available to be issued. Under the terms of the 2014-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 at the time of the initial stock option grant. As of June 30, 2014, there were no options exercised, 93,750 options outstanding and 706,250 options or shares still available to be issued under the 2014-SIP.

The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the six-month periods ended June 30, 2014 and 2013 was \$2.42 and \$5.39 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:

	For the three months ended		For the six months ended	
	June 30, 2014	June 30, 2013	June 30, 2014	June 30, 2013
Expected term (in years)	4.5	3.5	5.8	3.5
Expected volatility	61.50%	93.80%	61.50 % - 86.67 %	93.80 %- 101.30%
Expected dividend yield	0%	0%	0 %	0 %
Risk-free interest rate	0.83%	0.34%	0.83 % - 1.33 %	0.34 % - 0.40%

The Company's results for the three-month periods ended June 30, 2014 and 2013 include share-based compensation expense totaling \$148,300 and \$84,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$200 and \$26,000, respectively), research and development (\$9,400 and \$22,000, respectively) and selling, general and administrative expenses (\$138,700 and \$36,000, respectively). The results for the six-month periods ended June 30, 2014 and 2013 include share-based compensation expense totaling \$218,000 and \$222,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$3,000 and \$56,000, respectively), research and development (\$28,000 and \$62,000, respectively) and selling, general and administrative expenses (\$187,000 and \$104,000, respectively). The income tax benefit has been recognized in the statement of operations for share-based compensation arrangements.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2014  
(UNAUDITED)

Stock option compensation expense for the three and six-month periods ended June 30, 2014 and 2013 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.

The following table provides stock option activity for the six months ended June 30, 2014:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Stock Options Outstanding at December 31, 2013	656,398	\$ 2.57	1.65 years	\$ 801,888
Granted	343,750	3.43		
Exercised	(318,750)	1.04		
Forfeited/expired/cancelled	(24,903 )	3.15		
Outstanding at June 30, 2014	656,495	\$ 3.62	4.42 years	\$ 110,112
Exercisable at June 30, 2014	223,495	\$ 3.62	2.38 years	\$ 83,062

As of June 30, 2014, there was \$785,000 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 2.63 years. The total fair value of stock options vested during the six-month periods ended June 30, 2014 and 2013 was approximately \$165,000 and \$174,000, 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, 2014	June 30, 2013	June 30, 2014	June 30, 2013
Africa	\$418,343	\$1,009,899	\$1,249,805	\$1,857,221
Asia	23,711	31,353	74,757	50,619
Europe	34,966	69,324	71,025	76,929
North America	2,769,529	2,464,060	6,532,678	5,285,578
South America	4,001,921	1,487,055	4,224,370	4,104,534
	\$7,248,470	\$5,061,691	\$12,152,635	\$11,374,881



CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2014  
(UNAUDITED)

## g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

	June 30, 2014	December 31, 2013
Accounts payable – suppliers	\$1,861,955	\$1,815,369
Accrued commissions	500,220	371,905
Accrued royalties / license fees	675,932	1,028,286
Accrued payroll	289,276	328,564
Accrued vacation	264,168	203,444
Accrued bonuses	-	317,372
Accrued expenses – other	204,321	244,550
TOTAL	\$3,795,872	\$4,309,490

## h) Recent Accounting Pronouncements Affecting the Company

## Revenue from Contracts with Customers

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, "Revenue from Contracts with Customers: Topic 606" (ASU 2014-09), to supersede nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing U.S. GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective for us in our first quarter of fiscal 2017 using either of two methods: (i) retrospective to each prior reporting period presented with the option to elect certain practical expedients as defined within ASU 2014-09; or (ii) retrospective with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application and providing certain additional disclosures as defined per ASU 2014-09. We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statement.

## NOTE 3 — COLLABORATIVE RESEARCH AND DEVELOPMENT ARRANGEMENTS:

## a) National Institutes of Health (NIH) Grant:

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 \$248,300 and \$331,000 for the six-month periods ended June 30, 2014 and 2013, respectively from this grant. The Company earned \$2,714,300 from this grant from inception through June 30, 2014, of which \$964,200 was paid to sub-contractors.

