

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

CHEMBIO DIAGNOSTICS, INC.

Form 10-Q

November 06, 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 September 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)

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

Yes No  x

As of November 4, 2014, the Registrant had 9,611,139 shares outstanding of its \$.01 par value common stock.

---

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

Table of Contents

Chembio Diagnostics, Inc.

	Page
<b>Part I. FINANCIAL INFORMATION:</b>	
Item 1. Financial Statements:	
Condensed Consolidated Balance Sheets as of September 30, 2014 (unaudited) and December 31, 2013	2
Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2014 and 2013	3
Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 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	10
Item 4. Controls and Procedures	17
<b>Part II. OTHER INFORMATION:</b>	
Item 6. Exhibits	18
<b>SIGNATURES</b>	19
<b>EXHIBITS</b>	

---

## PART I

## Item 1. FINANCIAL STATEMENTS

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

## - ASSETS -

	September 30, 2014 (Unaudited)	December 31, 2013
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$3,672,702	\$9,650,275
Accounts receivable, net of allowance for doubtful accounts of \$24,000 at September 30, 2014 and December 31, 2013, respectively	8,315,651	4,592,121
Inventories	3,975,250	3,188,726
Prepaid expenses and other current assets	1,035,435	1,099,379
<b>TOTAL CURRENT ASSETS</b>	<b>16,999,038</b>	<b>18,530,501</b>
FIXED ASSETS, net of accumulated depreciation	2,118,756	1,978,232
<b>OTHER ASSETS:</b>		
Deferred tax asset, net of valuation allowance	3,829,549	3,590,207
License agreements, net of current portion	246,250	326,875
Deposits on manufacturing equipment	479,869	16,410
Deposits and other assets	255,157	44,367
<b>TOTAL ASSETS</b>	<b>\$23,928,619</b>	<b>\$24,486,592</b>
<b>- LIABILITIES AND STOCKHOLDERS' EQUITY -</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$3,819,271	\$4,309,490
<b>TOTAL LIABILITIES</b>	<b>3,819,271</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 September 30, 2014 and December 31, 2013, respectively	96,112	93,248
Additional paid-in capital	47,445,750	46,875,027
Accumulated deficit	(27,432,514)	(26,791,173)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>20,109,348</b>	<b>20,177,102</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$23,928,619</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 nine months ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
<b>REVENUES:</b>				
Net product sales	\$7,247,881	\$9,044,714	\$19,400,515	\$20,419,595
License and royalty revenue	8,482	898	15,613	898
R&D, milestone and grant revenue	57,946	572,027	1,133,850	1,268,821
<b>TOTAL REVENUES</b>	<b>7,314,309</b>	<b>9,617,639</b>	<b>20,549,978</b>	<b>21,689,314</b>
Cost of product sales	4,663,919	5,561,453	12,644,427	12,658,063
<b>GROSS MARGIN</b>	<b>2,650,390</b>	<b>4,056,186</b>	<b>7,905,551</b>	<b>9,031,251</b>
<b>OPERATING EXPENSES:</b>				
Research and development expenses	972,439	1,602,297	3,438,714	4,148,201
Selling, general and administrative expenses	1,940,424	1,379,845	5,344,914	3,702,181
	2,912,863	2,982,142	8,783,628	7,850,382
<b>(LOSS) INCOME FROM OPERATIONS</b>	<b>(262,473 )</b>	<b>1,074,044</b>	<b>(878,077 )</b>	<b>1,180,869</b>
<b>OTHER INCOME (EXPENSE):</b>				
(Loss) gain on sale of fixed asset	-	-	(5,707 )	7,500
Interest income	1,136	1,477	4,527	3,712
Interest expense	-	-	-	(335 )
	1,136	1,477	(1,180 )	10,877
<b>(LOSS) INCOME BEFORE INCOME TAXES</b>	<b>(261,337 )</b>	<b>1,075,521</b>	<b>(879,257 )</b>	<b>1,191,746</b>
Income tax (benefit) provision	9,284	358,850	(237,916 )	398,940
<b>NET (LOSS) INCOME</b>	<b>\$(270,621 )</b>	<b>\$716,671</b>	<b>\$(641,341 )</b>	<b>\$792,806</b>
Basic (loss) earnings per share	\$(0.03 )	\$0.08	\$(0.07 )	\$0.09
Diluted (loss) earnings per share	\$(0.03 )	\$0.07	\$(0.07 )	\$0.08
Weighted average number of shares outstanding, basic	9,611,139	9,324,783	9,503,084	8,886,998
Weighted average number of shares outstanding, diluted	9,611,139	9,824,019	9,503,084	9,433,152

