

CHEMBIO DIAGNOSTICS, INC.  
Form 10-Q  
May 07, 2015

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

FORM 10 - Q

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

For the quarterly period ended March 31, 2015

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 No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer Accelerated filer  
Non-accelerated filer Smaller reporting company  
(Do not check if a smaller reporting company)

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  
Yes No

As of May 4, 2015, the Registrant had 9,628,248 shares outstanding of its \$.01 par value common stock.

---

Quarterly Report on FORM 10-Q  
For The Quarterly Period Ended  
March 31, 2015

Table of Contents

Chembio Diagnostics, Inc.

	Page
<b>Part I. FINANCIAL INFORMATION:</b>	
Item 1. Financial Statements:	
Condensed Consolidated Balance Sheets as of March 31, 2015 (unaudited) and December 31, 2014	2
Condensed Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2015 and 2014	3
Condensed Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2015 and 2014	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	20
<b>Part II. OTHER INFORMATION:</b>	
Item 6. Exhibits	21
<b>SIGNATURES</b>	<b>22</b>
<b>EXHIBITS</b>	

---

## PART I

## Item 1. FINANCIAL STATEMENTS

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

## - ASSETS -

	March 31, 2015 (Unaudited)	December 31, 2014
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$2,815,762	\$4,614,538
Accounts receivable, net of allowance for doubtful accounts of \$52,000 at March 31, 2015 and December 31, 2014, respectively	8,260,101	8,338,889
Inventories	3,698,623	3,638,299
Prepaid expenses and other current assets	1,427,579	1,066,473
<b>TOTAL CURRENT ASSETS</b>	<b>16,202,065</b>	<b>17,658,199</b>
FIXED ASSETS, net of accumulated depreciation	2,973,146	2,797,929
<b>OTHER ASSETS:</b>		
Deferred tax asset, net of valuation allowance	4,258,802	4,031,302
License agreements, net of current portion	374,773	256,875
Deposits on manufacturing equipment	26,757	20,017
Deposits and other assets	236,732	245,870
<b>TOTAL ASSETS</b>	<b>\$24,072,275</b>	<b>\$25,010,192</b>
<b>- LIABILITIES AND STOCKHOLDERS' EQUITY -</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$4,389,944	\$4,946,030
Deferred revenue	495,677	340,000
<b>TOTAL LIABILITIES</b>	<b>4,885,621</b>	<b>5,286,030</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; 9,627,248 and 9,611,139 shares issued and outstanding for March 31, 2015 and December 31, 2014, respectively	96,273	96,112
Additional paid-in capital	47,665,574	47,556,426
Accumulated deficit	(28,575,193)	(27,928,376)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>19,186,654</b>	<b>19,724,162</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$24,072,275</b>	<b>\$25,010,192</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	
	March 31, 2015	March 31, 2014
REVENUES:		
Net product sales	\$5,614,685	\$4,904,165
License and royalty revenue	7,051	160
R&D, milestone and grant revenue	609,401	908,748
TOTAL REVENUES	6,231,137	5,813,073
Cost of product sales	3,544,519	3,540,462
GROSS MARGIN	2,686,618	2,272,611
OPERATING EXPENSES:		
Research and development expenses	1,584,536	1,197,622
Selling, general and administrative expenses	1,977,574	1,457,728
	3,562,110	2,655,350
(LOSS) FROM OPERATIONS	(875,492 )	(382,739 )
OTHER INCOME:		
Interest income	1,175	1,830
	1,175	1,830
(LOSS) BEFORE INCOME TAXES	(874,317 )	(380,909 )
Income tax (benefit)	(227,500 )	(156,170 )
NET (LOSS)	\$(646,817 )	\$(224,739 )
Basic (loss) per share	\$(0.07 )	\$(0.02 )
Diluted (loss) per share	\$(0.07 )	\$(0.02 )
Weighted average number of shares outstanding, basic	9,624,691	9,339,181
Weighted average number of shares outstanding, diluted	9,624,691	9,339,181