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



In April 2013, the Company entered into a follow-on, milestone-based development agreement of up to an additional \$472,000, resulting in a total amount of \$953,000, 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 an additional period of approximately nine months in which the follow-on development activity is to be completed. The Company earned \$64,200 and \$265,000 for the six-month periods ended June 30, 2014 and 2013, respectively from this agreement. The Company earned \$985,250 from this grant from inception through June 30, 2014.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2014  
(UNAUDITED)

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.

The HSBC Security Agreement, which is 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, 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, 2014, 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").

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2014  
(UNAUDITED)

## NOTE 6 — COMMON STOCK, WARRANTS AND OPTIONS:

The Company entered into an employment agreement, effective March 13, 2014 ("Employment Agreement"), with Mr. Sperzel to serve as the Company's Chief Executive Officer, which included issuing incentive and non-incentive stock options to purchase 250,000 shares of the Company's common stock. Of these stock options, options to purchase 50,000 shares vest on each of the first five anniversaries of the effective date of the Employment Agreement. The exercise price for these options was to be equal to the volume-weighted average trading price for the Company's common stock on March 13, 2014, which was \$3.4163 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 Mr. Sperzel's employment with the Company or (b) the seventh anniversary of the effective date of the grant.

## 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, 2014		June 30, 2013		June 30, 2014		June 30, 2013		June 30, 2014	June 30, 2013
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales		
Customer 1	\$1,462,460	20	\$2,305,729	46	\$4,165,432	34	\$4,895,683	43	\$538,934	\$905,829
Customer 2	1,215,872	17	*	*	2,217,242	18	*	*	689,250	-
Customer 3	3,964,903	55	650,221	13	4,166,801	34	1,869,096	16	3,137,726	712,950

(\* ) 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				For the six months ended				Accounts Payable as of	
	June 30, 2014		June 30, 2013		June 30, 2014		June 30, 2013		June 30, 2014	June 30, 2013
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	\$341,534	13	\$239,539	6	\$622,220	14	\$565,384	9	\$90,469	\$67,945
Vendor 2	496,167	18	*	*	731,061	17	*	*	-	-

(\* ) 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.

11

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2014  
(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 three key employees. The contracts call for salaries presently aggregating \$929,500 per year. The Sperzel contract expires in March 2017, the Klugewicz contract expires in May 2015, and the Esfandiari contract expires in March 2016. In connection with the contract that expires in March 2017, the Company issued, in March 2014, 250,000 options to purchase common stock, with one-fifth vesting on each of the first five anniversaries of the grant. 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. 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 (benefit) for income taxes is estimated based on our calculated effective tax rate expected to be applied for the full year. This estimate is used to determine the income tax (benefit) on a year-to-date basis and may change in subsequent interim periods. Our effective tax rate for the six-months ended June 30, 2014 was a benefit of 40.0%. We calculated the current portion to be 8.6% of the (benefit), or \$(21,400), which was attributable to income tax (receivable) and the balance of \$(225,800) (increased) the carrying value of the deferred tax asset for the six months ended June 30, 2014. The 40.0% benefit rate is less than the 47.8% provision rate used for the year ended 2013 primarily as a result of a change in the percentage impact of nondeductible expenses.

## 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, 2013.

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 which are currently marketed under Chembio's label (DPP® HIV 1/2 Screening Assay and DPP® HIV 1/2 –Syphilis Assay), or which may be marketed pursuant to private label license or distribution agreements such as those with the Oswaldo Cruz Foundation ("FIOCRUZ"), Labtest, RVR and Bio-Rad.

