

CHEMBIO DIAGNOSTICS, INC.  
Form 10-Q  
August 06, 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 June 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

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)

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

As of August 3, 2015, the Registrant had 9,628,248 shares outstanding of its \$.01 par value common stock.

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Quarterly Report on FORM 10-Q  
For The Quarterly Period Ended  
June 30, 2015

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## PART I

## Item 1. FINANCIAL STATEMENTS

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

## - ASSETS -

	June 30, 2015 (Unaudited)	December 31, 2014
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$1,564,071	\$4,614,538
Accounts receivable, net of allowance for doubtful accounts of \$52,000 at June 30, 2015 and December 31, 2014, respectively	8,867,531	8,338,889
Inventories	3,781,704	3,638,299
Prepaid expenses and other current assets	1,521,238	1,066,473
<b>TOTAL CURRENT ASSETS</b>	<b>15,734,544</b>	<b>17,658,199</b>
FIXED ASSETS, net of accumulated depreciation	2,801,025	2,797,929
<b>OTHER ASSETS:</b>		
Deferred tax asset, net of valuation allowance	4,469,015	4,031,302
License agreements, net of current portion	290,228	256,875
Deposits on manufacturing equipment	-	20,017
Deposits and other assets	227,550	245,870
<b>TOTAL ASSETS</b>	<b>\$23,522,362</b>	<b>\$25,010,192</b>
<b>- LIABILITIES AND STOCKHOLDERS' EQUITY -</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$4,717,834	\$4,946,030
Deferred revenue	195,677	340,000
<b>TOTAL LIABILITIES</b>	<b>4,913,511</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; 9,628,248 and 9,611,139 shares issued and outstanding for June 30, 2015 and December 31, 2014, respectively	96,283	96,112
Additional paid-in capital	47,751,846	47,556,426
Accumulated deficit	(29,239,278)	(27,928,376)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>18,608,851</b>	<b>19,724,162</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$23,522,362</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		For the six months ended	
	June 30, 2015	June 30, 2014	June 30, 2015	June 30, 2014
<b>REVENUES:</b>				
Net product sales	\$6,321,554	\$7,248,470	\$11,936,239	\$12,152,635
License and royalty revenue	7,882	6,971	14,933	7,131
R&D, milestone and grant revenue	386,722	167,156	996,123	1,075,904
<b>TOTAL REVENUES</b>	<b>6,716,158</b>	<b>7,422,597</b>	<b>12,947,295</b>	<b>13,235,670</b>
Cost of product sales	3,697,026	4,440,046	7,241,545	7,980,508
<b>GROSS MARGIN</b>	<b>3,019,132</b>	<b>2,982,551</b>	<b>5,705,750</b>	<b>5,255,162</b>
<b>OPERATING EXPENSES:</b>				
Research and development expenses	1,757,007	1,268,653	3,341,543	2,466,275
Selling, general and administrative expenses	2,160,096	1,946,763	4,137,670	3,404,491
	3,917,103	3,215,416	7,479,213	5,870,766
<b>LOSS FROM OPERATIONS</b>	<b>(897,971 )</b>	<b>(232,865 )</b>	<b>(1,773,463 )</b>	<b>(615,604 )</b>
<b>OTHER INCOME (LOSS):</b>				
Loss on sale of fixed asset	-	(5,707 )	-	(5,707 )
Interest income	316	1,561	1,491	3,391
	316	(4,146 )	1,491	(2,316 )
<b>LOSS BEFORE INCOME TAXES</b>	<b>(897,655 )</b>	<b>(237,011 )</b>	<b>(1,771,972 )</b>	<b>(617,920 )</b>
Income tax benefit	(233,570 )	(91,030 )	(461,070 )	(247,200 )
<b>NET LOSS</b>	<b>\$(664,085 )</b>	<b>\$(145,981 )</b>	<b>\$(1,310,902 )</b>	<b>\$(370,720 )</b>
Basic loss per share	\$(0.07 )	\$(0.02 )	\$(0.14 )	\$(0.04 )
Diluted loss per share	\$(0.07 )	\$(0.02 )	\$(0.14 )	\$(0.04 )
Weighted average number of shares outstanding, basic	9,627,951	9,555,944	9,623,773	9,448,160
Weighted average number of shares outstanding, diluted	9,627,951	9,555,944	9,623,773	9,448,160

