

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, 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

(State or other jurisdiction of incorporation)

88-0425691

(IRS Employer Identification Number)

3661 Horseblock Road

Medford, New York 11763

(Address of principal executive offices including zip code)

(631) 924-1135

(Registrant's telephone number, including area code)

N/A

(Former Name or Former Address, if Changed Since Last Report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

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

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

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☐

Smaller reporting company ☒

(Do not check if a smaller reporting company)

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

Yes ☐ No ☒

As of November 2, 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
September 30, 2015

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PART I
Item 1. FINANCIAL STATEMENTS

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

- ASSETS -

	<u>September 30, 2015</u>	<u>December 31, 2014</u>
	(Unaudited)	
CURRENT ASSETS:		
Cash and cash equivalents	\$ 1,102,477	\$ 4,614,538
Accounts receivable, net of allowance for doubtful accounts of \$52,000 at September 30, 2015 and December 31, 2014, respectively	9,514,951	8,338,889
Inventories	3,010,537	3,638,299
Prepaid expenses and other current assets	1,537,070	1,066,473
TOTAL CURRENT ASSETS	15,165,035	17,658,199
FIXED ASSETS , net of accumulated depreciation	2,622,003	2,797,929
OTHER ASSETS:		
Deferred tax asset, net of valuation allowance	4,597,085	4,031,302
License agreements, net of current portion	205,682	256,875
Deposits on manufacturing equipment	-	20,017
Deposits and other assets	218,298	245,870
TOTAL ASSETS	\$ 22,808,103	\$ 25,010,192
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 4,414,150	\$ 4,946,030
Deferred revenue	150,000	340,000
TOTAL LIABILITIES	4,564,150	5,286,030
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized; none outstanding	-	-
Common stock - \$.01 par value; 100,000,000 shares authorized; 9,628,248 and 9,611,139 shares issued and outstanding for September 30, 2015 and December 31, 2014, respectively	96,283	96,112
Additional paid-in capital	47,824,105	47,556,426
Accumulated deficit	(29,676,435)	(27,928,376)
TOTAL STOCKHOLDERS' EQUITY	18,243,953	19,724,162
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 22,808,103	\$ 25,010,192

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, 2015	September 30, 2014	September 30, 2015	September 30, 2014
REVENUES:				
Net product sales	\$ 6,209,625	\$ 7,247,881	\$ 18,145,864	\$ 19,400,515
License and royalty revenue	19,084	8,482	34,017	15,613
R&D, milestone and grant revenue	658,665	57,946	1,654,788	1,133,850
TOTAL REVENUES	6,887,374	7,314,309	19,834,669	20,549,978
Cost of product sales	3,976,840	4,663,919	11,218,385	12,644,427
GROSS MARGIN	2,910,534	2,650,390	8,616,284	7,905,551
OPERATING EXPENSES:				
Research and development expenses	1,570,044	972,439	4,911,587	3,438,714
Selling, general and administrative expenses	1,919,551	1,940,424	6,057,221	5,344,914
	3,489,595	2,912,863	10,968,808	8,783,628
LOSS FROM OPERATIONS	(579,061)	(262,473)	(2,352,524)	(878,077)
OTHER INCOME (LOSS):				
Loss on sale of fixed asset	-	-	-	(5,707)
Interest expense	(749)	-	(749)	-
Interest income	353	1,136	1,844	4,527
	(396)	1,136	1,095	(1,180)
LOSS BEFORE INCOME TAXES	(579,457)	(261,337)	(2,351,429)	(879,257)
Income tax (benefit) provision	(142,300)	9,284	(603,370)	(237,916)
NET LOSS	\$ (437,157)	\$ (270,621)	\$ (1,748,059)	\$ (641,341)
Basic loss per share	\$ (0.05)	\$ (0.03)	\$ (0.18)	\$ (0.07)
Diluted loss per share	\$ (0.05)	\$ (0.03)	\$ (0.18)	\$ (0.07)
Weighted average number of shares outstanding, basic	9,628,248	9,611,139	9,625,282	9,503,084
Weighted average number of shares outstanding, diluted	9,628,248	9,611,139	9,625,282	9,503,084

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)

	<u>September 30, 2015</u>	<u>September 30, 2014</u>
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	\$ 18,468,607	\$ 16,826,448
Cash paid to suppliers and employees	(21,054,210)	(21,985,579)
Interest paid	(749)	-
Interest received	1,844	4,527
Net cash used in operating activities	(2,584,508)	(5,154,604)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of License	(450,000)	-
Acquisition of and deposits on fixed assets	(477,553)	(1,060,149)
Net cash used in investing activities	(927,553)	(1,060,149)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option exercises	-	237,180
Proceeds from credit line	600,000	-
Payment of credit line	(600,000)	-
Net cash provided by financing activities	-	237,180
DECREASE IN CASH AND CASH EQUIVALENTS	(3,512,061)	(5,977,573)
Cash and cash equivalents - beginning of the period	4,614,538	9,650,275
Cash and cash equivalents - end of the period	\$ 1,102,477	\$ 3,672,702
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net Loss	\$ (1,748,059)	\$ (641,341)
Adjustments:		
Depreciation and amortization	981,579	536,791
Deferred taxes	(603,370)	(239,342)
Share based compensation	267,850	336,407
Changes in assets and liabilities:		
Accounts receivable	(1,176,062)	(3,723,530)
Inventories	627,762	(786,524)
Prepaid expenses and other current assets	(249,915)	63,944
Deposits and other assets	-	(210,790)
Accounts payable and accrued liabilities	(494,293)	(490,219)
Customer deposits and deferred revenue	(190,000)	-
Net cash used in operating activities	\$ (2,584,508)	\$ (5,154,604)
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	\$ 20,017	\$ 63,960

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 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 lateral flow 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. In addition the Company has several products based on its patented Dual Path Platform (DPP®) technology, including a HIV test approved by the FDA in 2013 and CLIA-Waived in 2014. Lateral Flow Rapid HIV tests represented 41% of the Company's product revenues in the first nine months of 2015. The Company's products based on its DPP® platform represented approximately 56% of the Company's product revenues in the first nine months of 2015. The Company also has other rapid tests and components that together represented approximately 3% of product sales in the first nine 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®, STAT-VIEW® 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 September 30, 2015 and for the three and nine-month periods ended September 30, 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 September 30, 2015, its condensed consolidated results of operations for the three and nine-month periods ended September 30, 2015 and 2014, respectively, and its condensed consolidated cash flows for the nine-month periods ended September 30, 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.