See accompanying notes to condensed consolidated financial statements

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

	March 31, 2015	March 31, 2014
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Cash received from customers and grants	\$6,465,602	\$7,035,382
Cash paid to suppliers and employees	(7,408,585)	(7,687,516)
Interest received	1,175	1,830
Net cash (used in) operating activities	(941,808 )	(650,304 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of License	(450,000 )	-
Acquisition of and deposits on fixed assets	(406,968 )	(66,789 )
Net cash (used in) investing activities	(856,968 )	(66,789 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from option exercises	-	153,834
Net cash provided by financing activities	-	153,834
<b>(DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>(1,798,776)</b>	<b>(563,259 )</b>
Cash and cash equivalents - beginning of the period	4,614,538	9,650,275
Cash and cash equivalents - end of the period	\$2,815,762	\$9,087,016
<b>RECONCILIATION OF NET (LOSS) TO NET CASH (USED IN) PROVIDED BY OPERATING ACTIVITIES:</b>		
Net (Loss)	\$(646,817 )	\$(224,739 )
Adjustments:		
Depreciation and amortization	345,731	172,702
Deferred taxes	(227,500 )	(142,896 )
Share based compensation	109,309	70,430
Changes in assets and liabilities:		
Accounts receivable	78,788	1,222,309
Inventories	(60,324 )	(415,877 )
Prepaid expenses and other current assets	(140,424 )	(19,439 )
Deposits and other assets	(162 )	(271,773 )
Accounts payable and accrued liabilities	(556,086 )	(1,041,021)
Customer deposits and deferred revenue	155,677	-
Net cash (used in) operating activities	\$(941,808 )	\$(650,304 )
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	\$20,017	\$16,410

See accompanying notes to condensed consolidated financial statements



CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2015  
(UNAUDITED)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. (the "Company" or "Chembio") and its wholly-owned 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 52 % of the Company's product revenues in the first three months of 2015. The Company's products based on its patented Dual Path Platform (DPP®) platform represented approximately 44 % of the Company's product revenues in the first three months of 2015. The Company also has other rapid tests that together represented approximately 4 % of sales in the first three months of 2015. 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, 2014, which has been derived from audited financial statements, and (b) the unaudited interim condensed consolidated financial statements as of March 31, 2015 and for the three-month periods ended March 31, 2015 and 2014, 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, 2014, previously filed with the SEC.

In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present a fair statement of the Company's condensed consolidated financial position as of March 31, 2015, its condensed consolidated results of operations for the three-month periods ended March 31, 2015 and 2014, respectively, and its condensed consolidated cash flows for the three-month periods ended March 31, 2015 and 2014, 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. Advanced revenues not earned were \$496,000 and \$340,000 as of March 31, 2015 and December 31, 2014, respectively.

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.

5

---

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2015  
(UNAUDITED)

## c) Inventories:

Inventories consist of the following at:

	March 31, 2015	December 31, 2014
Raw materials	\$2,075,535	\$2,323,863
Work in process	469,033	346,494
Finished goods	1,154,055	967,942
	\$3,698,623	\$3,638,299

## 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-month periods ended March 31, 2015 and 2014, have been included in the earnings per share computations:

	For the three months ended	
	March 31, 2015	March 31, 2014
Basic	9,624,691	9,339,181
Diluted	9,624,691	9,339,181

The following securities, presented on a common share equivalent basis for the three-month periods ended March 31, 2015 and 2014, have been included in the diluted per share computations as the exercise prices of these securities were less than the stock price as of March 31, 2015 and 2014, respectively:

	For the three months ended	
	March 31, 2015	March 31, 2014
1999, 2008 and 2014 Plan Stock Options	-	-

There were 671,868 and 675,363 options outstanding as of March 31, 2015 and 2014, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended March 31, 2015 and 2014, respectively, because the effect would have been anti-dilutive as of March 31, 2015 and 2014, respectively.

## e) Employee Stock Option Plan:

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, non-incentive stock options, restricted stock and/or restricted stock units. The awards become vested at such times and under such conditions as determined by the Compensation Committee. As of March 31, 2015, there were 352,935 options exercised, 317,751 options outstanding and 79,314 options or shares still available to be issued under the SIP.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2015  
(UNAUDITED)

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 March 31, 2015, there were no options exercised, 129,750 options outstanding and 670,250 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 three-month periods ended March 31, 2015 and 2014, was none and \$3.42 per share, respectively, as the Company did not grant any options during the three months ended March 31, 2015. 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	
	March 31, 2015	March 31, 2014
Expected term (in years)	n/a	6.3
Expected volatility	n/a	96.10%
Expected dividend yield	n/a	0%
Risk-free interest rate	n/a	1.52%

The Company's results for the three-month periods ended March 31, 2015 and 2014 include share-based compensation expense totaling \$109,300 and \$70,430, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (none and \$3,050, respectively), research and development (\$18,200 and \$18,250, respectively), and selling, general and administrative expenses (\$91,100 and \$49,130, respectively). The income tax benefit has been recognized in the statement of operations for share-based compensation arrangements.

