

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

FORM 10 - Q

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

For the quarterly period ended September 30, 2017

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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Emerging growth company ☐

Accelerated filer ☒

Smaller reporting company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Yes ☐ No ☐

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 6, 2017, the Registrant had 12,318,570 shares outstanding of its \$.01 par value common stock.

Quarterly Report on FORM 10-Q
For The Quarterly Period Ended
September 30, 2017

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

	<u>September 30, 2017</u>	<u>December 31, 2016</u>
	(Unaudited)	
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 1,871,982	\$ 10,554,464
Accounts receivable, net of allowance for doubtful accounts of \$52,000 at September 30, 2017 and December 31, 2016, respectively	5,768,920	3,383,729
Inventories, net	5,235,164	3,335,188
Prepaid expenses and other current assets	842,532	840,145
TOTAL CURRENT ASSETS	<u>13,718,598</u>	<u>18,113,526</u>
FIXED ASSETS , net of accumulated depreciation	1,964,427	1,709,321
OTHER ASSETS:		
Goodwill	1,597,617	-
Intangible assets, net	1,573,518	-
Deposits on manufacturing equipment	243,755	31,900
Deposits and other assets	146,789	720,489
TOTAL ASSETS	<u>\$ 19,244,704</u>	<u>\$ 20,575,236</u>
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 3,870,161	\$ 3,013,133
Deferred revenue	-	392,517
TOTAL CURRENT LIABILITIES	3,870,161	3,405,650
OTHER LIABILITIES:		
Deferred tax liability	335,990	-
Long-term portion of loans payable	99,480	-
TOTAL LIABILITIES	<u>4,305,631</u>	<u>3,405,650</u>
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock - 10,000,000 shares authorized; none outstanding	-	-
Common stock - \$.01 par value; 100,000,000 shares authorized; 12,318,570 and 12,026,847 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	123,185	120,268
Additional paid-in capital	62,733,065	60,721,783
Accumulated other comprehensive income	128,616	-
Accumulated deficit	(48,045,793)	(43,672,465)
TOTAL STOCKHOLDERS' EQUITY	<u>14,939,073</u>	<u>17,169,586</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 19,244,704</u>	<u>\$ 20,575,236</u>

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

	For the three months ended		For the nine months ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
REVENUES:				
Net product sales	\$ 6,132,725	\$ 2,502,097	\$ 14,453,097	\$ 10,453,188
License and royalty revenue	150,000	77,754	477,631	133,850
R&D, milestone and grant revenue	1,304,649	1,166,610	3,096,626	3,026,927
TOTAL REVENUES	7,587,374	3,746,461	18,027,354	13,613,965
Cost of product sales	4,064,791	1,794,364	9,487,848	6,916,015
GROSS MARGIN	3,522,583	1,952,097	8,539,506	6,697,950
OPERATING EXPENSES:				
Research and development expenses	1,805,738	2,263,719	6,034,735	6,265,483
Selling, general and administrative expenses	2,305,358	1,832,451	6,903,055	5,430,668
	4,111,096	4,096,170	12,937,790	11,696,151
LOSS FROM OPERATIONS	(588,513)	(2,144,073)	(4,398,284)	(4,998,201)
OTHER INCOME:				
Interest income	3,852	5,855	24,956	9,729
	3,852	5,855	24,956	9,729
LOSS BEFORE INCOME TAXES	(584,661)	(2,138,218)	(4,373,328)	(4,988,472)
Income tax provision	-	-	-	5,800,818
NET LOSS	\$ (584,661)	\$ (2,138,218)	\$ (4,373,328)	\$ (10,789,290)
Foreign currency translation adjustments	4,375	-	128,616	-
Comprehensive loss	\$ (580,286)	\$ (2,138,218)	\$ (4,244,712)	\$ (10,789,290)
Basic loss per share	\$ (0.05)	\$ (0.19)	\$ (0.36)	\$ (1.06)
Diluted loss per share	\$ (0.05)	\$ (0.19)	\$ (0.36)	\$ (1.06)
Weighted average number of shares outstanding, basic	12,311,098	11,142,090	12,293,781	10,150,737
Weighted average number of shares outstanding, diluted	12,311,098	11,142,090	12,293,781	10,150,737

See accompanying notes to condensed consolidated financial statements

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

	<u>September 30, 2017</u>	<u>September 30, 2016</u>
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	\$ 15,249,646	\$ 11,928,304
Cash paid to suppliers and employees	(22,451,537)	(17,614,106)
Interest received	24,956	9,729
Net cash used in operating activities	<u>(7,176,935)</u>	<u>(5,676,073)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Payment for net assets of business acquired	(850,000)	-
Acquisition of and deposits on fixed assets	(789,827)	(79,877)
Net cash used in investing activities	<u>(1,639,827)</u>	<u>(79,877)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option exercises	34,800	57,575
Proceeds from equipment loan	99,480	-
Proceeds from sale of common stock, net	-	12,493,398
Net cash provided by financing activities	<u>134,280</u>	<u>12,550,973</u>
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(8,682,482)	6,795,023
Cash and cash equivalents - beginning of the period	<u>10,554,464</u>	<u>5,376,931</u>
Cash and cash equivalents - end of the period	<u><u>\$ 1,871,982</u></u>	<u><u>\$ 12,171,954</u></u>
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES		
Net Loss	\$ (4,373,328)	\$ (10,789,290)
Adjustments:		
Depreciation and amortization	1,011,349	876,103
Deferred taxes	-	5,800,818
Share based compensation	296,674	220,274
Changes in assets and liabilities:		
Accounts receivable	(2,385,191)	(1,785,261)
Inventories	(1,899,976)	150,867
Prepaid expenses and other current assets	(114,887)	(37,626)
Deposits and other assets	23,262	1,481
Accounts payable and accrued liabilities	657,679	(213,039)
Deferred revenue	(392,517)	99,600
Net cash used in operating activities	<u><u>\$ (7,176,935)</u></u>	<u><u>\$ (5,676,073)</u></u>
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	\$ 210,472	\$ 49,590
Accrual of contingent earn-out	148,000	-
Issuance of common stock for net assets of business acquired	1,682,725	-

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2017
(UNAUDITED)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. (the "Company" or "Chembio") and its wholly-owned subsidiaries, Chembio Diagnostic Systems Inc., and Chembio Diagnostics Malaysia Sdn Bhd ("CDM"), (formerly known as RVR Diagnostics Sdn Bhd), 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 38% of the Company's product revenues in the first nine months of 2017. The Company's products based on its DPP® platform represented approximately 48% of the Company's product revenues in the first nine months of 2017. The Company also has other rapid tests and components that together represented approximately 14% of product sales in the first nine months of 2017. 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 — ACQUISITION OF RVR DIAGNOSTICS SDN BHD NOW KNOWN AS CHEMBIO DIAGNOSTICS MALAYSIA SDN BHD:

On January 9, 2017, pursuant to a stock purchase agreement (the "Stock Purchase Agreement"), the Company acquired all of the outstanding common stock of RVR Diagnostics Sdn Bhd, a Malaysia corporation ("RVR"), for \$3,231,000, utilizing some of the proceeds from the funds raised by the Company in August 2016, the issuance of Chembio's common stock, and a contingent consideration, as described below, related to RVR reaching a milestone based on revenues that was valued at \$148,000. RVR, which subsequently changed its name to Chembio Diagnostics Malaysia Sdn Bhd ("CDM"), is a privately-held Malaysia based manufacturing company focused on assembly and sales of rapid medical assays. The Company acquired CDM to have a better presence in Asia, access to lower cost, shorter approval time of in-country regulatory approvals, and a lower cost assembly operation.