See accompanying notes to condensed consolidated financial statements

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

	September 30, 2014	September 30, 2013
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Cash received from customers and grants	\$ 16,826,448	\$ 21,005,456
Cash paid to suppliers and employees	(21,985,579)	(20,425,025)
Interest received	4,527	3,712
Interest paid	-	(335 )
Net cash (used in) provided by operating activities	(5,154,604 )	583,808
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of License	-	(30,000 )
Acquisition of and deposits on fixed assets	(1,060,149 )	(766,274 )
Net cash used in investing activities	(1,060,149 )	(796,274 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from option exercises	237,180	31,433
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	5,306,412
<b>(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(5,977,573 )</b>	<b>5,093,946</b>
Cash and cash equivalents - beginning of the period	9,650,275	2,951,859
Cash and cash equivalents - end of the period	\$ 3,672,702	\$ 8,045,805
<b>RECONCILIATION OF NET (LOSS) INCOME TO NET CASH (USED IN) PROVIDED BY OPERATING ACTIVITIES:</b>		
Net (Loss) Income	\$(641,341 )	\$ 792,806
Adjustments:		
Depreciation and amortization	536,791	446,235
Deferred taxes	(239,342 )	359,046
(Recovery of) doubtful accounts	-	(34,000 )
Share based compensation	336,407	284,152
Changes in assets and liabilities:		
Accounts receivable	(3,723,530 )	(649,858 )
Inventories	(786,524 )	(1,259,110 )
Prepaid expenses and other current assets	63,944	38,848
Deposits and other assets	(210,790 )	(2,200 )
Accounts payable and accrued liabilities	(490,219 )	631,113
Customer deposits and deferred revenue	-	(23,224 )
Net cash (used in) provided by operating activities	\$(5,154,604 )	\$ 583,808

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

Supplemental disclosures for non-cash investing and financing activities:

Deposits on manufacturing equipment transferred to fixed assets	\$63,960	\$296,788
---	----------	-----------

See accompanying notes to condensed consolidated financial statements

4

---

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 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 36 % of the Company's product revenues in the first nine months of 2014. The Company's products based on its patented Dual Path Platform (DPP®) platform represented approximately 61 % of the Company's product revenues in the first nine months of 2014. The Company also has other rapid tests that together represented approximately 3 % of sales in the first nine 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 September 30, 2014 and for the three- and nine-month periods ended September 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 September 30, 2014, its condensed consolidated results of operations for the three- and nine-month periods ended September 30, 2014 and 2013, respectively, and its condensed consolidated cash flows for the nine-month periods ended September 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 September 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.

c) Inventories:

Inventories consist of the following at:

	September 30, 2014	December 31, 2013
Raw materials	\$ 1,967,880	\$ 1,710,627
Work in process	606,795	464,481
Finished goods	1,400,575	1,013,618
	\$ 3,975,250	\$ 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 nine-month periods ended September 30, 2014 and 2013, have been included in the earnings per share computations:

	For the three months ended		For the nine months ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Basic	9,611,139	9,324,783	9,503,084	8,886,998
Diluted	9,611,139	9,824,019	9,503,084	9,433,152

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

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

	For the three months ended		For the nine months ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
1999, 2008 and 2014 Plan Stock Options	-	499,236	-	546,154

There were 547,825 and 169,662 options outstanding as of September 30, 2014 and 2013, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended September 30, 2014 and 2013, respectively. There were 649,465 and 169,662 options outstanding as of September 30, 2014 and 2013, respectively, that were not included in the calculation of diluted per common share equivalent for the nine months ended September 30, 2014 and 2013, respectively, because the effect would have been anti-dilutive as of September 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 September 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 September 30, 2014, there were 336,826 options exercised and 355,251 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 September 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 nine-month periods ended September 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 nine months ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Expected term (in years) -	-	-	6.3	3.0
Expected volatility	0.00%	0.00%	61.50 % - 96.11 %	93.80 %- 101.30%
Expected dividend yield	0%	0%	0 %	0 %
Risk-free interest rate	0.00%	0.00%	0.83 % - 1.52 %	0.34 % - 0.40%

The Company's results for the three-month periods ended September 30, 2014 and 2013 include share-based compensation expense totaling \$118,800 and \$62,200, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$- and \$500, respectively), research and development (\$8,400 and \$21,600, respectively) and selling, general and administrative expenses (\$110,400 and \$40,100, respectively). The results for the nine-month periods ended September 30, 2014 and 2013 include share-based compensation expense totaling \$336,900 and \$284,100, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$700 and \$13,900, respectively), research and development (\$36,100 and \$83,900, respectively) and selling, general and administrative expenses (\$300,100 and \$186,300, respectively). An operating expense, resulting in income tax benefit, has been recognized in the statement of operations for share-based compensation arrangements.