The Company currently has positive working capital, however, it has used approximately \$3.5 million in cash for the nine months ended September 30, 2015. The Company has the ability to borrow up to \$2.0 million on its HSBC Demand Note, if necessary. Approximately \$7.9 million of the total \$9.5 million of accounts receivable is comprised from one customer, and the Company has a high degree of confidence that the receivables are fairly stated and collectible from this customer. As of November 5, 2015 this customer has paid \$6.8 million against these receivables.

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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2015
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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 \$150,000 and \$340,000 as of September 30, 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.

c) Inventories:

Inventories consist of the following at:

	September 30, 2015	December 31, 2014
Raw materials	\$ 2,128,070	\$ 2,323,863
Work in process	437,357	346,494
Finished goods	445,110	967,942
	<u>\$ 3,010,537</u>	<u>\$ 3,638,299</u>

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, 2015 and 2014, have been included in the earnings per share computations:

	For the three months ended		For the nine months ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Basic	9,628,248	9,611,139	9,625,282	9,503,084
Diluted	9,628,248	9,611,139	9,625,282	9,503,084

As there were losses for the three and nine-month periods ended September 30, 2015 and 2014, no common share equivalents are included in the diluted per share computations.

There were 650,728 and 547,825 weighted-average number of options outstanding as of September 30, 2015 and 2014, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended September 30, 2015 and 2014, respectively. There were 661,570 and 649,465 weighted-average number of options outstanding as of September 30, 2015 and 2014, respectively, that were not included in the calculation of diluted per common share equivalent for the nine months ended September 30, 2015 and 2014, respectively, because the effect would have been anti-dilutive as of September 30, 2015 and 2014, respectively.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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e) Employee Stock Option Plans and Share-Based Compensation:

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, 2015, there were 353,935 options exercised and 314,110 options outstanding under the SIP.

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, 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.

There were no stock options granted during the nine months ended September 30, 2015. The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the nine-month period ended September 30, 2014, was \$2.42 per share. 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, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Expected term (in years)	n/a	n/a	n/a	6.3
Expected volatility	n/a	n/a	n/a	61.50 %- 96.11%
Expected dividend yield	n/a	n/a	n/a	0 %
Risk-free interest rate	n/a	n/a	n/a	0.83 % - 1.52%

The Company's results for the three-month periods ended September 30, 2015 and 2014 include share-based compensation expense, consisting solely of stock options, totaling \$72,300 and \$118,800, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (none and none, respectively), research and development (\$14,800 and \$8,400, respectively) and selling, general and administrative expenses (\$57,500 and \$110,400, respectively). The results for the nine-month periods ended September 30, 2015 and 2014 include share-based compensation expense, consisting solely of stock options, totaling \$267,900 and \$336,900, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (none and \$700, respectively), research and development (\$47,900 and \$36,100, respectively) and selling, general and administrative expenses (\$220,000 and \$300,100, respectively). An operating expense, resulting in income tax benefit, has been recognized in the statement of operations for share-based compensation arrangements.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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Stock option compensation expense for the three and nine-month periods ended September 30, 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. Accordingly, for stock options that vested immediately, the estimated fair value was expensed immediately.

The following table provides stock option activity for the nine months ended September 30, 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	-	0.00		
Exercised	(41,141)	2.25		
Forfeited/expired/cancelled	-	0.00		
Outstanding at September 30, 2015	650,728	\$ 3.75	3.45 years	\$ 319,478
Exercisable at September 30, 2015	348,478	\$ 3.87	2.21 years	\$ 165,801

As of September 30, 2015, there was \$363,100 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 2.13 years. The total fair value of stock options vested during the nine-month periods ended September 30, 2015 and 2014 was approximately \$332,500 and \$283,000, 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, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Africa	\$ 341,520	\$ 541,944	\$ 3,049,257	\$ 1,791,749
Asia	37,569	6,058	147,722	80,815
Europe	474,164	34,205	696,998	105,230
North America	1,579,588	2,479,410	3,965,356	9,012,447
South America	3,776,784	4,186,264	10,286,531	8,410,274
	\$ 6,209,625	\$ 7,247,881	\$ 18,145,864	\$ 19,400,515

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2015
(UNAUDITED)

g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

	September 30, 2015	December 31, 2014
Accounts payable – suppliers	\$ 1,377,824	\$ 1,980,120
Accrued commissions	1,133,092	947,451
Accrued royalties / license fees	1,028,540	1,034,062
Accrued payroll	290,090	106,487
Accrued vacation	256,556	219,924
Accrued bonuses	177,700	265,500
Accrued expenses – other	150,348	392,486
TOTAL	\$ 4,414,150	\$ 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.