See accompanying notes to condensed consolidated financial statements

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

	June 30, 2015	June 30, 2014
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Cash received from customers and grants	\$12,274,330	\$12,404,373
Cash paid to suppliers and employees	(14,441,822)	(14,943,293)
Interest received	1,491	3,391
Net cash used in operating activities	(2,166,001 )	(2,535,529 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of License	(450,000 )	-
Acquisition of and deposits on fixed assets	(434,466 )	(516,869 )
Net cash used in investing activities	(884,466 )	(516,869 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from option exercises	-	237,180
Net cash provided by financing activities	-	237,180
<b>DECREASE IN CASH AND CASH EQUIVALENTS</b>		
Cash and cash equivalents - beginning of the period	(3,050,467 )	(2,815,218 )
Cash and cash equivalents - end of the period	4,614,538	9,650,275
	\$1,564,071	\$6,835,057
<b>RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:</b>		
Net Loss	\$(1,310,902 )	\$(370,720 )
Adjustments:		
Depreciation and amortization	665,672	343,799
Deferred taxes	(461,070 )	(225,800 )
Share based compensation	195,591	217,626
Changes in assets and liabilities:		
Accounts receivable	(528,642 )	(831,297 )
Inventories	(143,405 )	(890,480 )
Prepaid expenses and other current assets	(234,083 )	(45,025 )
Deposits and other assets	-	(220,014 )
Accounts payable and accrued liabilities	(204,839 )	(513,618 )
Customer deposits and deferred revenue	(144,323 )	-
Net cash used in operating activities	\$(2,166,001 )	\$(2,535,529 )
<b>Supplemental disclosures for non-cash investing and financing activities:</b>		
Deposits on manufacturing equipment transferred to fixed assets	\$20,017	\$59,798

See accompanying notes to condensed consolidated financial statements



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

June 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 43 % of the Company's product revenues in the first six months of 2015. The Company's products based on its DPP® platform represented approximately 54 % of the Company's product revenues in the first six months of 2015. The Company also has other rapid tests and components that together represented approximately 3 % of sales in the first six 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 June 30, 2015 and for the three and six-month periods ended June 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 June 30, 2015, its condensed consolidated results of operations for the three and six-month periods ended June 30, 2015 and 2014, respectively, and its condensed consolidated cash flows for the six-month periods ended June 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 million in cash for the six months ended June 30, 2015. The Company has the ability to borrow up to \$2 million on its HSBC Demand Note, if necessary. Approximately \$7.4 million of the total \$8.9 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.





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

June 30, 2015

(UNAUDITED)

b) Revenue Recognition

The Company recognizes revenue for product sales in accordance with ASC 605, which provides that revenue is recognized when there is persuasive evidence of an arrangement, delivery has occurred or services have been rendered, the sales price is determinable, and collectability is reasonably assured. Revenue typically is recognized at time of shipment. Sales are recorded net of discounts, rebates and returns.

For certain contracts, the Company recognizes revenue from non-milestone 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 \$196,000 and \$340,000 as of June 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:

	June 30, 2015	December 31, 2014
Raw materials	\$2,153,595	\$2,323,863
Work in process	425,699	346,494
Finished goods	1,202,410	967,942
	\$3,781,704	\$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- and six-month periods ended June 30, 2015 and 2014, have been included in the earnings per share computations:

	For the three months ended		For the six months ended	
	June 30, 2015	June 30, 2014	June 30, 2015	June 30, 2014
Basic	9,627,951	9,555,944	9,623,773	9,448,160
Diluted	9,627,951	9,555,944	9,623,773	9,448,160

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

There were 651,768 and 737,183 weighted-average number of options outstanding as of June 30, 2015 and 2014, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended June 30, 2015 and 2014, respectively. There were 667,082 and 858,769 weighted-average number of options outstanding as of June 30, 2015 and 2014, respectively, that were not included in the calculation of diluted per common share equivalent for the six months ended June 30, 2015 and 2014, respectively, because the effect would have been anti-dilutive as of June 30, 2015 and 2014, respectively.

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

June 30, 2015

(UNAUDITED)

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 June 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 June 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 six months ended June 30, 2015. The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the six-month period ended June 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 June 30, 2015	June 30, 2014	For the six months ended June 30, 2015	June 30, 2014
Expected term (in years)	n/a	4.5	n/a	5.8	
Expected volatility	n/a	61.50%	n/a	61.50 % - 86.67%	
Expected dividend yield	n/a	0%	n/a	0 %	
Risk-free interest rate	n/a	0.83%	n/a	0.83 % - 1.33%	