Stock option compensation expense for the three and nine-month periods ended September 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.

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

The following table provides stock option activity for the nine months ended September 30, 2014:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
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	(25,529 )	3.17		
Outstanding at September 30, 2014	655,869	\$ 3.62	4.17 years	\$ 243,644
Exercisable at September 30, 2014	265,619	\$ 3.67	2.19 years	\$ 132,469

As of September 30, 2014, there was \$666,500 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 2.52 years. The total fair value of stock options vested during the nine-month periods ended September 30, 2014 and 2013 was approximately \$283,000 and \$39,000, 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 nine months ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Africa	\$ 541,944	\$ 1,030,108	\$ 1,791,749	\$ 2,887,328
Asia	6,058	32,011	80,815	82,229
Europe	34,205	5,540	105,230	82,869
North America	2,479,410	2,199,090	9,012,447	7,484,668
South America	4,186,264	5,777,965	8,410,274	9,882,501
	\$ 7,247,881	\$ 9,044,714	\$ 19,400,515	\$ 20,419,595

g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

	September 30, 2014	December 31, 2013
Accounts payable – suppliers	\$1,505,137	\$1,815,369
Accrued commissions	753,777	371,905
Accrued royalties / license fees	772,614	1,028,286
Accrued payroll	247,565	328,564
Accrued vacation	228,779	203,444
Accrued bonuses	-	317,372
Accrued expenses – other	311,399	244,550
<b>TOTAL</b>	<b>\$3,819,271</b>	<b>\$4,309,490</b>

#### 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 ASU2014-09 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.

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

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 \$349,200 and \$470,000 for the nine-month periods ended September 30, 2014 and 2013, respectively from this grant. The Company received \$2,815,200 from this grant from inception through September 30, 2014, of which \$1,018,900 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 \$316,000 for the nine-month periods ended September 30, 2014 and 2013, respectively from this agreement. The Company earned \$985,250 from this grant from inception through September 30, 2014.

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 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 mergers, 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 September 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").

**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. Sprezel's employment with the Company or (b) the seventh anniversary of the effective date of the grant.

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

## 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:

Customer	For the three months ended				For the nine months ended				Accounts Receivable as of	
	September 30, 2014		September 30, 2013		September 30, 2014		September 30, 2013		September 30, 2014	September 30, 2013
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales		
1	\$1,156,666	16	\$2,167,999	24	\$5,322,098	27	\$7,063,682	35	\$302,151	\$843,554
2	1,238,160	17	*	*	3,455,402	18	*	*	828,170	-
3	4,177,014	58	1,887,166	21	8,343,815	43	3,756,262	18	5,971,927	715,310
4	*	*	3,866,894	43	*	*	5,924,900	29	3,174	2,365,950

(\* ) 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:

Vendor	For the three months ended				For the nine months ended				Accounts Payable as of	
	September 30, 2014		September 30, 2013		September 30, 2014		September 30, 2013		September 30, 2014	September 30, 2013
	Purchases	Purc.	Purchases	Purc.	Purchases	Purc.	Purchases	Purc.		
1	\$321,938	14	\$275,539	11	\$944,157	14	\$840,923	10	\$116,583	\$57,555
2	508,705	22	*	*	1,239,766	18	*	*	-	-

(\* ) 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 \$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 nine months ended September 30, 2014 was a (benefit) of 27.0%. We calculated the current portion to be 8.6% of the (benefit), or \$1,426, which was attributable to income tax (receivable) and the balance of \$(239,342) (increased) the carrying value of the deferred tax asset for the nine months ended September 30, 2014. The 27.0% (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 September 30, 2014 decreased to \$66,000 from \$573,000 in the prior-year period. For the nine months ended September 30, 2014, these categories of revenues decreased to \$1,149,000 from \$1,270,000 in the prior-year period, which was the

result of a winding down of grants in 2014 over 2013.

R&D expenses in the third quarter of 2014 were \$.97 million, compared with \$1.60 million in the prior-year period. In the first nine months of 2014, R&D expenses were \$3.44 million, compared with \$4.15 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.

#### Research & Development Activities

**Ebola Point-of-Care (POC) Test:** In October 2014, we signed an agreement with Integrated BioTherapeutics, Inc. (IBT), to develop, validate, and commercialize a POC Ebola assay for the diagnostic market. This work involves applying IBT's Ebola reagents with Chembio's proprietary DPP® technology to generate a multiplexed unitary assay to diagnose Ebola, including the potential of a febrile illness multiplex test for expanded applications. The outcome of preliminary feasibility testing is encouraging.