Pursuant to the Stock Purchase Agreement, the Company acquired all of the issued and outstanding common stock and other equity interests of CDM for (i) a cash payment of \$1,400,000, of which \$550,000 was paid as a deposit in December 2016 and (ii) 269,236 shares of Chembio's common stock, with a value at closing of \$1,683,000, of which 7,277 shares are being held back to satisfy certain potential claims under the Stock Purchase Agreement and will become issuable to the sellers, if at all, on the one-year anniversary of the closing.

In addition, the Stock Purchase Agreement provides that the sellers may become entitled to receive certain milestone payments based on the achievement of performance goals related to sales by CDM during the 12 months ending December 31, 2017. CDM's actual sales during that period will be used to determine the "Milestone Proration Amount," which is a fraction that (i) the numerator of which is the positive amount, if any, by which actual sales for calendar year 2017 are greater than \$2,250,000, up to a maximum overage of \$250,000, and (ii) the denominator of which is \$250,000. Based on the actual sales achieved by CDM, the Sellers will be entitled to receive (i) a cash milestone payment equal to \$100,000 multiplied by the Milestone Proration Amount, for a maximum cash milestone payment of \$100,000, and (ii) a stock milestone payment equal to 21,830 shares of Chembio common stock multiplied by the Milestone Proration Amount, with a maximum stock milestone payment of 21,830 shares of Chembio common stock. As of March 31, 2017 the Company had accrued \$148,000 for the milestone. This amount is the estimated value of the common stock of \$85,000 based on the assumption of reaching the milestone of 74.5% and discounted by 15%, as well as the cash portion of the milestone payment valued at \$63,000. There was no change in the fair value of this contingent milestone payment through September 30, 2017.

As a result of the consideration paid exceeding the preliminary fair value of the net assets acquired, goodwill in the amount of \$1,503,361 was recorded in connection with this acquisition, none of which will be deductible for tax purposes. In addition, the Company recorded \$1,800,000 in intangible assets, which results largely from the addition of CDM's intellectual property, customer base and distribution channels, trade names, order backlog, industry reputation, and management talent and workforce. Our Condensed Consolidated Statements of Operations for the nine months ended September 30, 2017 include \$25,000 of transaction costs related to the CDM acquisition, which are reflected as general and administrative expenses.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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(UNAUDITED)

The acquisition was accounted for using the purchase method of accounting. The following table summarizes the preliminary allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed on the closing date of January 9, 2017:

	PRELIMINARY
Property, plant and equipment	\$ 235,141
Goodwill	1,503,361
Deferred tax liability	(307,636)
Other intangible assets (estimated useful life):	
Intellectual property (approximate 10 year weighted average)	800,000
Customer contracts / relationships (approximate 10 year weighted average)	700,000
Order backlog (3 months)	200,134
Trade names (approximate 11 year weighted average)	100,000
Total consideration *	\$ 3,231,000

* Total consideration includes the \$1,400,000 paid in cash, \$1,683,000 in shares of common stock and \$148,000 in contingent consideration.

The Company calculated the fair value of the fixed assets based on the net book value of CDM as that approximates fair value. The intellectual property, customer contracts and trade names were based on assumption by discounted cash flow using management estimates. The order backlog was based on an order that CDM had at the closing, which was shipped in the first quarter of 2017, and valued at an estimated net income.

As indicated, the allocation of the purchase price and estimated useful lives of property, plant and equipment, intangible assets and deferred tax liability shown above is preliminary, pending final completion of valuations. Upon completion of this analysis, an adjustment may be required.

For the period from January 10, 2017 to September 30, 2017, net sales and loss before income taxes from the acquisition was approximately \$1,489,500 and \$438,000, respectively, which have been included in the Condensed Consolidated Statement of Operations for the nine months ended September 30, 2017. The following represents unaudited pro forma operating results as if the operations of CDM had been included in the Company's Condensed Consolidated Statements of Operations as of January 1, 2016:

Proforma table	For the nine months ended September 30, 2016
Total revenues	\$ 14,782,544
Net loss	\$ (10,508,280)
Net loss per common share	\$ (1.06)
Diluted net loss per common share	\$ (1.06)

The pro forma financial information includes business combination accounting effects from the acquisition including amortization charges from acquired intangible assets of approximately \$339,000. The unaudited pro forma information as presented above is for informational purposes only and is not indicative of the results of operations that would have been achieved if the acquisition had taken place at the beginning of fiscal 2016.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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(UNAUDITED)

NOTE 3 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

a) *Basis of Presentation:*

The preceding (a) condensed consolidated balance sheet as of December 31, 2016, which has been derived from audited financial statements, and (b) the unaudited interim condensed consolidated financial statements as of September 30, 2017 and for the three and nine-month periods ended September 30, 2017 and 2016, 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, 2016, 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, 2017, its condensed consolidated results of operations for the three and nine-month periods ended September 30, 2017 and 2016, respectively, and its condensed consolidated cash flows for the nine-month periods ended September 30, 2017 and 2016, 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.

Going Concern

A fundamental principle of the preparation of financial statements in accordance with accounting principles generally accepted in the United States of America ("GAAP") is the assumption that an entity will continue in existence as a going concern, which contemplates continuity of operations and the realization of assets and settlement of liabilities occurring in the ordinary course of business. This principle is applicable to all entities except for entities in liquidation or entities for which liquidation appears imminent. In accordance with this requirement, the Company has prepared its consolidated financial statements on a going concern basis.

The Company has incurred significant operating losses in the previous three years as well as negative cash flow from operations. The Company currently has a working capital surplus of \$9.8 million. The Company's ability to continue as a going concern depends on its ability to execute its business plan, increase revenue and billings and reduce expenditures. During 2017, the Company began to focus on aligning its expense structure with revenue expectations which included tighter expense controls and overall operational efficiencies which better align the Company's current business plan on a run-rate basis. In addition, the Company recently increased its inventory in anticipation of orders which to date have not materialized and the plan includes reducing inventory levels to provide additional cash to fund operations. Another focus is on the Company's receivable balance which also increased over the nine months, partially due to increased product sales, and we are focusing on reducing days outstanding.

The Company also has an ATM (At-The-Market) in place, of over twenty million dollars, and anticipates the ability to raise additional funding if needed through this vehicle. In addition, the Company may be able to raise additional funds through a private offering. With these options available and the steps outlined above, the Company expects it will be able continue as a going concern into and beyond 2018. However, there can be no assurance that the Company will be able to obtain financing or that such financing will be on favorable terms. Any such financing would be dilutive to shareholders. Failure to generate sufficient revenue, control or further reduce expenditures and/or the inability to obtain financing will result in an inability of the Company to continue as a going concern.

Fair Value of Financial Instruments

The carrying value for cash and cash equivalents, accounts receivable and accounts payable, approximate fair value because of the immediate or short-term maturity of these financial instruments.

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 SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2017
(UNAUDITED)

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. Deferred revenues not earned were \$- and \$392,517 as of September 30, 2017 and December 31, 2016, 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, 2017	December 31, 2016
Raw materials	\$ 2,339,615	\$ 1,824,248
Work in process	413,800	535,320
Finished goods	2,481,749	975,620
	<u>\$ 5,235,164</u>	<u>\$ 3,335,188</u>

Inventories are stated net of reserves of approximately \$245,000 as of September 30, 2017 and December 31, 2016.