The Company's results for the three-month periods ended June 30, 2015 and 2014 include share-based compensation expense, consisting solely of stock options, totaling \$86,300 and \$148,300, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$- and \$200, respectively), research and development (\$14,800 and \$9,400, respectively) and selling, general and administrative expenses (\$71,500 and \$138,700, respectively). The results for the six-month periods ended June 30, 2015 and 2014 include share-based compensation expense, consisting solely of stock options, totaling \$195,600 and \$217,700, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$- and \$700, respectively), research and development (\$33,000 and \$27,700, respectively) and selling, general and administrative expenses (\$162,600 and \$189,300, 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**

**June 30, 2015**

(UNAUDITED)

Stock option compensation expense for the three and six-month periods ended June 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 six months ended June 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 June 30, 2015	650,728	\$ 3.75	3.70 years	\$ 784,191
Exercisable at June 30, 2015	305,728	\$ 3.87	2.57 years	\$ 339,771

As of June 30, 2015, there was \$435,000 of net unrecognized compensation cost related to stock options that have not vested, which is expected to be recognized over a weighted average period of approximately 2.24 years. The total fair value of stock options vested during the six-month periods ended June 30, 2015 and 2014 was approximately \$215,000 and \$165,000, respectively.

f) Geographic Information:

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

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

	For the three months ended		For the six months ended	
	June 30, 2015	June 30, 2014	June 30, 2015	June 30, 2014
Africa	\$ 1,131,684	\$ 418,343	\$ 2,707,738	\$ 1,249,805
Asia	59,340	23,711	110,153	74,757
Europe	157,689	34,966	222,835	71,025
North America	1,071,216	2,769,529	2,385,767	6,532,678
South America	3,901,625	4,001,921	6,509,746	4,224,370
	\$ 6,321,554	\$ 7,248,470	\$ 11,936,239	\$ 12,152,635



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

June 30, 2015

(UNAUDITED)

g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

	June 30, 2015	December 31, 2014
Accounts payable – suppliers	\$ 1,432,228	\$ 1,980,120
Accrued commissions	906,342	947,451
Accrued royalties / license fees	1,051,169	1,034,062
Accrued payroll	322,317	106,487
Accrued vacation	289,693	219,924
Accrued bonuses	355,400	265,500
Accrued expenses – other	360,685	392,486
TOTAL	\$4,717,834	\$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 six-month periods ended June 30, 2015 and 2014, respectively from this agreement. The Company earned \$1,253,000 from this



grant from inception through June 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

June 30, 2015

(UNAUDITED)

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 six-month periods ended June 30, 2015 and 2014, respectively from this agreement. The Company earned \$1,125,000 from this grant from inception through June 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 \$140,000 and \$0 for the six-month periods ended June 30, 2015 and 2014, respectively from this agreement. The Company earned \$200,000 from this grant from inception through June 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 \$252,500 and \$0 for the six-month periods ended June 30, 2015 and 2014, respectively from this agreement. The Company earned \$252,500 from this grant from inception through June 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 \$258,900 and \$0 for the six-month periods ended June 30, 2015 and 2014, respectively from this agreement. The Company earned \$258,900 from this grant from inception through June 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 \$75,000 and \$0 for the six-month periods ended June 30, 2015 and 2014, respectively from this agreement. The Company earned \$75,000 from this grant from inception through June 30, 2015.

NOTE4 — 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 June 30, 2015, no amount was outstanding on the Demand Note.

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

June 30, 2015

(UNAUDITED)

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. Sperzel'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**

**June 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 six months ended				Accounts Receivable as of	
	June 30, 2015		June 30, 2014		June 30, 2015		June 30, 2014		June 30, 2015	June 30, 2014
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales		
Customer 1	\$3,882,161	61	\$3,964,903	55	\$6,344,032	53	\$4,166,801	34	\$7,362,622	\$3,137,726
Customer 2	658,311	10	1,412,461	19	1,725,300	14	4,165,432	34	307,125	538,934
Customer 3	*	*	*	*	1,750,722	15	*	*	114,999	*
Customer 4	*	*	1,215,872	17	*	*	2,217,242	18	*	689,250

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

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

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

	For the three months ended				For the six months ended				Accounts Receivable as of	
	June 30, 2015		June 30, 2014		June 30, 2015		June 30, 2014		June 30, 2015	June 30, 2014
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	\$332,273	17	\$341,534	13	\$486,583	13	\$622,220	14	\$147,795	\$90,469
Vendor 2	*	*	496,167	18	*	*	731,061	17	*	-

(\* ) Purchases did not exceed 10% for the period indicated

The Company currently buys materials which are purchased under intellectual property rights agreements and are important components in its products. Management believes that other suppliers could provide similar materials on comparable terms 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

June 30, 2015

(UNAUDITED)

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 six months ended June 30, 2015 was a benefit of 26.0%. The calculated benefit of \$(461,070) increased the carrying value of the deferred tax asset for the six months ended June 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 six months ended June 30, 2015 decreased to \$996,000 from \$1,076,000 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. 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 six months ended June 30, 2015 were \$3.34 million, compared with \$2.47 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.