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 contemplated an additional period of approximately six months in which the follow-on development activity is to be completed. The Company earned \$217,000 and \$64,200 for the nine-month periods ended September 30, 2015 and 2014, respectively from these agreement. The Company earned \$1,253,000 from this grant from inception through September 30, 2015. As of June 30, 2015, we have successfully completed the product development, and the final report is being evaluated by the contracting entity.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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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 \$125,000 and \$750,000 for the nine-month periods ended September 30, 2015 and 2014, respectively from this agreement. The Company earned \$1,250,000 from this grant from inception through September 30, 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 \$240,000 and \$0 for the nine-month periods ended September 30, 2015 and 2014, respectively from this agreement. The Company earned \$300,000 from this grant from inception through September 30, 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 \$300,000 and \$0 for the nine-month periods ended September 30, 2015 and 2014, respectively from this agreement. The Company earned \$300,000 from this grant from inception through September 30, 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 \$307,000 and \$0 for the nine-month periods ended September 30, 2015 and 2014, respectively from this agreement. The Company earned \$307,000 from this grant from inception through September 30, 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 \$165,000 and \$0 for the nine-month periods ended September 30, 2015 and 2014, respectively from this agreement. The Company earned \$165,000 from this grant from inception through September 30, 2015.

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

NOTE 6 — COMMON STOCK, WARRANTS AND OPTIONS:

The Company entered into an employment agreement, effective March 13, 2014 ("Employment Agreement"), with John J. Sperzel III 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, 2015
(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:

	For the three months ended				For the nine months ended				Accounts Receivable as of	
	September 30, 2015		September 30, 2014		September 30, 2015		September 30, 2014		September 30, 2015	September 30, 2014
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales		
Customer 1	\$ 3,749,480	60	\$ 4,177,014	58	\$ 10,093,512	56	\$ 8,343,815	43	\$ 7,871,679	\$ 5,971,927
Customer 2	1,116,504	18	1,156,666	16	2,841,803	16	5,322,098	27	563,385	302,152
Customer 3	*	*	*	*	1,750,722	10	*	*	189,472	*
Customer 4	*	*	1,238,160	17	*	*	3,455,402	18	*	828,170

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

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

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

	For the three months ended				For the nine months ended				Accounts Payable as of	
	September 30, 2015		September 30, 2014		September 30, 2015		September 30, 2014		September 30, 2015	September 30, 2014
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	\$ 167,670	9	\$ 321,938	14	\$ 654,253	12	\$ 944,157	14	\$ 46,866	\$ 116,583
Vendor 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 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.

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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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c) *Employment Agreements:*

The Company has employment contracts with three key employees. The contracts call for salaries presently aggregating \$954,500 per year. The Sperzel contract expires in March 2017, the Klugewicz contract expires in May 2017, and the Esfandiari contract expires in March 2016 . In connection with the Sperzel 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 Klugewicz contract that expires in May 2017, no options were issued; however in connection with the prior Klugewicz contract that expired 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 Esfandiari 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, 2015 was a benefit of 26.0 %. The calculated benefit of \$(603,370) increased the carrying value of the deferred tax asset for the nine months ended September 30, 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 nine months ended September 30, 2015 increased to \$1.65 million from \$1.13 million in the prior-year period, which was primarily the result of increased R&D project revenues in 2015, partially offset by a non-recurring \$.75 million payment recognized in 2014 for a technology transfer agreement. Some projects are based on a milestone basis for which revenue cannot be recognized until the milestone is achieved, while expenses incurred to reach that milestone are expensed in the period incurred.

R&D expenses in the nine months ended September 30, 2015 were \$4.91 million, compared with \$3.44 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 other projects and grants.

Research & Development Activities

Sexually Transmitted Disease

- **DPP® HIV-Syphilis Assay:** The DPP® HIV-Syphilis Assay is a rapid, point-of-care (POC), multiplex test for the simultaneous detection of antibodies to HIV and to *Treponema Pallidum* (TP) bacteria (the causative agent of syphilis). This novel combination assay was developed to address the growing concern among public health officials regarding the rising co-infection rates of HIV and syphilis as well as mother-to-child transmission (MTCT) of HIV and syphilis. The product was successfully launched in Mexico during 2014, and received approval for commercial use by the Brazilian regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA). The DPP® HIV-Syphilis Assay is the only test cleared for commercialization in Brazil for rapid, POC detection of both HIV 1/2 and syphilis. We are developing a U.S. version of the DPP® HIV-Syphilis Assay, designed to meet the performance requirements for the "reverse" algorithm that is currently in clinical use for syphilis testing in the United States. We have completed our pre-clinical studies for this product with encouraging results, and are in the final stages of clinical site selection for our U.S. clinical studies. We plan to begin this clinical trial in the U.S. during first quarter of 2016, and expect that the trial will be completed in six to nine months from initiation.
- **DPP® HIV Ag/Ab Assay:** The DPP® HIV Ag/Ab Assay is a rapid, POC, multiplex test for the simultaneous detection of 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.

Fever Disease

- **DPP® Malaria Assay:** The DPP® Malaria Assay is a rapid, POC, multiplex test for the simultaneous detection of *plasmodium falciparum* and other *plasmodium* infections. In January 2015, we received a grant from the Bill & Melinda Gates Foundation to expedite the development and feasibility testing of a POC DPP® Malaria Assay. The Company recently completed this project which compared the new DPP® Malaria Assay to the world's leading currently-available POC malaria assay. Based on initial testing, the new DPP® Malaria Assay met the major objective of the feasibility project: a ten-fold improvement in sensitivity. Given these results, Chembio plans to develop and commercialize a family of DPP® Malaria Assays.
- **DPP® Fever Panel Assay:** The DPP® Fever Panel Assay is a rapid, POC, multiplex test for the simultaneous detection of Malaria, Dengue, Ebola, Lassa, Marburg, and Chikungunya. In October 2015, we received a \$2.1 million grant from the Paul G. Allen Ebola Program, to develop the DPP® Fever Panel Assay, which we expect be ready for field testing in the fourth quarter of 2016.
- **DPP® Ebola Assay and DPP® Malaria-Ebola Assay:** The DPP® Ebola Assay is a rapid POC test for the detection of Ebola and the DPP® Malaria-Ebola Assay is a rapid, POC, multiplex test for the simultaneous detection of Malaria and Ebola. In October 2014, we announced plans to develop, validate, and commercialize POC DPP® Assays for Ebola and Febrile Illness. We completed the development of the DPP® Ebola Assay and submitted for Emergency Use Authorization (EUA) with the Food & Drug Administration (FDA) and World Health Organization (WHO). During the third quarter of 2015, we sold DPP® Ebola Assays to the Centers for Disease Control & Prevention (CDC) for field studies in West Africa and we expect to sell DPP® Malaria-Ebola and DPP® Ebola Assays to the CDC during the fourth quarter of 2015, for further field testing.
- **DPP® Dengue Fever Assay:** The DPP® Dengue Fever Assay is a rapid, POC, multiplex test for the simultaneous detection of 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 fourth quarter of 2015. This program is fully funded by a partner. However, under the terms of our agreement, Chembio's partner is not being disclosed.