Stock option compensation expense for the three-month periods ended March 31, 2015 and 2014 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  
MARCH 31, 2015  
(UNAUDITED)

The following table provides stock option activity for the three months ended March 31, 2015:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2014	691,869	\$ 3.66	3.97 years	\$ 334,636
Granted	0	0.00		
Exercised	(37,500)	2.16		
Forfeited/expired/cancelled	-	-		
Outstanding at March 31, 2015	654,369	\$ 3.75	3.94 years	\$ 326,945
Exercisable at March 31, 2015	288,119	\$ 3.88	2.70 years	\$ 136,955

As of March 31, 2015, there was \$521,645 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 2.30 years. The total fair value of stock options vested during the three-month periods ended March 31, 2015 and 2014 was approximately \$357,484 and \$40,388, respectively.

f) Geographic Information:

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

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

	For the three months ended	
	March 31, 2015	March 31, 2014
Africa	\$1,576,054	\$831,462
Asia	50,813	51,047
Europe	65,146	36,059
North America	1,319,002	3,763,149
South America	2,603,670	222,448
	\$5,614,685	\$4,904,165

## g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

	March 31, 2015	December 31, 2014
Accounts payable – suppliers	\$1,631,940	\$1,980,120
Accrued commissions	772,657	947,451
Accrued royalties / license fees	876,081	1,034,062
Accrued payroll	265,116	106,487
Accrued vacation	260,671	219,924
Accrued bonuses	177,700	265,500
Accrued expenses – other	405,779	392,486
TOTAL	\$4,389,944	\$4,946,030

## 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2015  
(UNAUDITED)

NOTE 3 — COLLABORATIVE RESEARCH AND DEVELOPMENT ARRANGEMENTS:

a) Battelle/CDC DPP® Influenza Immunity Test:

In November 2014, the Company entered into a follow-on, milestone-based development agreement of up to an additional \$271,000, resulting in a total amount of \$1,268,000, 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 six months in which the follow-on development activity is to be completed. The Company earned \$221,000 and \$13,000 for the three-month periods ended March 31, 2015 and 2014, respectively from this agreement. The Company earned \$1,257,000 from this grant from inception through March 31, 2015.

b) RVR DPP® technology transfer agreement:

In February 2014, the Company entered into a technology transfer agreement with RVR Diagnostics for \$1,500,000. The agreement was modified in September 2014. The Company earned \$0 and \$750,000 for the three-month periods ended March 31, 2015 and 2014, respectively from this agreement. The Company earned \$1,125,000 from this grant from inception through March 31, 2015.

c) Dengue agreement:

In October 2014, the Company entered into a technology development agreement with a diagnostics company for \$300,000. The Company earned \$90,000 and \$0 for the three-month periods ended March 31, 2015 and 2014, respectively from this agreement. The Company earned \$150,000 from this grant from inception through March 31, 2015.

d) Brain Injury agreement:

In January 2015, the Company entered into a technology development agreement with Perseus Science Group LLC for \$846,000. The Company earned \$127,500 and \$0 for the three-month periods ended March 31, 2015 and 2014, respectively from this agreement. The Company earned \$127,500 from this grant from inception through March 31, 2015.

e) Malaria agreement:

In January 2015, the Company was awarded a grant from the Bill & Melinda Gates Foundation for \$307,000. The Company earned \$133,900 and \$0 for the three-month periods ended March 31, 2015 and 2014, respectively from this agreement. The Company earned \$133,900 from this grant from inception through March 31, 2015.

f) Cancer agreement:

In October 2014, the Company entered into a technology development agreement with an international diagnostics company for \$320,000. The Company earned \$75,000 and \$0 for the three-month periods ended March 31, 2015 and 2014, respectively from this agreement. The Company earned \$75,000 from this grant from inception through March 31, 2015.





CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2015  
(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 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 March 31, 2015, no amount was outstanding 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").

10

---

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2015  
(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				Accounts Receivable as of	
	March 31, 2015		March 31, 2014		March 31, 2015	March 31, 2014
	Sales	% of Sales	Sales	% of Sales		
Customer 1	\$2,461,871	44	% \$*	*	\$6,097,611	\$-
Customer 2	1,386,183	25	% *	*	1,134,327	-
Customer 3	1,016,989	18	%	2,702,972 55	% 345,502	682,724
Customer 4	*	*		1,001,370 20	% -	519,300

(\*) Product sales did not exceed 10 % for the period indicated.

Note that sales include product sales only while accounts receivable reflects the total due from the customer, which includes freight.