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### 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 third 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 a DPP® Febrile Illness Assay, including an assay for 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 third 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 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.

DPP® Malaria POC Rapid Assay: We were 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 test 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 & Melinda 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 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 under development for the US market. This version is designed to meet the performance requirements for the "reverse" algorithm that is currently in clinical use in the United States for syphilis testing. We are completing our pre-clinical work for this product, and have initiated activities for U.S. clinical site selection.

**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 continue to pursue an FDA submission for a version of this product under development to meet the requirement of the "reverse" algorithm used in the USA to diagnose Syphilis, and are completing our pre-clinical work, including clinical site selection for the U.S. clinical trial with our DPP® HIV-Syphilis Assay.

In June 2015, a discussion with the World Health Organization (WHO) was held regarding the study design and methodology applied by the WHO laboratory, specifically with respect to the sample selection used to evaluate the DPP HIV-Syphilis Assay, which resulted in termination of the prequalification application. The Company continues to plan to pursue the CE Mark application, and in the future will determine whether to resubmit a prequalification application to WHO.

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

Income:

For the three months ended June 30, 2015, Loss before income taxes was \$(898,000) compared to \$(233,000) for the three months ended June 30, 2014. Net Loss for the 2015 period was \$(664,000) as compared to \$(146,000) for 2014. The increase in Net Loss is primarily attributable to increased operating expenses of \$702,000, partially offset by increased gross margin. Gross margin increased in the three months ended June 30, 2015, as compared with the three months ended June 30, 2014, by \$37,000, or 1.2%.

Revenues:

Selected Product Categories:	For the three months ended			
	June 30, 2015	June 30, 2014	\$ Change	% Change
Lateral Flow HIV Tests and Components	\$2,226,094	\$1,886,909	\$ 339,185	17.98 %
DPP® Tests and Components	3,980,726	5,167,025	(1,186,299)	-22.96 %
Other	114,734	194,536	(79,802)	-41.02 %
Net Product Sales	6,321,554	7,248,470	(926,916)	-12.79 %
License and royalty revenue	7,882	6,971	911	13.07 %
R&D, milestone and grant revenue	386,722	167,156	219,566	131.35 %
Total Revenues	\$6,716,158	\$7,422,597	\$ (706,439)	-9.52 %

Revenues for our lateral flow HIV tests and related components during the three months ended June 30, 2015 increased by approximately \$339,000 from the same period in 2014. This was primarily attributable to increased sales to Africa, of approximately \$713,000, partially offset by decreased sales to North America, of approximately \$436,000. Revenues for our DPP® products during the three months ended June 30, 2015 decreased by approximately \$1,186,000 over the same period in 2014, primarily due to decreased sales in Mexico. 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			
	June 30, 2015	June 30, 2014	\$ Change	% Change
Gross Margin per Statement of Operations	\$3,019,132	\$2,982,551	\$ 36,581	1.23 %
Less: R&D, milestone, grant, license and royalty revenues	394,604	174,127	220,477	126.62 %
Gross Margin from Net Product Sales	\$2,624,528	\$2,808,424	\$ (183,896)	-6.55 %
Product Gross Margin %	41.52 %	38.75 %		

The overall gross margin dollar increase of \$37,000 included a \$184,000 decrease in gross margin from product sales and a \$220,000 increase in non-product revenues. The decrease in net product sales gross margin of \$184,000 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 \$927,000, which, at the 38.75% margin percentage for June 30, 2014 contributed \$359,000 to the decrease, and the

other is the increased change in margin percentage of 2.8%, which contributed \$175,000 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			
	June 30, 2015	June 30, 2014	\$ Change	% Change
<b>Clinical and Regulatory Affairs:</b>				
Wages and related costs	\$ 131,290	\$ 106,546	\$ 24,744	23.22 %
Consulting	14,104	22,089	(7,985 )	-36.15 %
Stock-based compensation	-	806	(806 )	-100.00 %
Clinical trials	244,110	29,712	214,398	721.59 %
Other	20,163	21,514	(1,351 )	-6.28 %
Total Regulatory	409,667	180,667	229,000	126.75 %
<b>R&amp;D Other than Regulatory:</b>				
Wages and related costs	745,996	614,897	131,099	21.32 %
Consulting	28,110	68,801	(40,691 )	-59.14 %
Stock-based compensation	14,834	8,631	6,203	71.87 %
Materials and supplies	417,756	288,438	129,318	44.83 %
Other	140,644	107,219	33,425	31.17 %
Total other than Regulatory	1,347,340	1,087,986	259,354	23.84 %