Research and development ("R&D"), milestone, and grant and royalty revenues for the three months ended June 30, 2014 decreased to \$167,000 from \$332,000 in the prior-year period, while these categories of revenues for the six months ended June 30, 2014 increased to \$1,076,000 from \$697,000 in the prior-year period, which was the result in the first quarter of a focus towards contract services and/or partnerships utilizing Chembio's patented Dual Path

Platform (DPP®) technology for the detection of multiple analytes or biomarkers. More specifically, a key factor in the increase in these categories of revenue relates to the agreement announced in February 2014 with RVR Diagnostics SDN BHD ("RVR"), a privately-held company in Malaysia, to support Chembio's strategy of establishing a market presence in Asia, and provides for collaboration with RVR as a licensee, distributor, and contract manufacturer of the DPP® platform. This agreement granted exclusive distribution rights to RVR in certain countries in the region and enables RVR to manufacture Chembio's DPP® HIV 1/2 Assay and Chembio's DPP® HIV-Syphilis Assay, as well as potentially other products developed by Chembio incorporating its patented DPP® technology. R&D expenses in the second quarter of 2014 were \$1.27 million, compared with \$1.50 million in the prior-year period, while R&D expenses in the first six months of 2014 were \$2.47 million, compared with \$2.55 million in the prior-year period. Development work continues on several assays utilizing Chembio's DPP® platform, including the DPP® HIV multiplex test that is designed to detect acute (early stage) HIV infection by means of detecting P24 antigen, as well as antibodies, to HIV1/2, and the DPP® HCV point-of-care rapid test.

13

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#### Sponsored Research & Development

DPP® Febrile Illness Multiplex test – During the second quarter of 2013 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. We have completed R&D activities for this project as anticipated, and have provided a total of 10,000 devices, pending results of a multi-center clinical trial in multiple countries. We continue to explore commercial opportunities outside the scope of the government agreement for this application.

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.

Chembio's work to finalize the 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. The grant application has been extended to September 2014, and is progressing on track.

In addition to the above-mentioned research and development work sponsored by governmental agencies and/or their contractors, we continue to seek additional opportunities for sponsored research and development activity in our efforts to foster innovation and identify opportunities for new product development and commercialization.

#### Regulatory Activities

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. The CLIA waiver was submitted in November 2013, and in February 2014 we received a letter from the FDA on the current status of review of our CLIA waiver application. Since that time, we have had multiple discussions with the FDA, and additional in-house laboratory studies were requested by the FDA to complete its review of the application for CLIA waiver. These in-house studies have been conducted and were submitted to the FDA in June 2014.

DPP® HIV-Syphilis – We have developed this product for international and U.S. marketing. For the international market, the product has been registered in Mexico. 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.

Our discussions with the FDA concerning the clinical studies that will be required for PMA submission indicate that the assay shows excellent performance with respect to those with active syphilis infections. However, there is a potential that infections that could become active may be missed based on the current clinical algorithm used in the United States to assess the syphilis component performance of this assay. Thus, we will need to modify the assay for the United States to meet FDA requirements.

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, 2013, see our Annual Report on Form 10-K for the twelve months ended December 31, 2013, which was filed with the SEC on March 6, 2014.

## RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED JUNE 30, 2014 AS COMPARED WITH THE THREE MONTHS ENDED JUNE 30, 2013

Income:

For the three months ended June 30, 2014, Loss before income taxes was \$(237,000) compared to Loss before income taxes of \$(371,000) for the three months ended June 30, 2013. Net Loss for the 2014 period was \$(146,000) as compared to a Net Loss of \$(241,000) for 2013. The decrease in net loss is primarily attributable to increased gross margin, partially offset by increased operating expenses. Gross margin increased in the three months ended June 30, 2014, as compared with the three months ended June 30, 2013, by \$701,000, or 30.8%. This increased gross margin was partially offset by increased operating expenses, the most significant of which was an increase in commissions of \$389,000 along with increased wages and related expenses of \$260,000, which accounted for most of the change in net loss.