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, 2017 and 2016, have been included in the earnings per share computations:

	For the three months ended		For the nine months ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Basic	12,311,098	11,142,090	12,293,781	10,150,737
Diluted	12,311,098	11,142,090	12,293,781	10,150,737

As there were losses for the three and nine months ended September 30, 2017 and 2016, no common share equivalents are included in the diluted per share computations.

There were 699,663 and 614,949 weighted-average number of options outstanding as of September 30, 2017 and 2016, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended September 30, 2017 and 2016 respectively, because the effect would have been anti-dilutive. There were 668,510 and 677,050 weighted-average number of options outstanding as of September 30, 2017 and 2016, respectively, that were not included in the calculation of diluted per common share equivalent for the nine months ended September 30, 2017 and 2016, respectively, because the effect would have been anti-dilutive.

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, 2017, there were 228,177 options outstanding under the SIP, with 480,172 options previously having been exercised.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2017
(UNAUDITED)

Effective June 19, 2014, the Company's stockholders voted to approve the 2014 Stock Incentive Plan ("2014-SIP"), with 800,000 shares of Common Stock available to be issued. Under the terms of the 2014-SIP, the Compensation Committee of the Company's Board has the discretion to select the persons to whom awards are to be granted and the number of shares of common stock to be covered by each grant. Awards can be incentive stock options, restricted stock and/or restricted stock units. The awards become vested at such times and under such conditions as determined by the Compensation Committee at the time of the initial stock option grant. As of September 30, 2017, there were 22,000 options exercised, 250,625 options outstanding and 527,375 options or shares still available to be issued under the 2014-SIP.

There were 142,875 and 106,875 stock options granted during the nine months ended September 30, 2017 and 2016, respectively. The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the nine months ended September 30, 2017 and September 30, 2016, was \$2.22 and \$2.77 per share, respectively. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon the historical volatility of our stock. The expected term is based on historical information.

The assumptions made in calculating the fair values of options granted during the periods indicated are as follows:

	For the three months ended		For the nine months ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Expected term (in years)	4.5	n/a	4.8	4.8
Expected volatility	41.22%	n/a	43.01%	46.18%
Expected dividend yield	0%	n/a	0%	0%
Risk-free interest rate	1.48%	n/a	1.54%	0.93%

The Company's results for the three-month periods ended September 30, 2017 and 2016 include share-based compensation expense, consisting solely of stock options, totaling \$87,100 and \$74,100, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of product sales (\$12,800 and none), research and development (\$12,100 and \$27,300, respectively) and selling, general and administrative expenses (\$62,200 and \$46,800, respectively). The results for the nine-month periods ended September 30, 2017 and 2016 include share-based compensation expense, consisting solely of stock options, totaling approximately \$296,700 and \$220,300, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of product sales (\$34,200 and none), research and development (\$77,300 and \$62,000, respectively) and selling, general and administrative expenses (\$185,200 and \$158,300, respectively). An operating expense, resulting in income tax benefit, has been recognized in the statement of operations for share-based compensation arrangements.

Stock option compensation expense for the three and nine months ended September 30, 2017 and 2016 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, 2017:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2016	600,549	\$ 4.55	3.43 years	\$ 1,463,052
Granted	142,875	5.84		
Exercised	56,969	4.19		
Forfeited/expired/cancelled	785	5.56		
Outstanding at September 30, 2017	685,670	\$ 4.84	3.35 years	\$ 1,092,813
Exercisable at September 30, 2017	347,295	\$ 4.34	2.85 years	\$ 693,550

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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As of September 30, 2017, there was \$387,192 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 2.34 years. The total fair value of stock options vested during the nine-month periods ended September 30, 2017 and 2016 was \$323,113 and \$237,095, 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 table below represents product revenues for different geographic regions.

	For the three months ended		For the nine months ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Africa	\$ 965,606	\$ 577,108	\$ 1,797,285	\$ 1,686,327
Asia	93,101	34,116	1,637,065	187,105
Europe	401,730	313,664	1,441,890	642,427
North America	1,115,473	903,327	2,874,934	3,953,469
South America	3,556,815	673,882	6,701,923	3,983,860
	\$ 6,132,725	\$ 2,502,097	\$ 14,453,097	\$ 10,453,188

g) Accounts Payable and Accrued Liabilities:

Accounts payable and accrued liabilities consist of:

	September 30, 2017	December 31, 2016
Accounts payable – suppliers	\$ 2,352,192	\$ 1,437,290
Accrued commissions	339,380	221,982
Accrued royalties / license fees	219,505	352,660
Accrued payroll	248,563	167,575
Accrued vacation	313,490	289,587
Accrued bonuses	-	282,500
Accrued expenses – other	397,031	261,539
TOTAL	\$ 3,870,161	\$ 3,013,133

h) Goodwill and Intangible Assets:

Goodwill represents the excess of the purchase price we paid over the fair value of the net tangible and identifiable intangible assets acquired in our acquisition of CDM in January 2017. Goodwill is not amortized but rather is tested annually for impairment or more frequently if we believe that indicators of impairment exist. Current U.S. generally accepted accounting principles permit us to make a qualitative evaluation about the likelihood of goodwill impairment. If we conclude that it is more likely than not that the fair value of a reporting unit is greater than its carrying amount, then we would not be required to perform the two-step quantitative impairment test. Otherwise, performing the two-step impairment test is necessary. The first step of the two-step quantitative impairment test involves comparing the fair values of the applicable reporting unit with its aggregate carrying value, including goodwill. If the carrying value of a reporting unit exceeds the reporting unit's fair value, we perform the second step of the test to determine the amount of the impairment loss, if any. The second step involves measuring any impairment by comparing the implied fair values of the affected reporting unit's goodwill and intangible assets with the respective carrying values.

If actual future results are not consistent with management's estimates and assumptions, we may have to take an impairment charge in the future related to our goodwill. Future impairment tests will be performed annually in the first day of the fiscal fourth quarter, or sooner if a triggering event occurs. This is a change from our previously disclosed annual testing date of the fiscal first quarter of each annual period. This change does not represent a material change to a method of applying an accounting principle. There was no impairment recorded for the three and nine months ended September 30, 2017.

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Goodwill	
Beginning balance 1/1/17	\$ -
Acquisition of CDM	1,503,361
Changes in foreign currency exchange rate	94,256
Balance at September 30, 2017	\$ 1,597,617

In addition, the Company recorded certain intangible assets as part of the CDM acquisition which are as follows as of September 30, 2017.

	Cost	Accumulated Amortization	Net Book Value September 30, 2017
Intellectual property	\$ 850,158	\$ 63,762	\$ 786,396
Customer contracts/relationships	743,889	55,792	688,097
Order backlog	212,682	212,682	-
Trade names	106,270	7,245	99,025
	<u>\$ 1,912,999</u>	<u>\$ 339,481</u>	<u>\$ 1,573,518</u>

Amortization expenses for the nine months ended September 30, 2017 was approximately \$339,000.

i) Recent Accounting Pronouncements Affecting the Company:

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, "Revenue from Contracts with Customers" (Topic 606), which supersedes nearly all existing revenue recognition guidance under accounting principles generally accepted in the United States ("U.S. GAAP"). The core principle of Topic 606 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. Topic 606 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP. The new guidance also includes a cohesive set of disclosure requirements intended to provide users of financial statements with comprehensive information about the nature, amount, timing and uncertainty of revenue and cash flows arising from a company's contracts with customers.