**Cancer POC Test:** In October 2014, we also signed a development agreement for a POC diagnostic test for a specific type of cancer. This scope of the agreement involves product development of an existing assay, utilizing Chembio's DPP® technology. The goal is to optimize the existing lateral flow assay design, conduct verification and validation studies, and to produce pilot lots to support preclinical studies. Under the terms of the agreement, neither Chembio's partner nor the specific type of cancer is being disclosed. This project represents the first application of the DPP® technology outside of the infectious disease field.

**DPP® HIV-Syphilis:** Although the assay shows excellent performance with respect to those with active syphilis infections, development activity is in progress to modify the assay for the United States to meet FDA requirements, which is based on a clinical algorithm that requires the detection of infections that have the potential to become active.

**DPP® Dengue Development:** Based on our 2013 experience developing a DPP® Febrile Illness Assay in partnership with a U.S. government agency, we signed an agreement to develop a stand-alone DPP® Dengue Fever Assay which would be able to detect IgG/IGM and NS1 antigens. The goal is to conduct verification and validation studies, as well as produce pilot lots, to support preclinical studies. Under the terms of the agreement, Chembio's partner is not being disclosed.

**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, for a multi-center clinical trial in multiple countries. We have received preliminary data from West Africa from the clinical trials, which is currently under review.

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 now complete. Studies were conducted in Bangladesh, Brazil, Haiti, Vietnam, and South Africa. The field studies yielded results as expected and are being compiled into a final report to be provided to the NIH by late November 2014. Chembio is considering whether further feasibility will be conducted, including additional funding by an external agency.

#### Regulatory Activities

DPP® HIV 1/2 Screening Assay for Use with oral fluid or blood samples – We received Food and Drug Administration (FDA) approval of our Pre-Marketing Application (PMA) for this product on December 19, 2012. On October 29, 2014, the FDA has granted the waiver for DPP® HIV 1/2 Assay for Oral Fluid, Fingerstick Whole Blood and Venous Whole Blood under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations.

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, and successfully launched and sold in this region. 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. In October 2014, WHO conducted a three day audit of our facilities as follow up to pre-qualification activities for the DPP® HIV-Syphilis Assay, including other products submitted for pre-qualification through WHO. No major non-conformances were identified during this audit, and we continue to work with WHO to obtain pre-qualification approval status for this device.

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 SEPTEMBER 30, 2014 AS COMPARED WITH THE THREE MONTHS ENDED SEPTEMBER 30, 2013

##### Income:

For the three months ended September 30, 2014, Loss before income taxes was \$(261,000) compared to Income before income taxes of \$1,076,000 for the three months ended September 30, 2013. Net Loss for the 2014 period was \$(271,000) as compared to a Net Income of \$717,000 for 2013. The change from a Net Income to a Net Loss is primarily attributable to decreased revenues and decreased gross margin, partially offset by decreased operating

expenses. Gross margin decreased in the three months ended September 30, 2014, as compared with the three months ended September 30, 2013, by \$1,406,000, or 34.7%. This decreased gross margin was partially offset by decreased operating expenses.

Revenues:

Selected Product Categories:	For the three months ended				
	September 30, 2014	September 30, 2013	\$ Change	% Change	
Lateral Flow HIV Tests and Components	\$1,669,694	7,018,407	\$(5,348,713)	-76.21	%
DPP Tests and Components	5,409,724	1,879,866	3,529,858	187.77	%
Other	168,463	146,441	22,022	15.04	%
Net Product Sales	7,247,881	9,044,714	(1,796,833)	-19.87	%
License and royalty revenue	8,482	898	7,584	844.54	%
R&D, milestone and grant revenue	57,946	572,027	(514,081)	-89.87	%
Total Revenues	\$7,314,309	9,617,639	\$(2,303,330)	-23.95	%

Revenues for our lateral flow HIV tests and related components during the three months ended September 30, 2014 decreased by approximately \$5,349,000 from the same period in 2013. This was primarily attributable to decreased sales to South America, of approximately \$3,882,000, decreased sales to the U.S., of approximately \$1,011,000, and decreased sales to Africa, of approximately \$488,000. Revenues for our DPP® products during the three months ended September 30, 2014 increased by approximately \$3,530,000 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 were nearing completion during that period. 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:

	For the three months ended			
	September 30, 2014	September 30, 2013	\$ Change	% Change
Gross Margin per Statement of Operations	\$2,650,390	\$4,056,186	\$(1,405,796)	-34.66 %
Less: R&D, milestone, grant, license and royalty revenues	66,428	572,925	(506,497)	-88.41 %
Gross Margin from Net Product Sales	\$2,583,962	\$3,483,261	\$(899,299)	-25.82 %
Product Gross Margin %	35.65 %	38.51 %		