Revenues:

Selected Product Categories:	For the three months ended			
	June 30, 2014	June 30, 2013	\$ Change	% Change
Lateral Flow HIV Tests and Components	\$ 1,886,909	\$ 4,158,354	\$ (2,271,445)	-54.62 %
DPP Tests and Components	5,167,025	694,816	4,472,209	643.65 %
Other	194,536	208,521	(13,985)	-6.71 %
Net Product Sales	7,248,470	5,061,691	2,186,779	43.20 %
License and royalty revenue	6,971	-	6,971	100.00 %
R&D, milestone and grant revenue	167,156	331,831	(164,675)	-49.63 %
Total Revenues	\$ 7,422,597	\$ 5,393,522	\$ 2,029,075	37.62 %

Revenues for our lateral flow HIV tests and related components during the three months ended June 30, 2014 decreased by approximately \$2,271,000 from the same period in 2013. This was primarily attributable to decreased sales to South America, of approximately \$778,000, decreased sales to the U.S., of approximately \$843,000, and decreased sales to Africa, of approximately \$592,000. Revenues for our DPP® products during the three months ended June 30, 2014 increased by approximately \$4,472,000 over the same period in 2013, primarily due to increased sales in Brazil to FIOCRUZ. The decrease in R&D, and in milestone and grant revenue, was primarily due to a reduction in revenue from certain development projects that are nearing completion. 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, 2014	June 30, 2013	\$ Change	% Change
Gross Margin per Statement of Operations	\$2,982,551	\$2,281,175	\$701,376	30.75 %
Less: R&D, milestone, grant, license and royalty revenues	174,127	331,831	(157,704)	-47.53 %
Gross Margin from Net Product Sales	\$2,808,424	\$1,949,344	\$859,080	44.07 %
Product Gross Margin %	38.75 %	38.51 %		

The gross margin dollar increase of \$701,000 included a \$859,000 increase in gross margin from product sales and was partially offset by a \$158,000 decrease in non-product revenues. The increase in product gross margin of \$859,000 is primarily attributable to the higher product sales compared to 2013. The product gross margin increase is comprised of two components, one is the increase in product sales of \$2,187,000, which at the 38.51% margin percentage contributed \$842,000 to the increase, and second, the increased change in margin percentage of .24% contributed the balance of \$17,000 to the increase in our product gross margin.

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, 2014	June 30, 2013	\$ Change	% Change
<b>Clinical and Regulatory Affairs:</b>				
Wages and related costs	\$106,546	\$108,466	\$ (1,920 )	-1.77 %
Consulting	22,089	7,463	14,626	195.98 %
Stock-based compensation	806	3,027	(2,221 )	-73.37 %
Clinical trials	29,712	421,768	(392,056)	-92.96 %
Other	21,514	24,466	(2,952 )	-12.07 %
Total Regulatory	180,667	565,190	(384,523)	-68.03 %
<b>R&amp;D Other than Regulatory:</b>				
Wages and related costs	614,897	538,789	76,108	14.13 %
Consulting	68,801	42,326	26,475	62.55 %
Stock-based compensation	8,631	19,334	(10,703 )	-55.36 %
Materials and supplies	288,438	251,716	36,722	14.59 %
Other	107,219	83,290	23,929	28.73 %
Total other than Regulatory	1,087,986	935,455	152,531	16.31 %
Total Research and Development	\$1,268,653	\$1,500,645	\$ (231,992)	-15.46 %

Expenses for Clinical & Regulatory Affairs for the three months ended June 30, 2014 decreased by \$385,000 as compared to the same period in 2013. This was primarily due to a decrease of \$392,000 in clinical trial expenses, partially offset by an increase in consulting.

R&D expenses other than Clinical & Regulatory Affairs increased by \$153,000 in the three months ended June 30, 2014, as compared with the same period in 2013. 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, 2014	June 30, 2013	\$ Change	% Change
Wages and related costs	\$638,377	\$452,103	\$186,274	41.20 %
Consulting	159,603	100,061	59,542	59.51 %
Commissions	481,276	92,002	389,274	423.11 %
Stock-based compensation	137,592	34,867	102,725	294.62 %
Marketing materials	41,114	22,294	18,820	84.42 %
Investor relations/investment bankers	41,277	39,023	2,254	5.78 %
Legal, accounting and compliance	83,450	73,587	9,863	13.40 %
Travel, entertainment and trade shows	111,914	69,554	42,360	60.90 %
Other	252,160	276,765	(24,605 )	-8.89 %
Total S, G &A	\$1,946,763	\$1,160,256	\$786,507	67.79 %