Technology Collaboration

- **DPP® Cancer Assay:** The DPP® Cancer Assay is a rapid, POC, multiplex test for the early detection and monitoring of a specific type of cancer. In October 2014, we entered into collaboration with an international diagnostics company to develop a POC diagnostic test for a specific type of cancer. The cancer project represents an application of the DPP® technology outside of the infectious disease field and the scope of the agreement involves product development of a quantitative reader-based cancer assay for two cancer markers, utilizing Chembio's DPP® technology and DPP® Micro Reader. This program is fully funded by a partner. However, under the terms of the agreement, neither Chembio's partner nor the specific type of cancer is being disclosed. During the third quarter of 2015, we completed successful feasibility and our partner agreed to fund continued development of the DPP® Cancer Assay.
- **DPP® Traumatic Brain Injury Assay:** The DPP® Traumatic Brain Injury Assay is a rapid POC test for the detection of traumatic brain injury (TBI) and sports-related concussion. In January 2015, we entered into an agreement with the Concussion Science Group (CSG) Division of Perseus Science Group LLC, to combine CSG's patented biomarker with our proprietary DPP® platform and DPP® Micro Reader, to develop a semi-quantitative or quantitative POC test, to diagnose TBI. In May 2015, an Informational Meeting was conducted at the FDA to present the technology and intended use, as well to initiate dialogue regarding the regulatory pathway for this product. The DPP® Traumatic Brain Injury Assay is in the feasibility stage.
- **DPP® FLU Immunostatus Assay –** The DPP® FLU Immunostatus Assay is a rapid, POC, multiplex influenza immunity test. In November 2014, we entered into a follow-on, milestone-based development agreement with a private contracting organization acting on behalf of the U.S. government, for a multiplex POC influenza immunity test utilizing our patented DPP® technology. We successfully completed the product development of a 7-band multiplex DPP® Flu Immunostatus Assay with a digital reader during the first quarter of 2015 and subsequently applied for additional funding in response to a new request for proposal (RFP) from the U.S. Government, for which we expect a response in the first quarter of 2016.

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 SEPTEMBER 30, 2015 AS COMPARED WITH THE THREE MONTHS ENDED SEPTEMBER 30, 2014

Income:

For the three months ended September 30, 2015, Loss before income taxes was \$(579,000) compared to \$(261,000) for the three months ended September 30, 2014. Net Loss for the 2015 period was \$(437,000) as compared to \$(271,000) for 2014. The increase in Net Loss is primarily attributable to increased operating expenses of \$577,000, partially offset by increased gross margin. Gross margin increased in the three months ended September 30, 2015, as compared with the three months ended September 30, 2014, by \$260,000, or 9.8%.

Revenues:

Selected Product Categories:	For the three months ended		\$ Change	% Change
	September 30, 2015	September 30, 2014		
Lateral Flow HIV Tests and Components	\$ 2,286,629	\$ 1,669,694	\$ 616,935	36.95%
DPP® Tests and Components	3,783,581	5,409,724	(1,626,143)	-30.06%
Other	139,415	168,463	(29,048)	-17.24%
Net Product Sales	6,209,625	7,247,881	(1,038,256)	-14.32%
License and royalty revenue	19,084	8,482	10,602	124.99%
R&D, milestone and grant revenue	658,665	57,946	600,719	1,036.69%
Total Revenues	<u>\$ 6,887,374</u>	<u>\$ 7,314,309</u>	<u>\$ (426,935)</u>	<u>-5.84%</u>

Revenues for our lateral flow HIV tests and related components during the three months ended September 30, 2015 increased by approximately \$617,000 from the same period in 2014. This was primarily attributable to increased sales to North America of approximately \$341,000 and Europe of approximately \$440,000, partially offset by decreased sales to Africa, of approximately \$200,000. Revenues for our DPP® products during the three months ended September 30, 2015 decreased by approximately \$1,626,000 over the same period in 2014, primarily due to decreased sales in Mexico and Brazil. The increase in R&D, and in milestone and grant revenue, was primarily due to increased R&D project revenues in 2015. Some projects are based on a milestone basis for which revenue cannot be recognized until the milestone is achieved, while expenses incurred to reach that milestone are expensed in the period incurred.

Gross Margin:

	For the three months ended		\$ Change	% Change
	September 30, 2015	September 30, 2014		
Gross Margin per Statement of Operations	\$ 2,910,534	\$ 2,650,390	\$ 260,144	9.82%
Less: R&D, milestone, grant, license and royalty revenues	677,749	66,428	611,321	920.28%
Gross Margin from Net Product Sales	<u>\$ 2,232,785</u>	<u>\$ 2,583,962</u>	<u>\$ (351,177)</u>	<u>-13.59%</u>
Product Gross Margin %	<u>35.96%</u>	<u>35.65%</u>		