The overall gross margin dollar decrease of \$1,406,000 included a \$899,000 decrease in gross margin from product sales and a \$506,000 decrease in non-product revenues. The decrease in net product sales gross margin of \$899,000 is primarily attributable to the lower product sales compared to 2013, particularly the reduction of sales to our U.S. distributor in the third quarter which were at much higher margins. The net product sales gross margin decrease is comprised of two components, one is the decrease in product sales of \$1,797,000, which, at the 38.51% margin percentage, contributed \$692,000 to the decrease, and the other is the decreased change in margin percentage of 2.9% contributed the balance of \$207,000 to the decrease in our net product sales 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			
	September 30, 2014	September 30, 2013	\$ Change	% Change
<b>Clinical and Regulatory Affairs:</b>				
Wages and related costs	\$103,954	\$103,164	\$ 790	0.77 %
Consulting	1,578	4,331	(2,753)	-63.56 %
Stock-based compensation	-	2,425	(2,425)	-100.00 %
Clinical trials	5,948	505,202	(499,254)	-98.82 %
Other	34,993	31,393	3,600	11.47 %
Total Regulatory	146,473	646,515	(500,042)	-77.34 %
<b>R&amp;D Other than Regulatory:</b>				
Wages and related costs	553,703	581,663	(27,960)	-4.81 %
Consulting	3,300	46,642	(43,342)	-92.92 %
Stock-based compensation	8,429	19,206	(10,777)	-56.11 %
Materials and supplies	160,928	217,772	(56,844)	-26.10 %
Other	99,606	90,499	9,107	10.06 %
Total other than Regulatory	825,966	955,782	(129,816)	-13.58 %
<b>Total Research and Development</b>	<b>\$972,439</b>	<b>\$1,602,297</b>	<b>\$(629,858)</b>	<b>-39.31 %</b>

Expenses for Clinical & Regulatory Affairs for the three months ended September 30, 2014 decreased by \$500,000 as compared to the same period in 2013. This was primarily due to a decrease of \$499,000 in clinical trial expenses.

R&D expenses other than Clinical & Regulatory Affairs decreased by \$130,000 in the three months ended September 30, 2014, as compared with the same period in 2013. The decreases were primarily related to a decrease in wages and related costs, and in material and supplies, as support for our sponsored research has decreased, partially offset by an increase in internal development programs.

Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended			
	September	September		%
	30, 2014	30, 2013	\$ Change	Change
Wages and related costs	\$595,287	\$500,768	\$94,519	18.87 %
Consulting	142,694	77,562	65,132	83.97 %
Commissions	488,034	265,262	222,772	83.98 %
Stock-based compensation	110,353	40,217	70,136	174.39 %
Marketing materials	82,937	33,623	49,314	146.67 %
Investor relations/investment bankers	30,370	50,782	(20,412 )	-40.20 %
Legal, accounting and compliance	210,337	151,758	58,579	38.60 %
Travel, entertainment and trade shows	73,649	33,724	39,925	118.39 %
Other	206,763	226,149	(19,386 )	-8.57 %
Total S, G &A	\$1,940,424	\$1,379,845	\$560,579	40.63 %

Selling, general and administrative expenses for the three months ended September 30, 2014, increased by \$561,000 as compared with the same period in 2013, a 41% increase. This increase resulted primarily from significant increases in commissions due to increased sales to Brazil, along with increases in wages and related costs, stock-based compensation, consulting and travel entertainment and trade shows, which were partially offset by a decrease in investor relation and other expenses.

Other Income and (Expense):

	For the three months ended			
	September			
	30, 2014	September 30, 2013	\$ Change	% Change
Other income (expense)	\$-	\$ -	\$ -	100.00 %
Interest income	1,136	1,477	- 341	-23.09 %
Total Other Income and (Expense)	\$1,136	\$ 1,477	\$ (341 )	-23.09 %

Other income (expense) for the three months ended September 30, 2014 decreased approximately \$300, to an income of \$1,100 from an income of \$1,400 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 NINE MONTHS ENDED SEPTEMBER 30, 2014 AS COMPARED WITH THE NINE MONTHS ENDED SEPTEMBER 30, 2013

Income:

For the nine months ended September 30, 2014, Loss before income taxes was \$(879,000) compared to Income before taxes of \$1,192,000 for the nine months ended September 30, 2013. Net Loss for the 2014 period was \$(641,000) as compared to a Net Income of \$793,000 for 2013. The change from Net Income to Net Loss is primarily attributable to decreased revenues, decreased gross margin, and increased operating expenses. Gross margin decreased in the nine months ended September 30, 2014 as compared with the nine months ended September 30, 2013, by \$1,126,000, or 12.5%. This decreased gross margin and increased operating expenses, the most significant of which were an increase in wages and related expenses of \$637,000, an increase in commissions of \$483,000, consulting expenses of \$237,000, marketing materials and shows of \$179,000, and stock-based compensation of \$106,000, partially offset by decreased clinical trial expenses of \$868,000, accounted for most of the change in Net Loss.