Selling, general and administrative expenses for the three months ended June 30, 2014, increased by \$787,000 as compared with the same period in 2013, a 68% increase. Significant increases in commissions due to increased sales to Brazil, along with increases in wages and related costs, which for 2014 included the COO (not included in 2013), consulting and travel entertainment and trade shows, which were partially offset by a decrease in other expenses.

Other Income and (Expense):

	For the three months ended			
	June 30, 2014	June 30, 2013	\$ Change	% Change
Other income (expense)	\$ (5,707)	\$7,500	\$ (13,207)	-176.09%
Interest income	1,561	897	664	74.02 %
Total Other Income and (Expense)	\$ (4,146)	\$8,397	\$ (12,543)	-149.37%

Other income (expense) for the three months ended June 30, 2014 decreased approximately \$12,000, to an expense of \$4,000 from an income of \$8,000 in the same period in 2013, as a result of the sale of a fixed asset partially offset by an increase in interest income.

## RESULTS OF OPERATIONS FOR THE SIX MONTHS ENDED JUNE 30, 2014 AS COMPARED WITH THE SIX MONTHS ENDED JUNE 30, 2013

Income:

For the six months ended June 30, 2014, Loss before income taxes was \$(618,000) compared to Income before taxes of \$116,000 for the six months ended June 30, 2013. Net Loss for the 2014 period was \$(371,000) as compared to a Net Income of \$76,000 for 2013. The decrease in net income is primarily attributable to increased operating expenses. Gross margin increased in the six months ended June 30, 2014 as compared with the six months ended June 30, 2013, by \$280,000, or 5.6%. This increased gross margin was offset by increased operating expenses, the most significant of which was an increase in wages and related expenses of \$570,000 along with an increase in commissions of \$260,000 and consulting expenses of \$218,000, which accounted for most of the change in net loss.

Revenues:

Selected Product Categories:	For the six months ended			
	June 30, 2014	June 30, 2013	\$ Change	% Change
Lateral Flow HIV Tests and Components	\$5,423,608	\$9,095,215	\$ (3,671,607)	-40.37 %
DPP Tests and Components	6,335,795	1,837,651	4,498,144	244.78 %
Other	393,232	442,015	(48,783 )	-11.04 %
Net Product Sales	12,152,635	11,374,881	777,754	6.84 %
License and royalty revenue	7,131	-	7,131	100.00 %
R&D, milestone and grant revenue	1,075,904	696,794	379,110	54.41 %
Total Revenues	\$13,235,670	\$12,071,675	\$ 1,163,995	9.64 %

Revenues for our lateral flow HIV tests and related components during the six months ended June 30, 2014 decreased by approximately \$3,672,000 from the same period in 2013. This was primarily attributable to decreased sales to South America, of approximately \$1,963,000, decreased sales to the U.S. of \$730,000, and of other North American sales of \$293,000, along with decreased sales to Africa of \$607,000. Revenues for our DPP® products during the six months ended June 30, 2014 increased by approximately \$4,498,000 over the same period in 2013, primarily for sales in Brazil to FIOCRUZ. The increase in R&D, and in milestone and grant revenue, was primarily due to \$750,000 in revenue from the license contract we signed in February 2014 with RVR Diagnostics. This was partially offset by a reduction in revenue from certain development projects that are nearing completion. 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 six months ended			
	June 30, 2014	June 30, 2013	\$ Change	% Change
Gross Margin per Statement of Operations	\$5,255,162	\$4,975,065	\$ 280,097	5.63 %
Less: R&D, milestone, grant, license and royalty revenues	1,083,035	696,794	386,241	55.43 %
Gross Margin from Net Product Sales	\$4,172,127	\$4,278,271	\$ (106,144)	-2.48 %
Product Gross Margin %	34.33 %	37.61 %		