The overall gross margin dollar increase of \$260,000 included a \$351,000 decrease in gross margin from product sales and a \$611,000 increase in non-product revenues. The decrease in net product sales gross margin of \$351,000 is primarily attributable to the decreased product sales compared to 2014, particularly the decreased sales in Mexico. The net product sales gross margin decrease is primarily affected by two components, one is the decrease in product sales of \$1,038,000, which, at the 35.65% margin percentage for September 30, 2014 contributed \$370,000 to the decrease, and the other is the increased change in margin percentage of 0.3%, which contributed \$19,000 to partially offset 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		\$ Change	% Change
	September 30, 2015	September 30, 2014		
Clinical and Regulatory Affairs:				
Wages and related costs	\$ 111,948	\$ 103,954	\$ 7,994	7.69%
Consulting	3,189	1,578	1,611	102.09%
Clinical trials	9,329	5,948	3,381	56.84%
Other	23,177	34,993	(11,816)	-33.77%
Total Regulatory	147,643	146,473	1,170	0.80%
R&D Other than Regulatory:				
Wages and related costs	671,950	553,703	118,247	21.36%
Consulting	31,436	3,300	28,136	852.61%
Stock-based compensation	14,838	8,429	6,409	76.04%
Materials and supplies	566,558	160,928	405,630	252.06%
Other	137,619	99,606	38,013	38.16%
Total other than Regulatory	1,422,401	825,966	596,435	72.21%
Total Research and Development	\$ 1,570,044	\$ 972,439	\$ 597,605	61.45%

Expenses for Clinical & Regulatory Affairs for the three months ended September 30, 2015 increased by \$1,000 as compared to the same period in 2014.

R&D expenses other than Clinical & Regulatory Affairs increased by \$596,000 in the three months ended September 30, 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, in order to support the increase in our sponsored research.

Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended		\$ Change	% Change
	September 30, 2015	September 30, 2014		
Wages and related costs	\$ 632,308	\$ 595,287	\$ 37,021	6.22%
Consulting	77,367	142,694	(65,327)	-45.78%
Commissions	476,850	488,034	(11,184)	-2.29%
Stock-based compensation	57,420	110,353	(52,933)	-47.97%
Marketing materials	46,895	82,937	(36,042)	-43.46%
Investor relations/investment bankers	54,977	30,370	24,607	81.02%
Legal, accounting and compliance	179,223	210,337	(31,114)	-14.79%
Travel, entertainment and trade shows	146,309	73,649	72,660	98.66%
Other	248,202	206,763	41,439	20.04%
Total S, G & A	\$ 1,919,551	\$ 1,940,424	\$ (20,873)	-1.08%

Selling, general and administrative expenses for the three months ended September 30, 2015, decreased by \$21,000 as compared with the same period in 2014, a 1% decrease. This decrease resulted primarily from decreases in consulting, stock-based compensation, commissions, marketing materials and professional fees, which were partially offset by increases in staffing, wages and related costs, travel, entertainment and trade shows, investor relations expenses and other expenses.

Other Income (Expense):

	For the three months ended		\$ Change	% Change
	September 30, 2015	September 30, 2014		
Interest income	\$ 353	\$ 1,136	\$ (783)	-68.93%
Interest expense	(749)	-	(749)	100.00%
Total Other Income (Loss)	\$ (396)	\$ 1,136	\$ (1,532)	-134.86%

Other income (expense) for the three months ended September 30, 2015 decreased \$1,500, to an expense of \$400 from an income of \$1,100 in the same period in 2014, as a result of less cash to invest and interest expense from borrowing on our credit line during the period.

RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2015 AS COMPARED WITH THE NINE MONTHS ENDED SEPTEMBER 30, 2014**Income:**

For the nine months ended September 30, 2015, Loss before income taxes was \$(2,351,000) compared to \$(879,000) for the nine months ended September 30, 2014. Net Loss for the 2015 period was \$(1,748,000) as compared to \$(641,000) for 2014. The increase in Net Loss is primarily attributable to increased operating expenses of \$2,185,000 and decreased revenues, partially offset by increased gross margin. Gross margin increased in the nine months ended September 30, 2015, as compared with the nine months ended September 30, 2014, by \$711,000, or 9.0%.

Revenues:

Selected Product Categories:	For the nine months ended		\$ Change	% Change
	September 30, 2015	September 30, 2014		
Lateral Flow HIV Tests and Components	\$ 7,403,260	\$ 7,093,301	\$ 309,959	4.37%
DPP® Tests and Components	10,227,409	11,745,519	(1,518,110)	-12.93%
Other	515,195	561,695	(46,500)	-8.28%
Net Product Sales	18,145,864	19,400,515	(1,254,651)	-6.47%
License and royalty revenue	34,017	15,613	18,404	117.88%
R&D, milestone and grant revenue	1,654,788	1,133,850	520,938	45.94%
Total Revenues	\$ 19,834,669	\$ 20,549,978	\$ (715,309)	-3.48%

Revenues for our lateral flow HIV tests and related components during the nine months ended September 30, 2015 increased by approximately \$310,000 from the same period in 2014. This was primarily attributable to increased sales to Africa, of approximately \$1,258,000 and sales to Europe of approximately \$592,000, partially offset by decreased sales to North America, of approximately \$1,589,000. Revenues for our DPP® products during the nine months ended September 30, 2015 decreased by approximately \$1,518,000 over the same period in 2014, primarily due to decreased sales in Mexico, partially offset by increased sales in Brazil to FIOCRUZ. The increase in R&D, and in milestone and grant revenue, was primarily due to increased R&D project revenues in 2015 and was partially offset by \$750,000 recognized in 2014 for a technology transfer agreement. Some projects are based on a milestone basis for which revenue cannot be recognized until the milestone is achieved, while expenses incurred to reach that milestone are expensed in the period incurred.