Revenues:

Selected Product Categories:	For the nine months ended			
	September 30, 2014	September 30, 2013	\$ Change	% Change
Lateral Flow HIV Tests and Components	\$7,093,301	\$16,113,622	\$ (9,020,321)	-55.98 %
DPP Tests and Components	11,745,519	3,717,517	8,028,002	215.95 %
Other	561,695	588,456	(26,761 )	-4.55 %
Net Product Sales	19,400,515	20,419,595	(1,019,080)	-4.99 %
License and royalty revenue	15,613	898	14,715	1,638.64%
R&D, milestone and grant revenue	1,133,850	1,268,821	(134,971 )	-10.64 %
Total Revenues	\$20,549,978	\$21,689,314	\$ (1,139,336)	-5.25 %

Revenues for our lateral flow HIV tests and related components during the nine months ended September 30, 2014 decreased by approximately \$9,020,000 from the same period in 2013. This was primarily attributable to decreased sales to South America, of approximately \$5,830,000, decreased sales to the U.S. of \$1,742,000, and decreased sales to Africa of \$1,096,000. Revenues for our DPP® products during the nine months ended September 30, 2014 increased by approximately \$8,028,000 over the same period in 2013, primarily for 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 were nearing completion during the period, partially offset by \$750,000 in revenue from the license contract we signed in February 2014 with RVR Diagnostics. 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:

	For the nine months ended			
	September 30, 2014	September 30, 2013	\$ Change	% Change
Gross Margin per Statement of Operations	\$7,905,551	\$9,031,251	\$ (1,125,700)	-12.46 %
Less: R&D, milestone, grant, license and royalty revenues	1,149,463	1,269,719	(120,256 )	-9.47 %
Gross Margin from Net Product Sales	\$6,756,088	\$7,761,532	\$ (1,005,444)	-12.95 %
Product Gross Margin %	34.82 %	38.01 %		



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

The overall gross margin dollar decrease of \$1,126,000 included a \$1,005,000 decrease in gross margin from net product sales and a \$120,000 decrease in non-product revenues. The decrease in net product sales gross margin of \$1,005,000 is primarily attributable to the change in product mix compared to 2013, particularly the reduction of sales to our U.S. distributor in the third quarter which were at much higher margins. The net product sales gross margin decrease is comprised of two components, one is the decreased change in margin percentage of 3.2% which contributed \$618,000 to the decrease, and the other is the decrease in product sales of \$1,019,000, which at the 38.01% margin contributed the balance of \$387,000. The 3.2% decrease in the percentage, from 37.6% in 2013 to 34.3% in 2014, was primarily due to a larger amount of unapplied overhead along with the reduced sales to our U.S. distributor.

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 nine months ended			
	September 30, 2014	September 30, 2013	\$ Change	% Change
<b>Clinical and Regulatory Affairs:</b>				
Wages and related costs	\$316,643	\$317,120	\$ (477 )	-0.15 %
Consulting	26,086	29,520	(3,434 )	-11.63 %
Stock-based compensation	3,231	17,057	(13,826 )	-81.06 %
Clinical trials	156,443	1,024,746	(868,303)	-84.73 %
Other	74,751	59,937	14,814	24.72 %
Total Regulatory	577,154	1,448,380	(871,226)	-60.15 %
<b>R&amp;D Other than Regulatory:</b>				
Wages and related costs	1,736,373	1,628,247	108,126	6.64 %
Consulting	116,651	98,806	17,845	18.06 %
Stock-based compensation	32,885	66,847	(33,962 )	-50.81 %
Materials and supplies	685,524	650,668	34,856	5.36 %
Other	290,127	255,253	34,874	13.66 %
Total other than Regulatory	2,861,560	2,699,821	161,739	5.99 %
Total Research and Development	\$3,438,714	\$4,148,201	\$ (709,487)	-17.10 %

Expenses for Clinical & Regulatory Affairs for the nine months ended September 30, 2014 decreased by \$871,000 as compared to the same period in 2013. This was primarily due to a decrease of \$868,000 in clinical trial expenses.