The gross margin dollar increase of \$280,000 included a \$106,000 decrease in gross margin from product sales and was offset by a \$386,000 increase in non-product revenues. The decrease in product gross margin of \$106,000 is primarily attributable to the change in product mix compared to 2013. The product gross margin decrease is comprised of two components, one is the decreased change in margin percentage of 3.3% which contributed \$399,000

to the decrease, and second, the increase in product sales of \$778,000, which at the 37.6% margin percentage partially offset the decrease by \$(293,000). The 3.3% decrease in the percentage, from 37.6% in 2013 to 34.3% in 2014, was primarily due to a larger amount of unapplied overhead.

18

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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		\$ Change	% Change
	June 30, 2014	June 30, 2013		
<b>Clinical and Regulatory Affairs:</b>				
Wages and related costs	\$212,689	\$213,957	\$ (1,268 )	-0.59 %
Consulting	24,508	25,189	(681 )	-2.70 %
Stock-based compensation	3,231	14,632	(11,401 )	-77.92 %
Clinical trials	150,495	519,544	(369,049)	-71.03 %
Other	39,758	28,544	11,214	39.29 %
Total Regulatory	430,681	801,866	(371,185)	-46.29 %
<b>R&amp;D Other than Regulatory:</b>				
Wages and related costs	1,182,670	1,046,583	136,087	13.00 %
Consulting	113,351	52,163	61,188	117.30 %
Stock-based compensation	24,457	47,641	(23,184 )	-48.66 %
Materials and supplies	524,596	432,896	91,700	21.18 %
Other	190,520	164,755	25,765	15.64 %
Total other than Regulatory	2,035,594	1,744,038	291,556	16.72 %

Total Research and Development \$2,466,275 \$2,545,904 \$ (79,629 ) -3.13 %

Expenses for Clinical & Regulatory Affairs for the six months ended June 30, 2014 decreased by \$371,000 as compared to the same period in 2013. This was primarily due to a decrease of \$369,000 in clinical trial expenses.

R&D expenses other than Clinical & Regulatory Affairs increased by \$292,000 in the six months ended June 30, 2014, as compared with the same period in 2013. 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 six months ended		\$ Change	% Change
	June 30, 2014	June 30, 2013		
Wages and related costs	\$1,328,879	\$893,575	\$435,304	48.71 %
Consulting	263,350	106,261	157,089	147.83 %
Commissions	511,711	251,910	259,801	103.13 %
Stock-based compensation	186,726	103,533	83,193	80.35 %
Marketing materials	65,100	29,257	35,843	122.51 %
Investor relations/investment bankers	88,109	113,886	(25,777 )	-22.63 %
Legal, accounting and compliance	296,430	313,644	(17,214 )	-5.49 %
Travel, entertainment and trade shows	151,462	97,305	54,157	55.66 %
Bad debt allowance (recovery)	-	(33,450 )	33,450	-100.00 %
Other	512,724	446,415	66,309	14.85 %
Total S, G & A	\$3,404,491	\$2,322,336	\$1,082,155	46.60 %

Selling, general and administrative expenses for the six months ended June 30, 2014, increased by \$1,082,000 as compared with the same period in 2013, a 46.6% increase. Significant increases in wages and related costs, which for

2014 included the COO (not included in 2013), consulting expenses, the cost of the CEO search, and commissions due to increased sales to Brazil, which were partially offset by a decrease in investor relations/investment bankers, and a decrease in professional fees.

19

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Other Income and (Expense):

	For the six months ended			
	June 30, 2014	June 30, 2013	\$ Change	% Change
Other income (expense)	\$ (5,707)	\$ 7,500	\$ (13,207)	-176.09%
Interest income	3,391	2,235	1,156	51.72 %
Interest expense	-	(335 )	335	-100.00%
Total Other Income and (Expense)	\$ (2,316)	\$ 9,400	\$ (11,716)	-124.64%

Other income (expense) for the six months ended June 30, 2014 decreased approximately \$11,700, to an expense of \$2,300 from an income of \$9,400 in the same period in 2013, as a result of an increase in interest income and a decrease in interest expense due on the term loan with HSBC.