The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients; or (ii) a retrospective approach with the cumulative effect of initially adopting Topic 606 recognized at the date of adoption (which includes additional footnote disclosures). We have evaluated the impact of our pending adoption of Topic 606 on our consolidated financial statements and have determined to use the modified retrospective method by which we will reflect the cumulative effect in the adoption of the standard in 2018. The Company has hired an independent firm to assist the Company in analyzing its revenue streams based on its sales contracts with customers. Based on the analysis to date, the Company does not expect its product sales to have a material impact on its consolidated financial statements. Revenue from product sales are recognized when control of the goods transfer to the customer which we expect to be the date of shipment. The Company will make the accounting policy election to treat shipping and handling as fulfillment activities. The Company is evaluating the impact of Topic 606 on its other revenue streams, including R&D, milestone and grants, and on its disclosures for its financial statement footnotes and expects to complete its implementation of the new standard in 2017.

In November 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2015-17, Income Taxes (Topic 740) Balance Sheet Classification of Deferred Assets. This ASU is intended to simplify the presentation of deferred taxes on the balance sheet and will require an entity to present all deferred tax assets and deferred tax liabilities as non-current on the balance sheet. Under the current guidance, entities are required to separately present deferred taxes as current or non-current. Netting deferred tax assets and deferred tax liabilities by tax jurisdiction will still be required under the new guidance. This guidance had no material effect in 2017. The Company does not believe this new accounting standard update will have a material impact on its consolidated financial statements in the future.

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In February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, which amends the ASC and creates Topic 842, Leases. Topic 842 will require lessees to recognize lease assets and lease liabilities for those leases classified as operating leases under previous US GAAP on the balance sheet. This guidance is effective for annual periods beginning after December 15, 2018 and early adoption is permitted. We are in the initial stages of evaluating the effect of the standard on our financial statements and will continue to evaluate. While not yet in a position to assess the full impact of the application of the new standard, the Company expects that the impact of recording the lease liabilities and the corresponding right-to-use assets will have a significant impact on its total assets and liabilities with a minimal impact on equity and operating results.

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, which will change certain aspects of accounting for share-based payments to employees. ASU 2016-09 is effective for fiscal years (and interim reporting periods within those years) beginning after December 15, 2016. The Company adopted the provisions of ASU 2016-09 on January 1, 2017. The Company evaluated this standard and the adoption of it did not have a material impact on its consolidated financial statements.

In January 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2017-04 *Intangibles - Goodwill and Other (Topic 350)* which would eliminate the requirement to calculate the implied fair value of goodwill to measure a goodwill impairment charge. Instead, the amount of an impairment charge would be recognized if the carrying amount of a reporting unit is greater than its fair value. ASU 2017-04 is effective for public companies for fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently evaluating the impact of the provisions of ASU 2017-04.

NOTE 4 — COLLABORATIVE RESEARCH AND DEVELOPMENT ARRANGEMENTS:

a) *Brain Injury agreement:*

In January 2015, the Company entered into a technology development agreement with Perseus Science Group LLC for \$946,000 and a follow-on agreements in December 2016 and during 2017 aggregating to \$1,060,000. The Company earned \$293,000 and \$180,000 for the nine-month periods ended September 30, 2017 and 2016, respectively, from this agreement. The Company earned \$1,060,000 from this grant from inception through September 30, 2017, so that as of September 30, 2017, the Company has received the entire amount of this grant.

b) *Malaria agreement:*

In April 2016, the Company was awarded a grant from the Bill & Melinda Gates Foundation for \$678,000. The Company earned \$159,000 for the nine-month period ended September 30, 2017 from this agreement. The Company earned \$678,000 from this grant from inception through September 30, 2017, so that as of September 30, 2017, the Company has received the entire amount of this grant.

c) *Fever Panel agreement:*

In October 2015, the Company entered into a technology development agreement with the Paul G. Allen Ebola Program for \$2,118,000 and a follow-on agreement in February 2016 for \$550,000. The Company earned none and \$2,260,000 for the nine-month periods ended September 30, 2017 and 2016, respectively, from this agreement. The Company earned \$2,668,000 from this grant from inception through September 30, 2017.

d) *BARDA Zika agreement:*

In August 2016, the Company was awarded a grant for \$5,934,000 from BARDA, which is part of the U.S. Department of Health And Human Resources. The Company earned \$1,900,000 and none , for the nine-month period ended September 30, 2017 and 2016, respectively, from this agreement. The Company earned \$2,373,000 from this grant from inception through September 30, 2017.

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e) USDA Bovid:

In September 2016, the Company entered into a Phase II agreement with the USDA for an additional \$600,000 to develop a Bovid TB assay. The Phase I agreement was for \$100,000. Revenue for these agreements are being recognized under a proportional performance method. The Company earned \$222,000 for the nine-month period ended September 30, 2017 from these agreements. The Company earned \$274,000 from these agreements from inception through September 30, 2017.

f) FIND agreement:

In March 2017, the Company entered into a technology development agreement with FIND for \$999,000. The Company earned \$500,000 for the nine-month period ended September 30, 2017 from this agreement. The Company earned \$500,000 from this grant from inception through September 30, 2017.

NOTE 5 — RIGHTS AGREEMENT:

In March 2016, the Company entered into a Rights Agreement dated as of March 8, 2016 (the "Rights Agreement") between the Company and Action Stock Transfer Corp., as Rights Agent. Pursuant to the Rights Agreement, the Company declared a dividend 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, 2016, 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 20% 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 20% 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:

During the third quarter of 2017, options to purchase 46,000 shares of the Company's common stock were exercised for cash and on a cashless basis into 19,448 shares of common stock at an average exercise price of \$4.24. The exercise prices of the options exercised on a cashless basis were paid by the exercising option holders surrendering options and shares of common stock already owned as payment of the exercise price.

During the third quarter of 2017, the Company issued options to one of its directors pursuant to the Company's compensation policy for directors. The director was issued options to purchase 46,875 shares of common stock. The options become exercisable in five equal annual installments starting on the date of issue. The options issued have an exercise price of \$6.05 per share, which was the last traded price of the common stock on the day issued. The options expire five years from date of issue.

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The Company entered into an employment agreement, effective as of May 22, 2017 (the "Klugewicz Employment Agreement"), with Sharon Klugewicz to serve as the Company's President of the Americas, for an additional term of one year through May 22, 2018. Pursuant to the Klugewicz Employment Agreement, the Company issued to Ms. Klugewicz incentive stock options to purchase 10,000 shares of the Company's common stock. Fifty percent of these options vest on each of the second and third anniversary of the effective date. The exercise price for these options was equal to the last trading price for the Company's common stock on September 17, 2017, which was \$5.90 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 Ms. Klugewicz's employment with the Company or (b) on the five year anniversary of the effective date of the grant.

During the second quarter of 2017, no options were granted or exercised.

During the first quarter of 2017, options to purchase 10,969 shares of the Company's common stock were exercised on a cashless basis into 3,039 shares of common stock at an exercise price of \$4.19 by surrendering options and shares of common stock already owned as payment of the exercise price.

The Company completed the acquisition of CDM on January 9, 2017. Pursuant to the Stock Purchase Agreement, the Company acquired all of the issued and outstanding common stock and other equity interests of CDM from the sellers for (i) a cash payment of \$1,400,000, (ii) contingent consideration of \$148,000 and (iii) 269,236 shares of the Company's common stock, of which 7,277 shares are being held back to satisfy certain potential claims under the Stock Purchase Agreement and will become issuable to the Sellers, if at all, on the one-year anniversary of the closing. The closing price of our common stock on January 9, 2017 was \$6.25.