Total Research and Development \$ 1,757,007 \$ 1,268,653 \$ 488,354 38.49 %

Expenses for Clinical & Regulatory Affairs for the three months ended June 30, 2015 increased by \$229,000 as compared to the same period in 2014. The increase is primarily due to the increase in clinical trials of \$214,000.

R&D expenses other than Clinical & Regulatory Affairs increased by \$259,000 in the three months ended June 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			
	June 30, 2015	June 30, 2014	\$ Change	% Change
Wages and related costs	\$ 849,002	\$ 638,377	\$ 210,625	32.99 %
Consulting	73,500	159,603	(86,103 )	-53.95 %
Commissions	468,033	481,276	(13,243 )	-2.75 %
Stock-based compensation	71,448	137,592	(66,144 )	-48.07 %
Marketing materials	71,048	41,114	29,934	72.81 %
Investor relations/investment bankers	39,965	41,277	(1,312 )	-3.18 %
Legal, accounting and compliance	209,974	83,450	126,524	151.62 %
Travel, entertainment and trade shows	122,904	111,914	10,990	9.82 %
Other	254,222	252,160	2,062	0.82 %
Total S, G & A	\$ 2,160,096	\$ 1,946,763	\$ 213,333	10.96 %

Selling, general and administrative expenses for the three months ended June 30, 2015, increased by \$213,000 as compared with the same period in 2014, an 11% increase. This increase resulted primarily from increases in staffing,

wages and related costs, travel, entertainment and trade shows, professional fees, and marketing materials, which were partially offset by decreases in consulting, stock-based compensation and commissions.

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Other Income:

	For the three months ended			
	June			
	30, 2015	June 30, 2014	\$ Change	% Change
(Loss) gain on sale of fixed asset	\$-	\$ (5,707)	\$5,707	-100.00%
Interest income	316	1,561	(1,245)	-79.76%
Total Other Income (Loss)	\$316	\$ (4,146)	\$4,462	-107.62%

Other income for the three months ended June 30, 2015 increased approximately \$4,462, to an income of \$316 from an expense of \$4,146 in the same period in 2014, as a result of a loss on the sale of an asset.

**RESULTS OF OPERATIONS FOR THE SIX MONTHS ENDED JUNE 30, 2015 AS COMPARED WITH THE SIX MONTHS ENDED JUNE 30, 2014**

Income:

For the six months ended June 30, 2015, Loss before income taxes was \$(1,773,000) compared to \$(616,000) for the six months ended June 30, 2014. Net Loss for the 2015 period was \$(1,311,000) as compared to \$(371,000) for 2014. The increase in Net Loss is primarily attributable to increased operating expenses of \$1,608,000 and decreased revenues, partially offset by increased gross margin. Gross margin increased in the six months ended June 30, 2015, as compared with the six months ended June 30, 2014, by \$451,000, or 8.6%.

Revenues:

Selected Product Categories:	For the six months ended			
	June 30, 2015	June 30, 2014	\$ Change	% Change
Lateral Flow HIV Tests and Components	\$5,116,631	\$5,423,608	\$ (306,977)	-5.66%
DPP® Tests and Components	6,443,828	6,335,795	108,033	1.71%
Other	375,780	393,232	(17,452)	-4.44%
Net Product Sales	11,936,239	12,152,635	(216,396)	-1.78%
License and royalty revenue	14,933	7,131	7,802	109.41%
R&D, milestone and grant revenue	996,123	1,075,904	(79,781)	-7.42%
Total Revenues	\$12,947,295	\$13,235,670	\$ (288,375)	-2.18%

Revenues for our lateral flow HIV tests and related components during the six months ended June 30, 2015 decreased by approximately \$307,000 from the same period in 2014. This was primarily attributable to decreased sales to North America, of approximately \$1,881,000, partially offset by increased sales to Africa, of approximately \$1,458,000. Revenues for our DPP® products during the six months ended June 30, 2015 increased by approximately \$108,000 over the same period in 2014, primarily due to increased sales in Brazil to FIOCRUZ, partially offset by decreased sales in Mexico. 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. 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 six months ended		\$ Change	% Change	
	June 30, 2015	June 30, 2014			
Gross Margin per Statement of Operations	\$5,705,750	\$5,255,162	\$450,588	8.57	%
Less: R&D, milestone, grant, license and royalty revenues	1,011,056	1,083,035	(71,979 )	-6.65	%
Gross Margin from Net Product Sales	\$4,694,694	\$4,172,127	\$522,567	12.53	%
Product Gross Margin %	39.33	% 34.33			%