The following table discloses purchases the Company made from each vendor that sold to the Company in excess of 10% of the Company's total purchases for the periods indicated:

	For the three months ended				Accounts Receivable as of March	
	March 31, 2015		March 31, 2014		31, March 2015	31, 2014
	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	\$* *		\$280,686 17	% \$-	\$145,950	
Vendor 2	* *		234,894 14	% -	-	

(\*) 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 as the vendors shown in this table. A change in suppliers, however, could cause a delay in manufacturing and a possible loss of sales, which could adversely affect operating results.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2015  
(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 three months ended March 31, 2015 was a benefit of 26.0%. The calculated benefit of \$(227,500) increased the carrying value of the deferred tax asset for the three months ended March 31, 2015. The 26.0% benefit rate is slightly less than the 26.6% provision rate used for the year ended 2014.

## 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, 2014.

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 revenues for the three months ended March 31, 2015 decreased to \$609,000 from \$909,000 in the prior-year period, which was primarily the result of a non-recurring \$750,000 payment recognized in 2014 for a technology transfer agreement partially offset by increased

R&D project revenues in 2015.

R&D expenses in the first quarter of 2015 were \$1.58 million, compared with \$1.20 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

---

### Research & Development Activities

The R&D projects outlined below represent activities resulting from external funding (eg. grant or service revenue):

- **Ebola and Febrile Illness Point-of-Care (POC) Assay:** 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. We are working closely with the CDC laboratory in Atlanta, GA, and estimate we will have product available for field evaluation in the second quarter of 2015. Additionally, we have applied for pre-qualification application to World Health Organization (WHO) as well as Emergency Use Authorization (EUA) with the FDA. In addition, we continue to develop DPP® Febrile illness Assay including Ebola. We continue to seek funding for these projects to accelerate development and potential supply.
- **Cancer POC Assay:** We have entered into a partnership with an international diagnostics company to develop a POC diagnostic test for the early detection and monitoring of a specific type of cancer. The cancer project represents the first application of the DPP® technology outside of the infectious disease field, as announced in October 2014. 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.
- **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. We anticipate starting pre-clinical studies in the second quarter of 2015. Under the terms of the agreement, Chembio's partner is not being disclosed.
- **DPP® FLU Immunostatus Assay:** We entered into a follow-on, milestone-based development agreement in November 2014 with a private contracting organization acting on behalf of the United States Centers for Disease Control and Prevention (CDC), for a multiplex POC influenza immunity test utilizing our patented Dual Path Platform (DPP®) technology. We have successfully completed the product development of a multiplex 7 bands DPP® Influenza Immunostatus Assay with a digital reader during the first quarter of 2015, and the final report is being evaluated by the private contracting organization.
- **DPP® Brain Injury Assay:** We entered into an agreement with the Concussion Science Group (CSG) Division of Perseus Science Group LLC, to utilize our patented DPP® technology to develop a POC diagnostic test for traumatic brain injury (TBI), including sports-related concussion. Under terms of the agreement, CSG's patented biomarker will be combined with Chembio's proprietary DPP® platform to develop a semi-quantitative or quantitative point-of-care test to diagnose TBI. CSG has agreed to pay Chembio milestone development payments during 2015. We have identified the reagents for this assay and we are currently working on product optimization. In addition, we have contacted FDA to discuss the requirements for regulatory approval of this product.
- **DPP® Malaria POC Rapid Assay:** Chembio was awarded a grant from the Bill & Melinda Gates Foundation in January 2015 to expedite the feasibility testing and development of a DPP® Malaria POC rapid diagnostic to accurately identify individuals infected with Plasmodium falciparum parasite. Chembio's DPP® technology was selected for this grant due to its exceptional sensitivity and potential to aid the Bill & Malinda Gates Foundation in its goal of eradicating malaria. To achieve this goal, diagnostics must be capable of detecting the malaria parasite in infected, but asymptomatic people. Current POC rapid diagnostics tests lack sufficient sensitivity to identify all individuals with transmissible infections.



Additionally, Chembio's product pipeline includes the following projects currently under "Product Development" for product commercialization:

- **DPP® HIV-Syphilis:** The Chembio DPP® HIV/Syphilis Assay is a rapid, multiplex test for the detection of antibodies to HIV and to *Treponema pallidum* (TP) bacteria (the causative agent of syphilis). The product was successfully launched in Mexico during 2014, and recently received approval for commercial use by the Brazilian regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA). The DPP® HIV-Syphilis Assay is the only POC test cleared for commercialization in Brazil for rapid, POC detection of both HIV 1/2 and syphilis. Chembio developed this novel combination assay to address the growing concern among public health officials regarding co-infection rates of HIV and syphilis as well as mother-to-child transmission (MTCT) of HIV and syphilis. Studies are in progress to evaluate a version of this test that has been developed for the US market, to meet the performance requirements for a combination test, including a "reverse" algorithm that is currently in clinical use in the United States for syphilis testing. Preliminary results of this pre-clinical field evaluation are encouraging
- **DPP® HIV Ag/Ab Assay:** DPP® HIV Multiplex Antigen-Antibody "Fourth Generation" Assay: Development work continues on a DPP® HIV multiplex test that is being designed to detect acute (early stage) HIV infection by means of detecting P24 antigen, as well as antibodies, to HIV1/2, in whole blood samples. In February 2015, we signed an agreement to secure a critical raw material source with a supplier, and we continue progress to optimize the design to meet or exceed the target specifications of product that is commercially available on the market.

#### Regulatory Activities

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. In February 2015, this product was granted approval from the Brazilian ANVISA. 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. We continue to pursue an FDA submission for this product, and are in the progress of studies to evaluate a version that has been developed for the US market, to meet the performance requirements for a combination test to detect both HIV and Syphilis, including a "reverse" algorithm that is currently in clinical use in the United States for syphilis testing.

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, 2014, see our Annual Report on Form 10-K for the twelve months ended December 31, 2014, which was filed with the SEC on March 5, 2015.



## RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2015 AS COMPARED WITH THE THREE MONTHS ENDED MARCH 31, 2014

Income:

For the three months ended March 31, 2015, Loss before income taxes was \$(874,000) compared to \$(381,000) for the three months ended March 31, 2014. Net Loss for the 2015 period was \$(647,000) as compared to \$(225,000) for 2014. The increase in Net Loss is primarily attributable to increased operating expenses of \$907,000, partially offset by increased revenues and increased gross margin. Gross margin increased in the three months ended March 31, 2015, as compared with the three months ended March 31, 2014, by \$414,000, or 18.2%.

Revenues:

Selected Product Categories:	For the three months ended			
	March 31, 2015	March 31, 2014	\$ Change	% Change
Lateral Flow HIV Tests and Components	\$2,894,988	\$3,536,699	\$ (641,711 )	-18.14 %
DPP Tests and Components	2,463,102	1,168,770	1,294,332	110.74 %
Other	256,595	198,696	57,899	29.14 %
Net Product Sales	5,614,685	4,904,165	710,520	14.49 %
License and royalty revenue	7,051	160	6,891	4,306.88%
R&D, milestone and grant revenue	609,401	908,748	(299,347 )	-32.94 %
Total Revenues	\$6,231,137	\$5,813,073	\$ 418,064	7.19 %

Revenues for our lateral flow HIV tests and related components during the three months ended March 31, 2015 decreased by approximately \$642,000 from the same period in 2014. This was primarily attributable to decreased sales to North America, of approximately \$1,457,000, partially offset by increased sales to Africa, of approximately \$745,000. Revenues for our DPP® products during the three months ended March 31, 2015 increased by approximately \$1,294,000 over the same period in 2014, primarily due to increased sales in Brazil to FIOCRUZ. The decrease in R&D, and in milestone and grant revenue, was primarily due to \$750,000 recognized in 2014 for a technology transfer agreement and was partially offset by increased R&D project revenues in 2015 .

Gross Margin:

	For the three months ended			
	March 31, 2015	March 31, 2014	\$ Change	% Change
Gross Margin per Statement of Operations	\$2,686,618	\$2,272,611	\$414,007	18.22 %
Less: R&D, milestone, grant, license and royalty revenues	616,452	908,908	(292,456)	-32.18 %
Gross Margin from Net Product Sales	\$2,070,166	\$1,363,703	\$706,463	51.80 %
Product Gross Margin %	36.87 %	27.81 %		

The overall gross margin dollar increase of \$414,000 included a \$706,000 increase in gross margin from product sales and a \$292,000 decrease in non-product revenues. The increase in net product sales gross margin of \$706,000 is primarily attributable to the increased product sales compared to 2014, particularly the increase in sales to our partner in Brazil. The net product sales gross margin increase is comprised of two components, one is the increase in product sales of \$711,000, which, at the 27.8% margin percentage for March 31, 2014, contributed \$197,000 to the increase, and the other is the increased change in margin percentage of 8.7% contributed, which the balance of \$509,000 to the

increase in our net product sales gross margin.