R&D expenses other than Clinical & Regulatory Affairs increased by \$161,000 in the nine months ended September 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 nine months ended			
	September 30, 2014	September 30, 2013	\$ Change	% Change
Wages and related costs	\$1,924,165	\$1,394,343	\$529,822	38.00 %
Consulting	406,044	183,823	222,221	120.89 %
Commissions	999,745	517,172	482,573	93.31 %
Stock-based compensation	297,078	143,750	153,328	106.66 %
Marketing materials	148,037	62,879	85,158	135.43 %
Investor relations/investment bankers	118,479	164,668	(46,189 )	-28.05 %
Legal, accounting and compliance	506,767	465,402	41,365	8.89 %
Travel, entertainment and trade shows	225,111	131,029	94,082	71.80 %
Bad debt allowance (recovery)	-	(33,450 )	33,450	-100.00 %
Other	719,488	672,565	46,923	6.98 %
Total S, G & A	\$5,344,914	\$3,702,181	\$1,642,733	44.37 %

Selling, general and administrative expenses for the nine months ended September 30, 2014, increased by \$1,643,000 as compared with the same period in 2013, a 44.4% increase. This increase resulted primarily from increases in wages and related costs, which for 2014 included the COO (not included in the first six months of 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.

Other Income and (Expense):

	For the nine months ended			
	September 30, 2014	September 30, 2013	\$ Change	% Change
Other income (expense)	\$ (5,707)	\$ 7,500	\$ (13,207)	-176.09 %
Interest income	4,527	3,712	815	21.96 %
Interest expense	-	(335 )	335	-100.00 %
Total Other Income and (Expense)	\$ (1,180)	\$ 10,877	\$ (12,057)	-110.85 %

Other income (expense) for the nine months ended September 30, 2014 decreased approximately \$12,000, primarily due to an expense of \$1,200 from an income of \$10,800 in the same period in 2013, as a result of a loss on sale of a fixed asset, and a decrease in interest income, partially offset by a decrease in interest expense due on the term loan with HSBC.

Income tax (benefit) provision:

For the nine months ended September 30, 2014 the Company recognized a \$(237,916) income tax benefit and increased its deferred tax assets by \$(239,342). 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		\$ Change	% Change
	September 30, 2014	December 31, 2013		
Cash and cash equivalents	\$3,672,702	\$9,650,275	\$ (5,977,573)	-61.94 %
Accounts receivable, net of allowance for doubtful accounts of \$24,000 at September 30, 2014 and December 31, 2013, respectively	8,315,651	4,592,121	3,723,530	81.09 %
Inventories	3,975,250	3,188,726	786,524	24.67 %
Fixed assets, net of accumulated depreciation	2,118,756	1,978,232	140,524	7.10 %
Deposits and other assets	255,157	44,367	210,790	475.11 %
Deferred tax asset, net of valuation allowance	3,829,549	3,590,207	239,342	6.67 %
Accounts payable and accrued liabilities	3,819,271	4,309,490	(490,219 )	-11.38 %

Cash decreased by \$5,978,000 from December 31, 2013, primarily due to net cash used in operating activities for the nine months of 2014. In addition there were increases in accounts receivable, net of allowance, of \$3,724,000, inventories of \$787,000, fixed assets of \$597,000 before depreciation, deposits and other assets of \$211,000 and deferred taxes of \$239,000. We experienced a decrease in accounts payable and accrued liabilities of \$490,000. The increase in accounts receivable was primarily attributable to the higher amount of credit sales at the end of September 2014 versus December of 2013. The increase in inventories is due to production for orders received to be shipped in the fourth 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 nine months ended			% Change
	September 30, 2014	September 30, 2013	\$ Change	
Net cash (used in) provided by operating activities	\$ (5,154,604)	\$583,808	\$ (5,738,412 )	-982.93 %
Net cash (used in) investing activities	(1,060,149)	(796,274 )	(263,875 )	33.14 %
Net cash provided by financing activities	237,180	5,306,412	(5,069,232 )	-95.53 %
(DECREASE) IN CASH AND CASH EQUIVALENTS	\$ (5,977,573)	\$5,093,946	\$ (11,071,519)	-217.35 %

The Company's cash decreased as of September 30, 2014 by \$5,978,000 from December 31, 2013, primarily due to net cash used in operating activities for the nine months of 2014.

The cash used in operations in 2014 was \$5,155,000, primarily due to an increase in accounts receivable of \$3,724,000, an increase in inventories of \$787,000, a reduction in accounts payable and other accrued liabilities of \$490,000, an increase in other assets of \$211,000, a decrease in prepaid and other current assets of \$64,000, and a net loss net of non-cash items of \$7,000. Net loss net of non-cash items includes net loss of \$641,000, \$239,000 in benefit for income taxes, partially offset by \$537,000 in depreciation and amortization, and \$336,000 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.