The overall gross margin dollar increase of \$451,000 included a \$523,000 increase in gross margin from product sales and a \$72,000 decrease in non-product revenues. The increase in net product sales gross margin of \$523,000 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. The net product sales gross margin increase is primarily affected by two components, one is the increased change in margin percentage of 5.0%, which contributed \$597,000 to the increase in our net product sales gross margin, and the other is a decrease in product sales of \$216,000, which, at the 34.3% margin percentage for June 30, 2014 reduced the increase by \$74,000.

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 six months ended		\$ Change	% Change	
	June 30, 2015	June 30, 2014			
<b>Clinical and Regulatory Affairs:</b>					
Wages and related costs	\$253,975	\$212,689	\$41,286	19.41	%
Consulting	22,361	24,508	(2,147 )	-8.76	%
Stock-based compensation	-	3,231	(3,231 )	-100.00	%
Clinical trials	356,140	150,495	205,645	136.65	%
Other	43,165	39,758	3,407	8.57	%
Total Regulatory	675,641	430,681	244,960	56.88	%
<b>R&amp;D Other than Regulatory:</b>					
Wages and related costs	1,510,001	1,182,670	327,331	27.68	%
Consulting	38,043	113,351	(75,308 )	-66.44	%
Stock-based compensation	33,041	24,457	8,584	35.10	%
Materials and supplies	820,888	524,596	296,292	56.48	%
Other	263,929	190,520	73,409	38.53	%
Total other than Regulatory	2,665,902	2,035,594	630,308	30.96	%

Total Research and Development \$3,341,543 \$2,466,275 \$875,268 35.49 %

Expenses for Clinical & Regulatory Affairs for the six months ended June 30, 2015 increased by \$245,000 as compared to the same period in 2014. The increase is primarily due to the increase in clinical trials of \$206,000.

R&D expenses other than Clinical & Regulatory Affairs increased by \$630,000 in the six months ended June 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 six months ended			
	June 30, 2015	June 30, 2014	\$ Change	% Change
Wages and related costs	\$ 1,722,799	\$ 1,328,879	\$ 393,920	29.64 %
Consulting	115,106	263,350	(148,244)	-56.29 %
Commissions	804,905	511,711	293,194	57.30 %
Stock-based compensation	162,551	186,726	(24,175 )	-12.95 %
Marketing materials	107,371	65,100	42,271	64.93 %
Investor relations/investment bankers	84,079	88,109	(4,030 )	-4.57 %
Legal, accounting and compliance	446,910	296,430	150,480	50.76 %
Travel, entertainment and trade shows	217,663	151,462	66,201	43.71 %
Other	476,286	512,724	(36,438 )	-7.11 %
Total S, G &A	\$ 4,137,670	\$ 3,404,491	\$ 733,179	21.54 %

Selling, general and administrative expenses for the six months ended June 30, 2015, increased by \$733,000 as compared with the same period in 2014, a 21.5% 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, other expenses, and stock-based compensation.

Other Income:

	For the six months ended			
	June 30, 2015	June 30, 2014	\$ Change	% Change
(Loss) gain on sale of fixed asset	\$-	\$ (5,707)	\$ 5,707	-100.00 %
Interest income	1,491	3,391	(1,900)	-56.03 %
Total Other Income (Loss)	\$ 1,491	\$ (2,316)	\$ 3,807	-164.38 %

Other income for the six months ended June 30, 2015 increased approximately \$3,807, to an income of \$1,491 from an expense of \$2,316 in the same period in 2014, as a result of a loss on the sale of an asset.