The Company entered into an employment agreement, effective as of March 13, 2017 (the "Sperzel Employment Agreement"), with John Sperzel to serve as the Company's Chief Executive Officer, for an additional term of three years through March 13, 2020. Pursuant to the Sperzel Employment Agreement, the Company issued to Mr. Sperzel incentive and non-qualified stock options to purchase 20,000 shares of the Company's common stock. These options vest on the third anniversary or March 31, 2020. The exercise price for these options was equal to the volume weighted trading price for the Company's common stock on March 31, 2017, which was \$5.3666 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.

During the first quarter of 2017, the Company issued options to purchase 5,000 shares of common stock to each of six members of the executive team. The options became exercisable on the date of issue. The options issued have an exercise price of \$5.25 per share, which was the last traded price of the common stock on the day issued. The options expire five years from date of issue.

During the first quarter of 2017, the Company issued options to purchase 36,000 shares of common stock to a newly-hired vice-president of operations. The options are exercisable in three equal annual installments starting on the first anniversary of the date of issue. The options issued have an exercise price of \$6.30 per share, which was the last traded price of the common stock on the day issued. The options expire five years from date of issue.

During the year 2016, options to purchase 191,804 shares of the Company's common stock were exercised for cash and on a cashless basis into 125,750 shares of common stock at exercise prices ranging from \$2.80 to \$5.56 by surrendering options and shares of common stock already owned.

During the fourth quarter of 2016, the Company issued options to purchase 36,000 shares of common stock to a newly-hired president of the EMEA and APAC regions. The options are exercisable in three equal annual installments starting on the first anniversary of the date of issue. The options issued have an exercise price of \$7.15 per share, which was the last traded price of the common stock on the day issued. The options expire five years from date of issue.

The Company closed an underwritten public offering of 2,300,000 shares of its common stock on August 3, 2016. The price per share of common stock sold in the offering was \$6.00 per share. The net proceeds of the offering, after deducting the underwriters' discounts and other offering expenses payable by the Company, was approximately \$12,493,000. The Company intends to use the net proceeds for business expansion and working capital, including product development, operational improvements, clinical trials, and sales and marketing.

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During the second quarter of 2016, the Company issued options to one of its directors pursuant to the Company's compensation policy for directors. The director was issued options to purchase 46,875 shares of common stock. The options become exercisable in five equal annual installments starting on the date of issue. The options issued have an exercise price of \$8.86 per share, which was the last traded price of the common stock on the day issued. The options expire five years from date of issue.

The Company entered into an employment agreement, effective as of March 5, 2016 (the "Esfandiari Employment Agreement"), with Javan Esfandiari to serve as the Company's Chief Scientific and Technical Officer, for an additional term of three years through March 5, 2019. Pursuant to the Esfandiari Employment Agreement, the Company issued to Mr. Esfandiari incentive and non-qualified stock options to purchase 60,000 shares of the Company's common stock. Of these stock options, options to purchase 20,000 shares vest on each of the first three anniversaries of March 11, 2016 which is the date on which the Esfandiari Employment Agreement was entered into. The exercise price for these options is equal to the trading price for the Company's common stock on March 11, 2016, which was \$5.64 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. Esfandiari's employment with the Company or (b) the fifth anniversary of the effective date of the grant.

NOTE 7 — COMMITMENTS, CONTINGENCIES, AND CONCENTRATIONS:

a) Economic Dependency:

The following table discloses product sales and accounts receivable the Company had with respect 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, 2017		September 30, 2016		September 30, 2017		September 30, 2016		September 30, 2017	September 30, 2016
	% of		% of		% of		% of			
	Sales	Sales	Sales	Sales	Sales	Sales	Sales	Sales		
Customer 1	\$ 3,530,364	58%	\$ 662,841	26%	\$ 6,426,158	45%	\$ 3,919,011	37%	\$ 3,262,125	\$ 2,683,910
Customer 2	*	*	*	*	*	*	1,796,477	17%	*	-
Customer 3	*	*	*	*	1,326,171	9%	*	*	-	*
Customer 4	602,087	10%	*	*	*	*	*	*	172,821	*

(*) 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 and accounts payable that the Company had with respect to 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, 2017		September 30, 2016		September 30, 2017		September 30, 2016		September 30, 2017	September 30, 2016
	% of		% of		% of		% of			
	Purchases	Purc.	Purchases	Purc.	Purchases	Purc.	Purchases	Purc.		
Vendor 1	\$ *	*	\$ 132,122	11%	*	*	\$ 558,044	12%	\$ *	\$ 53,682
Vendor 2	*	*	*	*	698,838	13%	*	*	-	*
Vendor 3	383,827	14%	*	*	711,865	13%	*	*	98,152	*
Vendor 4	420,410	16%	*	*	605,931	11%	*	*	-	*

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

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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, either from the logistics of changing suppliers or from product changes attributable to new components, which could result in a possible loss of sales, and 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 regulatory review. After marketing approval has been granted, Chembio must continue to comply with governmental regulations. Failure to comply with these regulations can result in significant penalties.

c) Employment Agreements:

The Company has employment contracts with five key employees: CEO John J. Sperzel III; CSTO Javan Esfandiari; President of the Americas, Sharon Klugewicz; Managing Director of CDM, Magentiren Vajuram; and Vice-President of CDM Dr. Avijit Roy. The contracts call for salaries presently aggregating \$1,280,000 per year. The Sperzel contract expires in March 2020, the Esfandiari contract expires in March 2019, the Klugewicz contract expires May 2018, and the Vajuram and Roy contracts expire in January 2018. In connection with the Sperzel contract that expires in March 2020, the Company issued, in March 2017, options to purchase 20,000 common shares of stock, which vest on the third anniversary of the grant. In connection with the Esfandiari contract that expires in March 2019, the Company issued, in March 2016, options to purchase 60,000 shares of common stock, with one-third vesting on each of the first, second and third anniversaries of the grant. In connection with the Klugewicz contract that expires in May 2018, the Company issued, in September 2017, options to purchase 10,000 shares of common stock, with one half vesting on each of the second and third anniversaries of the grant.

NOTE 8 — LOAN PAYBLE:

In September 2017, the Company entered into an agreement with an equipment vendor to purchase automated assembly equipment for approximately \$660,000. The terms called for prepayments of 30% down, 60% at time of factory acceptance testing and 10% after delivery. The vendor agreed to lend the Company certain portions of the prepayments, 15% of the first prepayment, 40% of the second prepayment and the last 10% on delivery. The Company will pay interest only at an annual rate of 12% until delivery. Thirty days after delivery the Company will begin making monthly payments of principal and interest of approximately \$20,150, at an annual rate of twelve percent, over a twenty-four month period.

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 subsidiaries 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, 2016, with the exception of goodwill.

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, which latter assay is not yet approved to be marketed in the U.S.), or which may be marketed pursuant to private label license or distribution agreements such as those with the Oswaldo Cruz Foundation ("FIOCRUZ"), Labtest, and Bio-Rad.

Research and development ("R&D"), milestone, and grant revenues for the nine months ended September 30, 2017 increased to \$3.10 million from \$3.03 million in the prior-year period, which was primarily the result of increased R&D project revenues in 2017.

R&D expenses in the nine months ended September 30, 2017 were \$6.03 million, compared with \$6.27 million in the prior-year period. Development work continues on several assays utilizing Chembio's DPP® platform, including the DPP® HIV multiplex tests that are designed to detect various infectious diseases such as Zika, Malaria, Dengue and other fever diseases partially funded by projects and grants.