16

---

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

Research and Development:

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

Selected expense lines:	For the three months ended				% Change
	March 31, 2015	March 31, 2014	\$ Change		
<b>Clinical and Regulatory Affairs:</b>					
Wages and related costs	\$ 122,686	\$ 106,143	\$ 16,543	15.59	%
Consulting	8,257	2,419	5,838	241.34	%
Stock-based compensation	-	2,425	(2,425 )	-100.00	%
Clinical trials	112,030	120,783	(8,753 )	-7.25	%
Other	23,002	18,244	4,758	26.08	%
Total Regulatory	265,975	250,014	15,961	6.38	%
<b>R&amp;D Other than Regulatory:</b>					
Wages and related costs	764,005	567,774	196,231	34.56	%
Consulting	9,933	44,550	(34,617 )	-77.70	%
Stock-based compensation	18,207	15,825	2,382	15.05	%
Materials and supplies	403,132	236,158	166,974	70.70	%
Other	123,284	83,301	39,983	48.00	%
Total other than Regulatory	1,318,561	947,608	370,953	39.15	%

Total Research and Development \$ 1,584,536 \$ 1,197,622 \$ 386,914 32.31 %

Expenses for Clinical & Regulatory Affairs for the three months ended March 31, 2015 increased by \$16,000 as compared to the same period in 2014.

R&D expenses other than Clinical & Regulatory Affairs increased by \$371,000 in the three months ended March 31, 2015, as compared with the same period in 2014. The increases were primarily related to an increase in wages and related costs, and in material and supplies, as support for our sponsored research has increased, and by an increase in internal development programs.

Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended				% Change
	March 31, 2015	March 31, 2014	\$ Change		
Wages and related costs	\$ 873,798	\$ 690,502	\$ 183,296	26.55	%
Consulting	41,606	103,747	(62,141 )	-59.90	%
Commissions	336,872	30,435	306,437	1,006.86	%
Stock-based compensation	91,102	49,134	41,968	85.42	%
Marketing materials	36,323	23,985	12,338	51.44	%
Investor relations/investment bankers	44,114	46,832	(2,718 )	-5.80	%
Legal, accounting and compliance	236,936	212,980	23,956	11.25	%
Travel, entertainment and trade shows	94,760	39,548	55,212	139.61	%
Other	222,063	260,565	(38,502 )	-14.78	%
Total S, G & A	\$ 1,977,574	\$ 1,457,728	\$ 519,846	35.66	%

Selling, general and administrative expenses for the three months ended March 31, 2015, increased by \$520,000 as compared with the same period in 2014, a 36% 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 travel entertainment and trade shows, which were partially offset by a decrease in consulting and other expenses.

17

---

Other Income:

	For the three months ended			
	March 31, 2015	March 31, 2014	\$ Change	% Change
Interest income	\$1,175	\$1,830	\$ (655 )	-35.79 %
Total Other Income	\$1,175	\$1,830	\$ (655 )	-35.79 %

Other income for the three months ended March 31, 2015 decreased approximately \$655, to an income of \$1,175 from an income of \$1,830 in the same period in 2014, as a result of a decrease in interest income.

Income tax benefit:

For the three months ended March 31, 2015 the Company recognized a \$227,500 income tax benefit and increased its deferred tax assets by 227,500. 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			
	March 31, 2015	December 31, 2014	\$ Change	% Change
Cash and cash equivalents	\$2,815,762	\$4,614,538	\$ (1,798,776)	-38.98 %
Prepaid expenses and other current assets	1,427,579	1,066,473	361,106	33.86 %
Fixed assets, net of accumulated depreciation	2,973,146	2,797,929	175,217	6.26 %
Deferred tax asset, net of valuation allowance	4,258,802	4,031,302	227,500	5.64 %
License agreements, net of current portion	374,773	256,875	117,898	45.90 %
Accounts payable and accrued liabilities	4,389,944	4,946,030	(556,086 )	-11.24 %
Deferred revenue	495,677	340,000	155,677	45.79 %

Cash decreased by \$1,799,000 from December 31, 2014, primarily due to net cash used in operating activities for the three months of 2015. In addition there were increases in prepaid expenses of \$361,000, deferred tax asset of \$227,500, licenses, net of current portion of \$118,000, fixed assets of \$407,000 before depreciation, and deferred revenue of \$156,000. We experienced a decrease in accounts payable and accrued liabilities of \$556,000.

**LIQUIDITY AND CAPITAL RESOURCES**

	For the three months ended			
	March 31, 2015	March 31, 2014	\$ Change	% Change
Net cash (used in) operating activities	\$ (941,808 )	\$ (650,304 )	\$ (291,504 )	44.83 %
Net cash (used in) investing activities	(856,968 )	(66,789 )	(790,179 )	1,183.10 %
Net cash provided by financing activities	-	153,834	(153,834 )	-100.00 %
(DECREASE) IN CASH AND CASH EQUIVALENTS	\$ (1,798,776)	\$ (563,259)	\$ (1,235,517)	219.35 %

The Company's cash decreased as of March 31, 2015 by \$1,799,000 from December 31, 2014, primarily due to net cash used in operating activities for the three months of 2015.