Income tax benefit:

For the six months ended June 30, 2015 the Company recognized a \$461,070 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

Selected Changes in Financial Condition	As of		\$ Change	% Change
	June 30, 2015	December 31, 2014		
Cash and cash equivalents	\$ 1,564,071	\$ 4,614,538	\$ (3,050,467)	-66.11 %
Accounts receivable, net of allowance for doubtful accounts of \$52,000 at June 30, 2015 and December 31, 2014, respectively	8,867,531	8,338,889	528,642	6.34 %
Prepaid expenses and other current assets	1,521,238	1,066,473	454,765	42.64 %
Deferred tax asset, net of valuation allowance	4,469,015	4,031,302	437,713	10.86 %
License agreements, net of current portion	290,228	256,875	33,353	12.98 %
Accounts payable and accrued liabilities	4,717,834	4,946,030	(228,196 )	-4.61 %
Deferred revenue	195,677	340,000	(144,323 )	-42.45 %

Cash decreased by \$3,050,000 from December 31, 2014, primarily due to net cash used in operating activities for the six months of 2015. In addition there were increases in accounts receivable of \$529,000 (primarily due to a large customer as described under "Liquidity And Capital Resources"), prepaid expenses of \$455,000 (primarily due to the acquisition of a license), deferred tax asset of \$437,700, licenses, net of current portion, of \$33,000, and deferred revenue of \$144,000. We experienced a decrease in accounts payable and accrued liabilities of \$228,000.

## LIQUIDITY AND CAPITAL RESOURCES

	For the six months ended		\$ Change	% Change
	June 30, 2015	June 30, 2014		
Net cash used in operating activities	\$ (2,166,001)	\$ (2,535,529)	\$ 369,528	-14.57 %
Net cash used in investing activities	(884,466 )	(516,869 )	(367,597)	71.12 %
Net cash provided by financing activities	-	237,180	(237,180)	-100.00 %
Decrease in cash and cash equivalents	\$ (3,050,467)	\$ (2,815,218)	\$ (235,249)	8.36 %

The Company's cash decreased as of June 30, 2015 by \$3,050,000 from December 31, 2014, primarily due to net cash used in operating activities and net cash used in investing activities for the six months of 2015.

The cash used in operations in 2015 was \$2,166,000, primarily due to an increase in accounts receivable of \$529,000, a decrease in accounts payable and accrued liabilities of \$228,000, an increase in inventories of \$143,000, an increase in prepaid assets of \$455,000, an increase in deferred revenue of \$144,000 and a net loss net of non-cash items of \$911,000. Net loss net of non-cash items includes net loss of \$1,310,000, \$461,000 in benefit for income taxes, partially offset by \$666,000 in depreciation and amortization, and \$196,000 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 \$434,000.

The Company currently has positive working capital, however, it has used approximately \$3 million in cash for the six months ended June 30, 2015. The Company has the ability to borrow up to \$2 million on its HSBC Demand Note, if necessary. Approximately \$7.4 million of the total \$8.9 million of accounts receivable is comprised from one customer and the Company has a high degree of confidence that the receivable is collectible from this customer.

## Fixed Asset Commitments

As of June 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

During the second quarter of 2015, Chembio continued to make progress toward each of its operational goals. Such advancements toward commercial, development and collaborative milestones have significantly shaped the evolution of our strategy, and in recent months, we have begun to categorize our activities into three distinct business areas: Sexually Transmitted Diseases; Fever and Tropical Diseases; and, Licensing Partnerships.

### Sexually Transmitted Diseases

Through the company's early work in HIV, Chembio first established itself as a leader in the point-of-care (POC) diagnostics marketplace. Compared to other indications, the HIV market demands unparalleled sensitivity and specificity, and Chembio's long-term success serving this patient population speaks to the company's commitment to the highest quality standards and product performance. Chembio has multiple products on the market today in the U.S. and abroad, including our HIV 1/2 STAT-PAK<sup>®</sup> Assay, the SURE CHECK<sup>®</sup> HIV 1/2 Assay, and the DPP<sup>®</sup> HIV 1/2 Assay. The company's development work in HIV continues today, and our proprietary DPP<sup>®</sup> technology allows us to significantly improve the diagnostic options available to this patient group. Specifically, DPP<sup>®</sup> allows us to test for multiple sexually transmitted diseases simultaneously with a single drop of blood. This is critical, as we are observing a rise in co-infection rates for diseases such as HIV and syphilis in the U.S. and abroad.

Chembio is actively working on multiple internal development initiatives in the sexually transmitted disease area, with our primary focus on the development of the DPP<sup>®</sup> HIV-Syphilis Assay for the U.S. market. While the company is successfully marketing an HIV-Syphilis combo assay in Latin America, regulatory standards require additional enhancements for the U.S. market. We are completing our pre-clinical work for this product and have started clinical site selection activities for the U.S. clinical trial with our DPP<sup>®</sup> HIV-Syphilis Assay. We have also discussed regulatory strategy with our EU Notified Body, and will submit the technical dossier for CE Mark, to pave the way for commercialization of the DPP<sup>®</sup> HIV-Syphilis Assay in Europe.