Income tax (benefit) provision:

For the six months ended June 30, 2014 the Company recognized a \$(247,200) income tax benefit and increased its deferred tax assets by \$(225,800). The Company maintains a full valuation allowance on research and development tax credits.

**MATERIAL CHANGES IN FINANCIAL CONDITION**

## Selected Changes in Financial Condition

	As of			
	June 30, 2014	December 31, 2013	\$ Change	% Change
Cash and cash equivalents	\$6,835,057	\$9,650,275	\$ (2,815,218)	-29.17 %
Accounts receivable, net of allowance for doubtful accounts of \$24,000 at June 30, 2014 and December 31, 2013, respectively	5,423,418	4,592,121	831,297	18.10 %
Inventories	4,079,206	3,188,726	890,480	27.93 %
Fixed assets, net of accumulated depreciation	2,126,956	1,978,232	148,724	7.52 %
Deposits and other assets	264,381	44,367	220,014	495.90 %
Deferred tax asset, net of valuation allowance	3,816,007	3,590,207	225,800	6.29 %
Accounts payable and accrued liabilities	3,795,872	4,309,490	(513,618 )	-11.92 %

Cash decreased by \$2,815,000 from December 31, 2013, primarily due to net cash used in operating activities for the six months of 2014. In addition there were increases in accounts receivable, net of allowance, of \$831,000, inventories of \$891,000, fixed assets of \$149,000, deposits and other assets of \$220,000 and deferred taxes of \$226,000. We experienced a decrease in accounts payable and accrued liabilities of \$514,000.

The increase in accounts receivable was primarily attributable to the higher amount of credit sales at the end of June 2014 versus December of 2013. The increase in inventories is due to production for orders received to be shipped in the third quarter of 2014. The increase in fixed assets is primarily due to the new warehouse facility. The increase in deposits and other assets is due to additional rental deposits and related capitalized expenses. Deferred tax asset increase is related to the provision for income tax benefit.

## LIQUIDITY AND CAPITAL RESOURCES

	For the six months ended			% Change
	June 30, 2014	June 30, 2013	\$ Change	
Net cash (used in) provided by operating activities	\$ (2,535,529)	\$ 802,771	\$ (3,338,300)	-415.85 %
Net cash (used in) investing activities	(516,869 )	(415,649 )	(101,220 )	24.35 %
Net cash provided by (used in) financing activities	237,180	5,306,411	(5,069,231)	-95.53 %
(DECREASE) IN CASH AND CASH EQUIVALENTS	\$ (2,815,218)	\$ 5,693,533	\$ (8,508,751)	-149.45 %

The Company's cash as of June 30, 2014 decreased by \$2,815,000 from December 31, 2013, primarily due to net cash used in operating activities for the six months of 2014.

The cash used in operations in 2014 was \$2,536,000, primarily due to an increase in accounts receivable of \$831,000, an increase in inventories of \$890,000, a reduction in accounts payable and other accrued liabilities of \$514,000, an increase in deposits and other assets of \$220,000, an increase in prepaid and other current assets of \$45,000, and a net loss net of non-cash items of \$35,000. Net loss net of non-cash items includes net loss of \$371,000, \$226,000 in benefit for income taxes, partially offset by \$344,000 in depreciation and amortization, and \$218,000 in share-based compensation. The use of cash from investing activities is primarily the purchase of fixed assets. The increase in cash from financing activities was proceeds from option exercises.

The increase in cash in 2013 was \$5,694,000, 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, and deferred tax asset of \$36,000. We experienced increases in inventories of \$1,360,000, fixed assets of \$416,000 and accounts payable and accrued expenses of \$626,000.