The cash used in operations in 2015 was \$942,000, primarily due to a decrease in accounts payable and accrued liabilities of \$556,000, an increase in inventories of \$60,000, an increase in prepaid assets of \$140,000 and a net loss net of non-cash items of \$419,000 partially offset by a decrease in accounts receivable of \$79,000 and an increase in deferred revenue of \$156,000. Net loss net of non-cash items includes net loss of \$419,000, \$228,000 in benefit for income taxes, partially offset by \$346,000 in depreciation and amortization, and \$109,000 in share-based

compensation. The use of cash from investing activities is primarily due to the purchase of licenses of \$450,000 and the purchase of fixed assets of \$407,000.

Fixed Asset Commitments

As of March 31, 2015, the Company had paid deposits on various pieces of equipment aggregating \$26,757, which is reflected in deposits on manufacturing equipment on the balance sheet. The Company has commitments for \$23,559 in additional equipment purchase obligations.



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

As reported in our Annual Report, 2014 was a transformative year for the Company. We implemented a new strategy with a focus on commercialization, leveraging the DPP® technology and a dedication to growth. We are pleased to announce that the results of this effort were apparent in the first quarter of 2015.

During the first quarter of 2015, we achieved multiple important growth metrics. During the period our total revenue was \$6.23 million, an increase of 7.2% as compared to the first quarter of 2014. Product revenue for the first quarter of 2015 was \$5.61 million, an increase of 14.5% as compared to Q1 2014. One of the most important measures for the company is DPP® revenue, which was \$2.46 million during Q1 2015, an increase of 110.7% compared to the first quarter of 2014. We are also pleased to report an increase in product gross margin from 27.8% in the first quarter of 2014 to 36.9% for the first quarter of 2015. This improvement resulted from activities undertaken in the second half of 2014 to streamline our manufacturing operations by reducing indirect headcount as well as costs associated with materials and labor, through the implementation of our Lean And Operations Excellence initiatives.

Chembio's growth has been supported, in part, by the success we've had in the last few quarters expanding sales of our proprietary DPP® products. While most of this growth has occurred internationally, subsequent to the end of the first quarter of 2015, we secured a new U.S. customer order for approximately \$85,000. To support our U.S. commercial initiative, we established agreements with a number of premier distributors in the second half of 2014 and first quarter of 2015 including McKesson/PSS, Fisher Healthcare, Medline, and Henry Schein, for the distribution of both DPP® HIV 1/2 and HIV 1/2 STAT-PAK® Assays in the U.S. We expect to further expand our commercialization and distribution relationships in 2015 in order to strengthen our position in the U.S. market.

Contributing to our sales growth is the fact Chembio's product portfolio is the strongest it's ever been. As reported last year, we terminated our prior STAT-PAK® U.S. distribution agreement and developed the commercialization infrastructure required to service and expand our U.S. business. Today, we have 100% control of our DPP® products and STAT-PAK® products on a worldwide basis. And, as announced in January 2015, we finalized an agreement to regain full rights related to the SURE CHECK® HIV 1/2 Assay, including sales, marketing, distribution, manufacturing and trademark rights, which will become effective June 1, 2016. The DPP®, STAT-PAK® and SURE CHECK® HIV Assays are all approved by the U.S. Food and Drug Administration (FDA) and CLIA-waived for the detection of antibodies to HIV 1 and HIV 2. Most important, our assays are recognized as high-quality products and some of the most important tools in the fight against HIV and other infectious diseases. Just recently, the AIDS Institute / New York State Department of Health, added DPP® HIV 1/2 Assay to the list of CLIA-waived HIV rapid tests that are approved for funding making it the only oral fluid HIV rapid test on the list. We are proud to have the respect of the healthcare community and it is our goal to preserve and strengthen this reputation in the U.S. and around the world.

While all Chembio products are important contributors to our bottom line, we believe the DPP® platform represents the future of Chembio. As we reported throughout 2014, we signed multiple development partnerships leveraging the DPP® technology across a number of new and high-value indications. Today, we continue to make progress toward the development of DPP® assays addressing malaria, dengue fever, ebola, febrile illness, traumatic brain injury, flu immunostatus and a specific form of cancer. Our ebola and febrile illness programs in particular, are advancing at rapid pace and we anticipate that the Centers for Disease Control and Prevention (CDC) will initiate field testing of these assays in West Africa as soon as the second quarter of 2015. Although we had previously reported that field-testing would begin in the first quarter of 2015, the program was slowed due to a temporary situation. This situation has been cleared and no further delays are expected.