### Fever and Tropical Diseases

Over the last year, Chembio has partnered with a number of the world's leading healthcare organizations, including the Centers for Disease Control (CDC) and the Bill & Melinda Gates Foundation, in the quest to develop next generation diagnostics to support the eradication of serious fever and tropical diseases through early detection. All but one of these projects are funded by Chembio's partners with target diseases including Malaria, Dengue Fever and Ebola.

Chembio's DPP<sup>®</sup> technology serves as the cornerstone for each of its fever and tropical disease partnerships, and during the second quarter of 2015, we made great progress with a number of these programs. We are currently on track to provide DPP<sup>®</sup> Ultra-Sensitive Malaria Assays to the Bill & Melinda Gates Foundation in the third quarter of 2015 for laboratory verification. With our DPP<sup>®</sup> Malaria-Ebola Combo Assay, we are on track to deliver product to the CDC for field testing in West Africa in the third quarter of 2015. And, we are pleased to report that we provided DPP<sup>®</sup> Ebola Assays to the CDC in the second quarter of 2015, with field testing currently ongoing in West Africa. We also made progress with both of our DPP<sup>®</sup> Dengue Fever Assays, and we expect to begin a field study of our multi-strain assay in the third quarter of 2015.

While Chembio is committed to the success of each ongoing project, the company's priority in this segment is the development and launch of a DPP® Fever Panel that may have the ability to test for multiple diseases concurrently, with a single blood sample. We believe the company's multiple efforts in this area will ultimately prove synergistic, as fever or "febrile" illness is rapidly becoming a worldwide health concern, with many such diseases presenting with similar symptomatology. It is critical in areas that are afflicted with fever and/or tropical diseases that the appropriate diagnosis is made at the earliest possible opportunity to prevent spread. Further, for certain diseases, such as dengue fever, it is critical to diagnose the specific strain of such illness in order to optimize treatment.

With Chembio's ongoing work in a range of fever and tropical diseases, we know there is growing demand for POC diagnostics that can address multiple diseases simultaneously, and we intend to develop a DPP® Fever Disease Assay to address this serious and growing need. We further believe that there are numerous potential funding partners for a project of this scope. We look forward to reporting on our progress with this program in the coming months.

### Licensing/Partnerships

Beyond sexually transmitted disease and fever disease, the power and versatility of the DPP® platform has opened the door to a number of opportunities outside of our core business areas. Examples of these programs include our partnerships with Perseus Science for the development of a diagnostic for traumatic brain injury; the CDC and its contractor, Battelle, for a flu immunostatus diagnostic; and, an undisclosed partner for the development of a diagnostic for a specific form of cancer. In each of these cases, development work is funded by our partners, with an opportunity for Chembio to retain key commercialization rights upon success. And, as with our core business programs, we achieved important advances with each of these programs during the second quarter of 2015. Specifically, we advanced our feasibility testing of the traumatic brain injury diagnostic. We successfully completed feasibility with the cancer diagnostic, and have progressed to the product development and validation phase, which is also funded by our partner. And lastly, we successfully completed the product optimization phase of the flu immunostatus diagnostic program.

During the second quarter of 2015, Chembio made important advances in all of our internal development and collaborative programs, each of which is driven by our proprietary DPP® technology. DPP® is a unique POC technology platform that offers industry-leading sensitivity and specificity combined with the ability to test for multiple diseases simultaneously, with a single patient sample. DPP® is the foundation of our ongoing work in sexually transmitted disease and our priority internal program – the DPP® HIV-Syphilis Assay for the U.S. market. DPP® is the core asset that supports each of our fever and tropical disease partnerships and our lead project in this area—the DPP® Fever Panel Assay. And lastly, the broad applicability of DPP® allows Chembio to capture significant value beyond our core business focus in areas such as traumatic brain injury and a specific form of cancer. Chembio is aggressively pursuing each of these existing opportunities and we remain committed to leveraging the DPP® technology across every appropriate application to improve healthcare worldwide and create value for Chembio's stakeholders.

#### 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 six 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 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 (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.

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- 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 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.

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SIGNATURES

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

Chembio Diagnostics, Inc.

Date: August 6, 2015 By: /s/ John J. Sperzel III  
John J. Sperzel III  
Chief Executive Officer  
(Principal Executive Officer)

Date: August 6, 2015 By: /s / Richard J. Larkin  
Richard J. Larkin  
Chief Financial Officer  
(Principal Financial and Accounting Officer)