Gross Margin:

	For the nine months ended		\$ Change	% Change
	September 30, 2015	September 30, 2014		
Gross Margin per Statement of Operations	\$ 8,616,284	\$ 7,905,551	\$ 710,733	8.99%
Less: R&D, milestone, grant, license and royalty revenues	1,688,805	1,149,463	539,342	46.92%
Gross Margin from Net Product Sales	<u>\$ 6,927,479</u>	<u>\$ 6,756,088</u>	<u>\$ 171,391</u>	<u>2.54%</u>
Product Gross Margin %	<u>38.18%</u>	<u>34.82%</u>		

The overall gross margin dollar increase of \$711,000 included a \$171,000 increase in gross margin from product sales and a \$539,000 increase in non-product revenues. The increase in net product sales gross margin of \$171,000 is primarily attributable to the increased product gross margin percentage compared to 2014. Both our Operations Excellence Program, which has helped to reduce our manufacturing costs, along with product mix, were primarily responsible for the increased gross margin percentage from products, however due to low volume of product produced in the quarter these benefits were partially offset by underutilization of our resources resulting in a higher overhead allocation. Some of the product for sale in the third quarter was produced during the second quarter resulting in a reduction of approximately \$628,000 in inventory during the nine months. The net product sales gross margin increase is primarily affected by two components, one is the increased change in margin percentage of 3.4%, which contributed \$608,000 to the increase in our net product sales gross margin, and the other is a decrease in product sales of \$1,254,000, which, at the 34.8% margin percentage for September 30, 2014 reduced the increase by \$437,000.

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		\$ Change	% Change
	September 30, 2015	September 30, 2014		
Clinical and Regulatory Affairs:				
Wages and related costs	\$ 365,923	\$ 316,643	\$ 49,280	15.56%
Consulting	25,550	26,086	(536)	-2.05%
Stock-based compensation	-	3,231	(3,231)	-100.00%
Clinical trials	365,469	156,443	209,026	133.61%
Other	66,342	74,751	(8,409)	-11.25%
Total Regulatory	<u>823,284</u>	<u>577,154</u>	<u>246,130</u>	<u>42.65%</u>
R&D Other than Regulatory:				
Wages and related costs	2,181,951	1,736,373	445,578	25.66%
Consulting	69,479	116,651	(47,172)	-40.44%
Stock-based compensation	47,879	32,885	14,994	45.60%
Materials and supplies	1,387,446	685,524	701,922	102.39%
Other	401,548	290,127	111,421	38.40%
Total other than Regulatory	<u>4,088,303</u>	<u>2,861,560</u>	<u>1,226,743</u>	<u>42.87%</u>
Total Research and Development	<u>\$ 4,911,587</u>	<u>\$ 3,438,714</u>	<u>\$ 1,472,873</u>	<u>42.83%</u>

Expenses for Clinical & Regulatory Affairs for the nine months ended September 30, 2015 increased by \$246,000 as compared to the same period in 2014. The increase is primarily due to the increase in clinical trials of \$209,000.

R&D expenses other than Clinical & Regulatory Affairs increased by \$1,227,000 in the nine months ended September 30, 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, in order to support the increase in our sponsored research.

Selling, General and Administrative Expenses:

Selected expense lines:	For the nine months ended		\$ Change	% Change
	September 30, 2015	September 30, 2014		
Wages and related costs	\$ 2,355,107	\$ 1,924,165	\$ 430,942	22.40%
Consulting	192,473	406,044	(213,571)	-52.60%
Commissions	1,281,754	999,745	282,009	28.21%
Stock-based compensation	219,971	297,078	(77,107)	-25.96%
Marketing materials	154,267	148,037	6,230	4.21%
Investor relations/investment bankers	139,057	118,479	20,578	17.37%
Legal, accounting and compliance	626,133	506,767	119,366	23.55%
Travel, entertainment and trade shows	363,972	225,111	138,861	61.69%
Other	724,487	719,488	4,999	0.69%
Total S, G &A	\$ 6,057,221	\$ 5,344,914	\$ 712,307	13.33%

Selling, general and administrative expenses for the nine months ended September 30, 2015, increased by \$712,000 as compared with the same period in 2014, a 13.3% increase. This increase resulted primarily from significant increases in commissions due to increased sales to Brazil, along with increases in staffing, wages and related costs, travel, entertainment and trade shows, professional expenses, and marketing materials, which were partially offset by decreases in consulting, and stock-based compensation.

Other Income (Expense):

	For the nine months ended		\$ Change	% Change
	September 30, 2015	September 30, 2014		
(Loss) gain on sale of fixed asset	\$ -	\$ (5,707)	\$ 5,707	-100.00%
Interest expense	(749)	-	(749)	100.00%
Interest income	1,844	4,527	(2,683)	-59.27%
Total Other Income (Loss)	\$ 1,095	\$ (1,180)	\$ 2,275	-192.80%

Other income for the nine months ended September 30, 2015 increased \$2,300, to an income of \$1,100 from an expense of \$1,200 in the same period in 2014, as a result of a loss on the sale of an asset.

Income tax benefit:

For the nine months ended September 30, 2015 the Company recognized a \$603,000 income tax benefit and increased its deferred tax asset. 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, 2015	December 31, 2014		
Cash and cash equivalents	\$ 1,102,477	\$ 4,614,538	\$ (3,512,061)	-76.11%
Accounts receivable, net of allowance for doubtful accounts of \$52,000 at September 30, 2015 and December 31, 2014, respectively	9,514,951	8,338,889	1,176,062	14.10%
Inventories	3,010,537	3,638,299	(627,762)	-17.25%
Prepaid expenses and other current assets	1,537,070	1,066,473	470,597	44.13%
Deferred tax asset, net of valuation allowance	4,597,085	4,031,302	565,783	14.03%
License agreements, net of current portion	205,682	256,875	(51,193)	-19.93%
Accounts payable and accrued liabilities	4,414,150	4,946,030	(531,880)	-10.75%
Deferred revenue	150,000	340,000	(190,000)	-55.88%

Cash decreased by \$3,512,000 from December 31, 2014, primarily due to net cash used in operating activities for the nine months of 2015. In addition there were increases in accounts receivable of \$1,176,000 (primarily due to a large customer as described under "Liquidity And Capital Resources"), prepaid expenses of \$471,000 (primarily due to the acquisition of a license), and deferred tax asset of \$566,000. We experienced a decrease in inventories of \$628,000, licenses, net of current portion, of \$51,000, and deferred revenue of \$190,000.