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 received approval by the Mexican regulatory agency (COFEPRIS) in 2014, received approval by the Brazilian regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA) in 2015, and received CE mark approval in 2017. We have developed 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. The clinical trial to support the FDA application for the DPP® HIV-Syphilis Assay, which was initiated during first quarter of 2016, has been completed. In March 2017, the FDA requested further studies in addition to the clinical studies recently completed. These studies are in progress and expected to be complete during the fourth quarter of 2017, in preparation for filing the Premarket Approval Application.

Fever & Tropical 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 completed this project, which compared the new DPP® malaria assay to the world's leading currently-available POC Malaria Assay with favorable results: a ten-fold improvement in sensitivity. In April 2016, we received a second malaria grant from the Bill & Melinda Gates Foundation to expedite the feasibility testing and development of the world's first oral fluid/saliva POC diagnostic test to simply and accurately identify individuals infected with all species of malaria. We completed the feasibility and delivered DPP® Malaria Assay prototypes to a partner of the Bill & Melinda Gates Foundation for a lab evaluation, which was completed successfully during the third quarter of 2017.
- **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. During 2016, ChemBio announced collaborations with Bio-Manguinhos, the unit of the Oswaldo Cruz Foundation (Fiocruz) responsible for the development and production of vaccines, diagnostics, and biopharmaceuticals, primarily to meet the demands of Brazil's national public health system related to the DPP® Dengue Fever Assay. We completed verification and validation studies, and production of pilot lots, to support preclinical studies. During 2016, we initiated registration in Southeast Asia and initiated commercialization of the DPP® Dengue Assay in Southeast Asia during the first quarter of 2017.
- **DPP® Zika Assay:** The DPP® Zika Assay is a rapid POC stand-alone test for the simultaneous detection of IgM/IgG antibodies. In February 2016, we received a grant from The Paul G. Allen Family Foundation to initiate development of the DPP® Zika Assay. During 2016, ChemBio announced collaborations with Bio-Manguinhos, the unit of the Oswaldo Cruz Foundation (Fiocruz) responsible for the development and production of vaccines, diagnostics, and biopharmaceuticals, primarily to meet the demands of Brazil's national public health system, related to the DPP® Zika Assay. In August 2016, the Company received an award from the U.S. Government (HHS/ASPR/BARDA), granting the Company up to \$13.2 million (\$5.9 million to develop DPP® Zika Assay and obtain U.S. regulatory approval). The Company obtained CE mark in July 2016, and then began selling in the Caribbean region via its distribution partner, Isla Lab, LLC. In September 2016, the Company received a contract award from CDC, to initiate a Zika surveillance program in India, Peru, Guatemala, and Haiti, and we began selling the DPP® Zika IgM/IgG Assay to CDC for field testing purposes during the first quarter of 2017. The Company received approval by the Brazilian health regulatory authority, Agência Nacional de Vigilância Sanitária (ANVISA), for the DPP® Zika IgM/IgG Assay in November 2016 and for the DPP® Micro Reader in July 2017, in collaboration with Bio-Manguinhos/Fiocruz. In September 2017, the Company became the first to receive FDA Emergency Use Authorization for a rapid Zika test.
- **DPP® Chikungunya Assay:** The DPP® Chikungunya Assay is a rapid, POC, multiplex test for the simultaneous detection of IgG/IgM antibodies. During 2016, ChemBio announced collaborations with Bio-Manguinhos, the unit of the Oswaldo Cruz Foundation (Fiocruz) responsible for the development and production of vaccines, diagnostics, and biopharmaceuticals, primarily to meet the demands of Brazil's national public health system, related to the DPP® Chikungunya Assay. During 2017, we initiated registration to begin initial commercialization in Southeast Asia.

- **DPP® Zika/Dengue/Chikungunya Assay:** The DPP® Zika/Dengue/Chikungunya Assay is a rapid, POC, multiplex test for the simultaneous detection of IgM/IgG antibodies. In February 2016, we received a grant from The Paul G. Allen Family Foundation to initiate development of the DPP® Zika/Dengue/Chikungunya Assay. During 2016, Chembio announced collaborations with Bio-Manguinhos, the unit of the Oswaldo Cruz Foundation (Fiocruz) responsible for the development and production of vaccines, diagnostics and biopharmaceuticals, primarily to meet the demands of Brazil's national public health system, related to the DPP® Zika/Dengue/Chikungunya Assay. In August 2016, the Company received an award from the U.S. Government (HHS/ASPR/BARDA), granting the Company up to \$13.2 million (including an option of \$7.3 million to develop DPP® Zika/Dengue/Chikungunya Assay and obtain U.S. regulatory approval). In September 2016, the Company received a contract award from CDC to initiate a Zika, Dengue, and Chikungunya surveillance program in India, Peru, Guatemala, and Haiti, and we began selling the DPP® Zika/Dengue/Chikungunya IgM/IgG Assay to CDC during the first quarter of 2017.
- **DPP® Fever Panel Assay (1):** The DPP® Fever Panel Assay (1) is a rapid, POC, multiplex test for the simultaneous detection of Malaria, Dengue, Chikungunya, Zika, Ebola, Lassa, and Marburg. In October 2015, we received a \$2.1 million grant from the Paul G. Allen Ebola Program to develop the DPP® Fever Panel Assay (1) and a \$0.55 million follow-on grant to add a test for the detection of Zika virus. We completed the development of the DPP® Fever Panel Assay in 2016, including the addition of Zika, and we supplied 10,000 DPP® Fever Panel Assays (1) to FIND, which initiated field evaluation in Peru and Nigeria. The field evaluation is completed, FIND is analyzing the data, and expected to deliver the final report in the first quarter of 2018.
- **DPP® Fever Panel Assay (2):** The DPP® Fever Panel Assay (2) is a rapid, POC, multiplex test for the simultaneous detection of Malaria, Dengue, Chikungunya, Zika, leptospirosis, Rickettsia typhi, Burkholderia pseudomallei, and Orientia tsutsugamushi. In April 2017, the Company announced collaboration with FIND, to develop a DPP® Fever Panel Assay (2) for the Asian market. Development is ongoing and on schedule.
- **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 it for Emergency Use Authorization (EUA) with the Food & Drug Administration (FDA) and World Health Organization (WHO), and we are actively engaged with these regulatory agencies. During the third and fourth quarters of 2015, we sold DPP® Ebola and DPP® Malaria-Ebola Assays to the Centers for Disease Control & Prevention (CDC) for field studies in West Africa, which is ongoing.

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. This program is fully funded by this partner. However, under the terms of the agreement, neither Chembio's partner nor the specific type of cancer is being disclosed. 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. During the third quarter of 2015, we completed successful feasibility, and our partner agreed to fund continued development and verification of the DPP® Cancer Assay, which are ongoing.
- **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. The DPP® Traumatic Brain Injury Assay is in the feasibility and pre-clinical stage. Under institutional review board (IRB) agreements with multiple hospitals, we are conducting pre-clinical studies of the prototype DPP® Traumatic Brain Injury Assay using patient samples.

· **DPP® Bovine Tuberculosis:** The DPP® BovidTB Assay is a rapid POC test for the detection of bovine tuberculosis (TB). In September 2016, the Company was awarded a \$600,000 grant from the United States Department of Agriculture (USDA) to develop the DPP® BovidTB Assay. The grant is managed by the Small Business Innovation Research Program (SBIR) of the National Institute of Food and Agriculture (NIFA), a federal agency within the USDA, and the assay is being developed in collaboration with National Animal Disease Center (NADC) and Infectious Disease Research Institute (IDRI). Under the two-year grant, Chembio is using its patented DPP® technology to undertake to develop a simple, rapid, accurate and cost-effective test for bovine TB in cattle. The DPP® BovidTB Assay is being designed to provide results within 20 minutes, thereby significantly improving on the time-consuming, tedious and inadequate diagnostic methods currently in use.