Another product program that advanced during the first quarter of 2015 is Chembio's DPP® HIV-Syphilis Assay for commercialization in the U.S. During the quarter, product design was finalized and we initiated pre-clinical testing with the goal of meeting FDA requirements for the product. Preliminary results of this pre-clinical field evaluation

are encouraging. Chembio originally developed this novel combination assay to address the growing concern among public health officials regarding co-infection rates of HIV and syphilis as well as mother-to-child transmission (MTCT) of HIV and syphilis, and we are currently selling the DPP<sup>®</sup> HIV-Syphilis Assay internationally. Interest in the product has been significant from healthcare agencies around the world, leading us to believe that this product will continue to represent a great growth opportunity abroad and at home in the U.S.

On the regulatory front, Chembio received several critical approvals in 2014, and we are on track to secure additional approvals in 2015. In February 2015, the DPP<sup>®</sup> HIV-Syphilis Assay was granted approval from the Brazilian Agência Nacional de Vigilância Sanitária (ANVISA). The Chembio DPP<sup>®</sup> HIV-Syphilis Assay is the only POC test cleared for commercialization in Brazil for rapid, POC detection of both HIV 1/2 and syphilis. Subsequent to the end of the first quarter of 2015, the Company received a European CE Mark for HIV self-testing, via its partners, allowing it to become the first company to market a private label version of SURE CHECK<sup>®</sup> HIV 1/2 Assay for self-testing in several European countries. The CE Marking for the DPP<sup>®</sup> HIV 1/2 Assay and Chembio's filing for CE Marking to reflect a new trade name of STAT-VIEW<sup>®</sup> HIV 1/2 Assay (formerly SURE CHECK<sup>®</sup>) for sale in the EU market are both expected in 2015.

Chembio's decisions and execution in 2014 paved the way to new partners, new products and new markets. During the first quarter of 2015, we observed significant, and in some cases, tremendous growth in total revenue, product revenue, DPP<sup>®</sup> revenue and product gross margins. Our partnership programs, as well as our internal development programs are advancing – each moving a step closer to adding value to the Chembio pipeline. The first quarter of 2015 provided a strong signal validating our strategy, commercialization organization, products, team and most importantly, our capabilities. More so than ever, we believe we are on the path to brand expansion and global growth.

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, 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 under the Exchange Act that occurred during the Company's first three months of fiscal 2015 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)
4.3	2008 Stock Incentive Plan, as amended. (3)
4.4	Form of Option, for 2008 Stock Incentive Plan (4)
4.5	2014 Stock Incentive Plan (5)
4.6	Form of Option, for 2014 Stock Incentive Plan (6)
4.7	Rights Agreement, dated March 8, 2010 (7)
4.8	Form of Warrant (to be filed by amendment)
10.1*	Employment Agreement dated March 13, 2014 with John J. Sperzel III (4)
10.2*	Employment Agreement dated March 5, 2013 with Javan Esfandiari (8)
10.3*	Employment Agreement dated May 22, 2013 with Sharon Klugewicz (9)
10.3	HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Alere and StatSure. (10)
10.4	HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (10)
10.5	Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (10)
10.6	Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (10)
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 (9)
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 (9)
10.1	2015 Omnibus Agreement (11)
14.1	Ethics Policy (12)
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 definitive proxy statement on Schedule 14A filed with the Commission on August 3, 2012.
4	Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on May 8, 2014.
5	

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

Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on April 29, 2014.

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

7 Incorporated by reference to the Registrant's registration statement on Form 8-A filed with the Commission on March 11, 2010.

8 Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Commission on March 7, 2013.

9 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on August 8, 2013.

10 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.

11 Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Commission on March 5, 2015.

12 Incorporated by reference to the Registrant's Annual Report on Form 10-KSB filed with the Commission on March 30, 2006.

(\*) An asterisk (\*) beside an exhibit number indicates the exhibit contains a management contract, compensatory plan or arrangement which is required to be identified in this report.

21

---

SIGNATURES

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

Chembio Diagnostics, Inc.

Date: May 7, 2015 By: /s/ John J. Sperzel III  
John J. Sperzel III  
Chief Executive Officer  
(Principal Executive Officer)

Date: May 7, 2015 By: /s / Richard J. Larkin  
Richard J. Larkin  
Chief Financial Officer  
(Principal Financial and Accounting Officer)