LIQUIDITY AND CAPITAL RESOURCES

	For the nine months ended		\$ Change	% Change
	September 30, 2015	September 30, 2014		
Net cash used in operating activities	\$ (2,584,508)	\$ (5,154,604)	\$ 2,570,096	-49.86%
Net cash used in investing activities	(927,553)	(1,060,149)	132,596	-12.51%
Net cash provided by financing activities	-	237,180	(237,180)	-100.00%
Decrease in cash and cash equivalents	\$ (3,512,061)	\$ (5,977,573)	\$ 2,465,512	-41.25%

The Company's cash decreased as of September 30, 2015 by \$3,512,000 from December 31, 2014, primarily due to net cash used in operating activities and net cash used in investing activities for the nine months of 2015.

The cash used in operations in 2015 was \$2,585,000, which consisted primarily of an increase in accounts receivable of \$1,176,000, a decrease in accounts payable and accrued liabilities of \$494,000, an increase in prepaid assets of \$250,000, a decrease in deferred revenue of \$190,000 and a net loss net of non-cash items of \$1,102,000, partially offset by cash provided by a decrease in inventories of \$628,000. Net loss net of non-cash items includes net loss of \$1,748,000, which includes \$603,000 in benefit for income taxes, partially offset by non-cash expenses for \$982,000 in depreciation and amortization, and by \$268,000 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 \$478,000.

The Company currently has positive working capital, however, it has used approximately \$3.5 million in cash for the nine months ended September 30, 2015. The Company has the ability to borrow up to \$2.0 million on its HSBC Demand Note, if necessary. Approximately \$7.9 million of the total \$9.5 million of accounts receivable is related to one customer and the Company has a high degree of confidence that the receivable is collectible from this customer. As of November 5, 2015, this customer has paid \$6.8 million against these receivables.

Fixed Asset Commitments

As of September 30, 2015, the Company did not have any deposits on equipment. The Company had no commitments for additional equipment purchase obligations.

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

Chembio continues to focus on the following three business areas: Sexually Transmitted Diseases, Fever Diseases, and Technology Collaborations. During the third quarter of 2015, the Company achieved significant milestones in each of these areas and recognized a total of \$6.9 million in revenue – the highest quarterly revenue recorded in 2015. Revenues from our U.S. HIV product sales during the quarter increased by 21% as compared to the third quarter of 2014 and increased by 34% as compared to the second quarter of 2015.

Sexually Transmitted Diseases

In the second quarter of 2015, Chembio's European partners, AAZ and BioSure, launched sales of Chembio's SURE CHECK® HIV 1/2 self-testing kits in the U.K. and France, respectively. The launch of these private-label, self-testing kits in Europe was a great success, and we have received orders that will bring our total sales of these kits to approximately \$1.0 million in 2015. There are approximately 110,000 people living with HIV in the U.K., and an estimated 26,000 are unaware of their positive HIV status. In France, there are approximately 160,000 people living with HIV, and an estimated 29,000 are unaware of their positive HIV status. European health agencies continue to promote the importance of testing for HIV, and we believe our SURE CHECK® HIV 1/2 product is particularly well-suited for the emerging European self-testing segment, given its ability to provide simple, fast and reliable detection of antibodies to HIV 1 and HIV 2.

In Brazil, we continue to have a strong relationship with, and sales to, the Ministry of Health, our sole customer in the country. As of September 30, 2015, the Ministry of Health had accumulated an outstanding account payable of approximately \$7.9 million. We are pleased to report that in the first half of the fourth quarter, we received payments of \$6.8 million from the Ministry of Health in Brazil and the account receivable for this customer is current as of November 11, 2015. Initial indications for 2016 product demand from the Ministry of Health lead us to believe that Brazil will continue to be a strong market for Chembio.

As we've stated in previous quarters, our priority in the sexually transmitted disease area is to be the first-to-market with a DPP® HIV-Syphilis combination assay for the U.S. While the Company is already successfully marketing a DPP® HIV-Syphilis combo assay in Latin America, regulatory standards require additional enhancements for the U.S. market and completion of a clinical trial. We plan to initiate this clinical trial in the U.S. during first quarter of 2016. We anticipate that the trial will be completed in six to nine months and cost between \$1.0 and \$1.5 million. We are also in the process of submitting the technical dossier for CE Mark which will allow us to commercialize the DPP® HIV-Syphilis Assay in Europe.

Fever Diseases

Our Fever Diseases business had multiple significant advancements during the third quarter of 2015. We received a grant from the Paul G. Allen Ebola Program to develop a DPP® Fever Panel Assay, a point-of-care (POC) test for multiple fever diseases; we delivered our DPP® Ebola Assay to the Centers for Disease Control and Prevention (CDC) for field testing in West Africa, generating initial revenues of \$150,000 with committed orders of \$900,000 related to DPP® Malaria-Ebola and DPP® Ebola Assays for the fourth quarter; we made progress with our DPP® Dengue Fever Assay; and we made extraordinary strides to develop a DPP® Malaria Assay that is 10x more sensitive than the world's leading POC malaria test.

We believe there is a significant global need for a simple, cost-effective, POC diagnostic test capable of testing for multiple fever diseases simultaneously. The Paul G. Allen Ebola Program shares this view, and in the third quarter of 2015, that Program granted \$2.1 million to Chembio to fund the 12-month development of a DPP® Fever Panel Assay to simultaneously detect Malaria, Dengue, Ebola, Lassa, Marburg, and Chikungunya.

Today, these diseases are commonly misdiagnosed due largely to the fact that they have similar symptoms that are difficult to identify. Currently available POC diagnostics may lack the ability to test for multiple diseases simultaneously, and may lack the sensitivity and specificity required to detect infected but asymptomatic patients - information that is critical for preventing the spread of disease.