Regulatory Activities

· **DPP® HIV-Syphilis Assay:** We have developed 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. The clinical trial to support the FDA application for the DPP® HIV-Syphilis Assay, initiated during first quarter of 2016, has been completed. In March 2017, the FDA requested further studies in addition to the clinical studies recently completed, which are in progress and expected to be complete during the fourth quarter of 2017, in preparation for filing the Premarket Approval Application.

· **DPP® Zika IgM/IgG System:** The DPP® Zika IgM/IgG System, which includes the DPP® Zika Assay and DPP® Micro Reader, obtained CE mark, allowing the product to be commercialized in Europe as well as the majority of the Caribbean nations. In November of 2016, the Company received approval from ANVISA, Brazil's regulatory Agency, for the DPP® Zika IgM/IgG Assay, and in July 2017, the Company received ANVISA approval for the DPP® Micro Reader, in collaboration with Bio-Manguinhos. In September 2017, the Company received FDA Emergency Use Authorization, allowing the Company to commercialize the DPP® Zika System in the United States, Puerto Rico, and the U.S. Virgin Islands. The Company has also filed regulatory submissions with the World Health Organization (Emergency Use Assessment and Listing) and with COFEPRIS (Mexico), and we are actively engaged with these organizations.

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, goodwill, and income taxes. For a summary of our significant accounting policies, which have not changed from December 31, 2016, with the exception of goodwill, see our Annual Report on Form 10-K for the twelve months ended December 31, 2016, which was filed with the SEC on March 7, 2017.

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2017 AS COMPARED WITH THE THREE MONTHS ENDED SEPTEMBER 30, 2016

Income:

For the three months ended September 30, 2017, Loss before income taxes was \$585,000 compared to \$2,138,000 for the three months ended September 30, 2016. Net Loss for the 2017 period was \$585,000 as compared to \$2,138,000 for 2016. The decrease in Net Loss is primarily attributable to increased product revenues in the 2017 period over the 2016 period, together with smaller increases in R&D and royalty revenues, increased product gross margin, and a decrease in operating expenses. Product gross margin increased in the three months ended September 30, 2017, as compared with the three months ended September 30, 2016, by \$1,360,000 or 192.19%.

Revenues:

Selected Product Categories:	For the three months ended		\$ Change	% Change
	September 30, 2017	September 30, 2016		
Lateral Flow HIV Tests and Components	\$ 2,289,972	\$ 1,471,458	\$ 818,514	55.63%
DPP® Tests and Components	3,582,145	997,768	2,584,377	259.02%
Other	260,608	32,871	227,737	692.82%
Net Product Sales	6,132,725	2,502,097	3,630,628	145.10%
License and royalty revenue	150,000	77,754	72,246	92.92%
R&D, milestone and grant revenue	1,304,649	1,166,610	138,039	11.83%
Total Revenues	<u>\$ 7,587,374</u>	<u>\$ 3,746,461</u>	<u>\$ 3,840,913</u>	<u>102.52%</u>

Revenues for our lateral flow HIV (LF-HIV) tests and related components during the three months ended September 30, 2017 increased by approximately \$819,000 from the same period in 2016. This was primarily attributable to increased sales to Africa of approximately \$475,000, USA of approximately \$272,000, and Europe of approximately \$57,000. Revenues for our DPP® products during the three months ended September 30, 2017 increased by approximately \$2,584,000 over the same period in 2016, primarily due to increased sales in Brazil. The increase in R&D, milestone and grant revenue, was primarily due to increased R&D project revenues in 2017.

Management is also focused on sales by region as well as sales by product types. As a result, we are providing the following table which shows sales by region and by product type.

Region	For the three Months ended			Part-Type	For the three Months ended		
	September 30, 2017	September 30, 2016	\$ Change		September 30, 2017	September 30, 2016	\$ Change
Africa	\$ 965,606	\$ 483,088	\$ 482,518	DPP®	\$ 7,700	\$ 5	\$ 7,695
				LF-HIV	957,905	482,993	474,912
				OTHER	1	90	(89)
Asia	90,781	125,616	(34,835)	DPP®	984	100,250	(99,266)
				LF-HIV	23,805	20,026	3,779
				OTHER	65,992	5,340	60,652
Europe	401,730	315,669	86,061	DPP®	1,120	2,860	(1,740)
				LF-HIV	357,375	300,537	56,838
				OTHER	43,235	12,272	30,963
Latin America	3,556,815	731,291	2,825,524	DPP®	3,523,924	718,841	2,805,083
				LF-HIV	17,651	9,100	8,551
				OTHER	15,240	3,350	11,890
Other	2,320	5	2,315	DPP®	—	—	—
				LF-HIV	2,320	10	2,310
				OTHER	—	(5)	5
USA	1,115,473	846,428	269,045	DPP®	48,417	175,812	(127,395)
				LF-HIV	930,916	658,792	272,124
				OTHER	136,140	11,824	124,316
TOTALS	\$ 6,132,725	\$ 2,502,097	\$ 3,630,628		\$ 6,132,725	\$ 2,502,097	\$ 3,630,628

Gross Margin:

	For the three months ended		\$ Change	% Change
	September 30, 2017	September 30, 2016		
Gross Margin per Statements of Operations	\$ 3,522,583	\$ 1,952,097	\$ 1,570,486	80.45%
Less: R&D, milestone, grant, license and royalty revenues	1,454,649	1,244,364	210,285	16.90%
Gross Margin from Net Product Sales	\$ 2,067,934	\$ 707,733	\$ 1,360,201	192.19%
Product Gross Margin %	33.72%	28.29%		

The overall gross margin dollar increase of \$1,570,000 included a \$1,360,000 increase in gross margin from product sales and an increase in non-product revenues of \$210,000. The increase in net product sales gross margin of \$1,360,000 is primarily attributable to the increase in sales compared to 2016. The net product sales gross margin increase is primarily affected by two components, one is the increase in product sales of \$3,631,000, which, at the 28.3% margin percentage for September 30, 2016, contributed \$1,027,000 to the increase, and the other is the increased change in margin percentage of 5.43%, which contributed \$333,000 to the balance of the increase 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, 2017	September 30, 2016		
Clinical and Regulatory Affairs:				
Wages and related costs	\$ 130,331	\$ 153,500	\$ (23,169)	-15.09%
Consulting	20,352	11,849	8,503	71.76%
Clinical trials	293,400	322,518	(29,118)	-9.03%
Other	41,047	15,018	26,029	173.32%
Total Clinical and Regulatory Affairs	485,130	502,885	(17,755)	-3.53%
R&D other than Clinical Regulatory Affairs:				
Wages and related costs	731,251	732,775	(1,524)	-0.21%
Consulting	44,208	58,711	(14,503)	-24.70%
Stock-based compensation	12,101	27,263	(15,162)	-55.61%
Materials and supplies	399,051	802,144	(403,093)	-50.25%
Other	133,997	139,941	(5,944)	-4.25%
Total R&D other than Clinical Regulatory Affairs	1,320,608	1,760,834	(440,226)	-25.00%
Total Research and Development	\$ 1,805,738	\$ 2,263,719	\$ (457,981)	-20.23%

Expenses for Clinical & Regulatory Affairs for the three months ended September 30, 2017 decreased by \$18,000 as compared to the same period in 2016. This was primarily due to the decrease in clinical trial expenses of \$29,000.