## Fixed Asset Commitments

As of September 30, 2014, the Company had paid deposits on various pieces of equipment aggregating \$479,869, which is reflected in deposits on manufacturing equipment on the balance sheet. The Company has commitments for \$381,322 in additional equipment purchase obligations.

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

During the third quarter, Chembio generated revenues of \$7.3 million. These third quarter sales were consistent with second quarter sales for 2014, but decreased by 24% as compared to the third quarter of 2013. This decrease, in comparison to the third quarter of 2013, was primarily due to the shipment in the third quarter of 2013 of approximately \$3.87 million from a single \$5.3 million order, which did not recur in the third quarter of 2014.

During the third quarter, our regulatory team worked closely with the FDA to secure, in late October, a much anticipated CLIA Waiver for our lead product, DPP® HIV 1/2 Assay, which is a POC screening HIV assay for use with oral fluid or blood samples. Chembio's DPP® HIV 1/2 Assay was FDA-approved previously, and the CLIA Waiver will allow Chembio to expand its sales into important new channels that are closest to patient care, including physician-office-lab (POL) facilities, clinics and other community healthcare providers. Our DPP® HIV 1/2 Assay combines excellent sensitivity and specificity, simple and safe oral fluid sample collection, and exceptional ease of use. We believe this combination will lead to more testing, which will result in better detection, earlier treatment and lower exposure rates. We are very happy to be able to offer this important product to a broader healthcare market.

To support our growing commercialization program, in the third quarter we began discussions with a number of leading distributors to expand the sales of our DPP® HIV 1/2 and HIV 1/2 STAT-PAK® Assays in the U.S. We are pleased that three of these important distribution agreements were signed subsequent to the third quarter end, significantly adding to our sales reach in the U.S. market. This is particularly important as our former U.S. distributor for our HIV 1/2 STAT-PAK® Assay will soon deplete its existing inventory, and filling U.S. demand for HIV 1/2 STAT-PAK® Assay in the future will be exclusively Chembio's responsibility.

Beyond our sales and regulatory efforts during the quarter, Chembio initiated discussions with a range of potential development partners as indicated during the second quarter 2014 earnings call. Each of these organizations is a leader in a different sector of the diagnostics market, and all are attracted to the power and versatility that our DPP® technology offers. In recent weeks, our discussions converted into three executed development agreements, and we are eager and optimistic to begin the feasibility/development that we believe will demonstrate DPP®'s applicability to a number of important tests and sectors.

As we announced at the end of October, Chembio has entered into an exclusive agreement with Integrated BioTherapeutics, Inc. (IBT), through which the companies will combine Chembio's DPP® technology with IBT's proprietary Ebola reagents to develop a point-of-care (POC) diagnostic test for Ebola and possibly other febrile illness. Chembio will have exclusive rights to any POC product developed through this agreement. Based on our success with the development of a multiplexed febrile illness assay last year in conjunction with a U.S. government agency, we believe our Ebola diagnostics will be ready for clinical testing during the current outbreak.

Also announced last week, Chembio entered into an agreement with an unnamed partner to develop a POC diagnostic test for dengue fever virus based on Chembio's DPP® technology. The World Health Organization estimates there are 3 billion people living in dengue endemic countries, and the CDC estimates there are 400 million dengue virus infections annually, making dengue virus a leading cause of illness and death in the tropics and subtropics.

Chembio also announced in October that it has entered into an agreement with an unnamed international diagnostics company to develop a POC test for the early detection and monitoring of a specific type of cancer using DPP® technology. This project represents the first application of the DPP® technology outside of the infectious disease field, and it is our hope that bringing the DPP® technology to the oncology market will aid in improving outcomes for patients battling cancer.

In addition to these new collaborations, our existing relationship with RVR in Malaysia is making great progress. The site renovation is complete, and the RVR team is in the midst of manufacturing equipment set-up and validation.

The third quarter was exceptionally productive, not only in furthering our previously-existing activities, but also in setting new initiatives in motion. We look forward to these continuing and developing opportunities

..

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 nine 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. (13)
- 4.5 Rights Agreement, dated March 8, 2010 (6)
- 4.6 Form of Warrant (to be filed by amendment)
- 4.7 Form of Option, for 2014 Stock Incentive Plan. (14)
- 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.

13 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on May 8, 2014.

14 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on August 7, 2014.

(\*) 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.

18

---



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: November 6, 2014 By: /s/ John J. Sperzel III  
John J. Sperzel III  
Chief Executive Officer  
(Principal Executive Officer)

Date: November 6, 2014 By: /s/ Richard J. Larkin  
Richard J. Larkin  
Chief Financial Officer  
(Principal Financial and Accounting Officer)