It is the goal of both the Paul G. Allen Ebola Program and of Chembio to develop a simple, cost-effective, POC diagnostic test capable of testing for multiple diseases simultaneously, in order to limit the spread of infection through accurate diagnosis. We are honored that the Paul G. Allen Ebola Program selected Chembio's DPP® technology as a platform for this important project, and we look forward to delivering the first-ever POC multiplex test for fever diseases.

Another significant development was the result of a six-month feasibility project that sought to achieve enhanced sensitivity with Chembio's DPP® Malaria Assay. Based on initial testing, the DPP® Malaria Assay achieved the goal of a 10-fold improvement in sensitivity as compared to the current world-leading POC malaria assay.

We are extremely pleased with the performance of the DPP® Malaria Assay and believe it will significantly improve the diagnosis of malaria and provide healthcare workers with a new advantage in fighting this serious fever disease. Based on these results, we are aggressively working toward the development and launch of a new suite of DPP® Malaria Assays, including DPP® Malaria-Ebola Assay, which we expect to begin field testing in West Africa in 2015, and DPP® Fever Panel Assay, which is expected to be ready for field testing in 12 months.

Technology Collaborations

In our technology collaborations, we continue to work toward the development of products that may change diagnostic patterns for indications beyond sexually transmitted disease and fever diseases. During the third quarter, we had several notable advancements.

First, we successfully completed the feasibility testing of the biomarker in our cancer diagnostic program. This program, which targets a specific type of cancer, is funded by an undisclosed partner. Based on the results of the feasibility testing, we have now moved into the product development stage, which is also funded by our partner. While we are confident in the power of our DPP® technology to provide highly specific and sensitive results in our focus disease areas, we believe the utility of the DPP® platform may extend to other areas with significant need. While it is still early in development, it is our hope to find opportunities for DPP® in the broader oncology sector.

During the third quarter, we also made progress with our DPP® Traumatic Brain Injury Assay. This project, which is funded by Perseus Science Group, LLC, is in the feasibility phase. We are currently working with several hospitals to finalize institutional review board (IRB) agreements and develop the plan for conducting initial studies of the DPP® Traumatic Brain Injury Assay using patient samples.

Another significant achievement during the third quarter of 2015 was our launch of the DPP® Micro Reader as a result of our agreement with opTricon, a leading developer of mobile analysis devices for rapid diagnostic tests. Through our exclusive agreement, which covers the fields of sexually transmitted diseases, certain fever diseases, and a specific form of cancer, Chembio will market the DPP® Micro Reader as a complement to several of our proprietary assays.

The DPP® Micro Reader is simple, fast, palm-sized, battery-operated and cost-effective compared to traditional POC assay readers. The DPP® Micro Reader includes an innovative image sensor to provide a quantitative interpretation of diagnostic results when combined with Chembio's proprietary DPP® immunoassay technology. Using a state-of-the-art camera system, the DPP® Micro Reader is designed to provide definitive diagnostic results for low analyte concentrations, which may otherwise result in faint or ambiguous test results. In addition, the DPP® Micro Reader will provide customers with various options to capture, record, transmit and store test results.

As a leader in POC diagnostic testing, Chembio intends to stay at the forefront of technology and innovation. We strive to continuously deliver enhancements and always respond to the needs of our customers. The DPP® Micro Reader is an important piece of this strategy, allowing us to provide quantitative analysis and data management of testing results for those circumstances that require this capability.

ITEM 4. CONTROLS AND PROCEDURES

- (a) **Disclosure Controls and Procedures.** Under the supervision and with the participation of our senior management, consisting of our chief executive officer and our chief financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this report (the "Evaluation Date"). Based on that evaluation, the Company's management, including our chief executive officer and chief financial officer, concluded that as of the Evaluation Date our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our Exchange Act reports is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.
- (b) **Changes in Internal Control over Financial Reporting.** There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 under the Exchange Act that occurred during the Company's first nine months of fiscal 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 June 12, 2015 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 (11)
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 (11)
10.1	2015 Omnibus Agreement (12)
14.1	Ethics Policy (13)
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 Quarterly Report on Form 10-Q filed with the Commission on July 29, 2010.
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	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 Current Report on Form 8-K filed with the Commission on June 17, 2015.
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 Quarterly Report on Form 10-Q filed with the Commission on August 8, 2013.
12	Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Commission on March 5, 2015.
13	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.

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 12, 2015

By: /s/ John J. Sperzel III

John J. Sperzel III

Chief Executive Officer

(Principal Executive Officer)

Date: November 12, 2015

By: /s / Richard J. Larkin

Richard J. Larkin

Chief Financial Officer

(Principal Financial and Accounting Officer)

CERTIFICATION

I, John J. Sperzel III, certify that:

1. I have reviewed this Form 10-Q of Chembio Diagnostics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2015

/s/ John J. Sperzel III

John J. Sperzel III, Chief Executive Officer

CERTIFICATION

I, Richard J. Larkin, certify that:

1. I have reviewed this Form 10-Q of Chembio Diagnostics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2015 /s/ Richard J. Larkin
Richard J. Larkin, Chief Financial Officer

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q (the "Report") of Chembio Diagnostics, Inc. (the "Company") for the quarter ended September 30, 2015, each of the undersigned John J. Sperzel III, the Chief Executive Officer of the Company, and Richard J. Larkin, the Chief Financial Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of the undersigneds' knowledge and belief:

(1) This Form 10-Q for the quarter ended September 30, 2015 fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this Form 10-Q for the quarter ended September 30, 2015 fairly presents, in all material respects, the financial condition and results of operations of Chembio Diagnostics, Inc. for the periods presented therein.

Dated: November 12, 2015 /s/ John J. Sperzel III
John J. Sperzel III
Chief Executive Officer

Dated: November 12, 2015 /s/ Richard J. Larkin
Richard J. Larkin
Chief Financial Officer