## Fixed Asset Commitments

As of June 30, 2014, the Company had paid deposits on various pieces of equipment aggregating \$94,506, which is reflected in deposits on manufacturing equipment on the balance sheet. The Company has commitments for \$147,322 in additional equipment purchase obligations.

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

During the second quarter, our revenue increased by 37.6% compared to the prior year, and our June 30, 2014 year-to-date revenue increased by 9.6% compared to the prior year.

Looking forward, we firmly believe our patented DPP® technology will be an important growth driver for the Company. The Chembio DPP® HIV 1/2 Assay is FDA-approved for use with oral fluid or blood samples. As we updated last quarter, the FDA agreed to review our CLIA waiver application for the DPP® HIV 1/2 Assay based on additional data from studies to be conducted at Chembio. The requested studies were completed on schedule, data was submitted to the FDA during Q2, and we anticipate a response from the FDA during Q3 2014.

Concurrent with this work, we achieved an important milestone in the U.S. by establishing a Chembio sales and marketing organization to serve end-user customers and distribution partners. While this effort is new and initially focused on Chembio's FDA-approved and CLIA-waived STAT-PAK HIV 1/2 Assay, we believe this initiative is important for future growth. The Company is currently in the process of hiring additional sales representatives to expand the commercialization team in anticipation of the potential CLIA waiver for the DPP® HIV 1/2 Assay. A CLIA waiver will allow Chembio to expand the current market for this product to include CLIA-waived sites, such as physician-office-lab (POL) facilities, clinics and other community healthcare providers.

Other important developments during the quarter include exploring opportunities to apply our DPP® technology not only within the infectious disease field but also across a wider spectrum of disease areas. While these discussions are early, we are thrilled to have the attention of a number of leading organizations, all of which share our commitment to improving healthcare through early and accurate diagnostic testing.

And, to facilitate future sales growth from current products or those in development, Chembio made essential investments in technology and the Company's manufacturing infrastructure during the second quarter. Importantly, we expanded our FDA-approved manufacturing facility in Medford, NY, which will significantly increase our production capacity.

Outside the U.S., Chembio continues to work with our partners to build successful markets in Latin America and Asia. Our partnerships in Latin America continue to contribute significantly toward the success of the Company. Our partnership with RVR (Malaysia) has the potential to be a key contributor for growth, allowing Chembio to expand its commercial presence in the Asia region.

As we reach the mid-point of the year, we are very pleased with our key accomplishments. Revenue increased on a quarterly and year-to-date basis, compared to prior-year periods. We successfully launched our U.S. commercial organization and expanded our production capacity. We are optimistically awaiting the FDA response to our CLIA waiver application for the Chembio DPP® HIV 1/2 Assay, which, if positive, would provide us access to significant new markets. Our international partners continue to build demand for our products overseas. And lastly, our leadership team is actively evaluating opportunities for new product development and strategic partnerships beyond infectious disease. We anticipate that the Company's progress in some or all of these areas will sustain Chembio's growth in the future.

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.

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 (b) under the Exchange Act that occurred during the Company's first six months of fiscal 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 Form of Option, for 2008 Stock Incentive Plan.
- 4.5 Rights Agreement, dated March 8, 2010 (6)
- 4.6 Form of Warrant (to be filed by amendment) [to be revised]
- 4.7 Form of Option, for 2014 Stock Incentive Plan.
- 10.1\* Employment Agreement dated March 13, 2014 with John J. Sperzel III
- 10.2\* Employment Agreement dated March 5, 2013 with Javan Esfandiari (10).
- 10.3\* Employment Agreement dated May 22, 2013 with Sharon Klugewicz (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)
- 10.8 Secured Revolving Demand Note, dated as of April 30, 2013, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (12)
- 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 (12)
- 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.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.
- 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.

12 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on August 8, 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.

24

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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 7, 2014 By: /s/ John J. Sperzel III  
John J. Sperzel III  
Chief Executive Officer  
(Principal Executive Officer)

Date: August 7, 2014 By: /s / Richard J. Larkin  
Richard J. Larkin  
Chief Financial Officer  
(Principal Financial and Accounting Officer)