R&D expenses other than Clinical & Regulatory Affairs decreased by \$440,000 in the three months ended September 30, 2017, as compared with the same period in 2016. The decreases were primarily related to a decrease in material and supplies, that resulted from the decrease in our sponsored research.

Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended		\$ Change	% Change
	September 30, 2017	September 30, 2016		
Wages and related costs	\$ 943,436	\$ 844,123	\$ 99,313	11.77%
Consulting	102,008	5,969	96,039	1,608.96%
Commissions	333,800	147,652	186,148	126.07%
Stock-based compensation	62,154	46,750	15,404	32.95%
Marketing materials	22,631	153,465	(130,834)	-85.25%
Investor relations/investment bankers	62,574	67,607	(5,033)	-7.44%
Legal, accounting and compliance	312,311	250,129	62,182	24.86%
Travel, entertainment and trade shows	136,347	115,701	20,646	17.84%
Other	330,097	201,055	129,042	64.18%
Total S, G & A	\$ 2,305,358	\$ 1,832,451	\$ 472,907	25.81%

Selling, general and administrative expenses for the three months ended September 30, 2017, increased by \$473,000 as compared with the same period in 2016, a 25.8% increase. This increase resulted primarily from increases in commissions, primarily due to increased sales to Brazil, wages and related costs due to an increase in sales staff, consulting, professional fees, travel, entertainment and trade shows, and other expenses which were partially offset by decreases in marketing material, and decreases in investor relations expense.

Other Income:

	For the three months ended		\$ Change	% Change
	September 30, 2017	September 30, 2016		
Interest income	\$ 3,852	\$ 5,855	\$ (2,003)	-34.21%
Total Other Income	\$ 3,852	\$ 5,855	\$ (2,003)	-34.21%

Other income for the three months ended September 30, 2017 decreased to \$3,852, from income of \$5,855 in the same period in 2016, primarily as a result of less interest income received as a result of less cash to invest.

Income tax provision:

The Company recorded a full valuation allowance for the three months ended September 30, 2017, on its deferred tax assets.

RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2017 AS COMPARED WITH THE NINE MONTHS ENDED SEPTEMBER 30, 2016**Income:**

For the for the nine months ended September 30, 2017, Loss before income taxes was \$4,373,000 compared to \$4,988,000 for the for the nine months ended September 30, 2016, primarily as a result of higher net product sales, non-product revenues and reduction in R&D expenses partially offset by increased selling, general and administrative expenses. Net Loss for the 2017 period was \$4,373,000 as compared to \$10,789,000 for 2016. The decrease in Net Loss is primarily attributable to recording of a full valuation of approximately \$5,801,000 on our Deferred Tax Asset (DTA) in the 2016 period, an increase in product revenues, an increase in R&D and royalty revenues, and increased product gross margin. Product gross margin increased in the nine months ended September 30, 2017, as compared with the nine months ended September 30, 2016, by \$1,428,000 or 40.37%.

Revenues:

Selected Product Categories:	For the nine months ended		\$ Change	% Change
	September 30, 2017	September 30, 2016		
Lateral Flow HIV Tests and Components	\$ 5,520,073	\$ 5,696,745	\$ (176,672)	(3.10)%
DPP® Tests and Components	6,969,815	4,490,214	2,479,601	55.22%
Other	1,963,209	266,229	1,696,980	637.41%
Net Product Sales	14,453,097	10,453,188	3,999,909	38.26%
License and royalty revenue	477,631	133,850	343,781	256.84%
R&D, milestone and grant revenue	3,096,626	3,026,927	69,699	2.30%
Total Revenues	\$ 18,027,354	\$ 13,613,965	\$ 4,413,389	32.42%

Revenues for our lateral flow HIV (LF-HIV) tests and related components for the nine months ended September 30, 2017 decreased by approximately \$177,000 from the same period in 2016. This was primarily attributable to decreased sales in the U.S. of approximately \$985,000, decreased sales to Latin America of approximately \$61,000, and decreased sales to Asia of approximately \$27,000, and partially offset by increased sales to Europe of approximately \$768,000 and increased sales to Africa of approximately \$140,000. Revenues for our DPP® products during the nine months ended September 30, 2017 increased by approximately \$2,480,000 over the same period in 2016, primarily due to increased sales in Brazil, partially offset by decreased sales in Asia. Revenues for our other products for the nine months ended September 30, 2017 increased by approximately \$1,697,000, primarily as a result of sales from our Malaysia subsidiary. The increase in R&D, milestone and grant revenue, was primarily due to increased royalty revenues in 2017.

Management is also focused on sales by region as well as sales by product types. As a result, we are providing the following table which shows sales by region and by product type.

Region	For the nine months ended			Part-Type	For the nine months ended		
	September 30, 2017	September 30, 2016	\$ Change		September 30, 2017	September 30, 2016	\$ Change
Africa	\$ 1,797,285	\$ 1,576,233	\$ 221,052	DPP®	\$ 96,080	\$ 18,515	\$ 77,565
				LF-HIV	1,698,033	1,557,608	140,425
				OTHER	3,172	110	3,062
Asia	1,633,490	272,638	1,360,852	DPP®	8,384	104,650	(96,266)
				LF-HIV	129,132	156,468	(27,336)
				OTHER	1,495,974	11,520	1,484,454
Europe	1,441,890	647,582	794,308	DPP®	4,970	3,110	1,860
				LF-HIV	1,368,185	600,393	767,792
				OTHER	68,735	44,079	24,656
Latin America	6,701,923	4,147,284	2,554,639	DPP®	6,420,768	3,975,011	2,445,757
				LF-HIV	75,861	136,843	(60,982)
				OTHER	205,294	35,430	169,864
Other	3,575	4,323	(748)	DPP®	1,000	750	250
				LF-HIV	2,575	3,566	(991)
				OTHER	0	7	(7)
USA	2,874,934	3,805,128	(930,194)	DPP®	438,613	388,177	50,436
				LF-HIV	2,246,287	3,231,403	(985,116)
				OTHER	190,034	185,548	4,486
TOTALS	\$ 14,453,097	\$ 10,453,188	\$ 3,999,909		\$ 14,453,097	\$ 10,453,188	\$ 3,999,909

Gross Margin:

	For the nine months ended		\$ Change	% Change
	September 30, 2017	September 30, 2016		
Gross Margin per Statements of Operations	\$ 8,539,506	\$ 6,697,950	\$ 1,841,556	27.49%
Less: R&D, milestone, grant, license and royalty revenues	3,574,257	3,160,777	413,480	13.08%
Gross Margin from Net Product Sales	\$ 4,965,249	\$ 3,537,173	\$ 1,428,076	40.37%
Product Gross Margin %	34.35%	33.84%		

The overall gross margin dollar increase of \$1,842,000 included a \$1,428,000 increase in gross margin from product sales and a \$413,000 increase in non-product revenues. The increase in net product sales gross margin of \$1,428,000 is primarily attributable to the increase in sales compared to 2016. The net product sales gross margin increase is primarily affected by two components, one is the increase in product sales of \$4,000,000, which, at the 33.84% margin percentage for September 30, 2016, contributed \$1,354,000 to the increase, and the other is the increased change in margin percentage of 0.51%, which contributed \$74,000 to the balance of the increase 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 nine months ended		\$ Change	% Change
	September 30, 2017	September 30, 2016		
Clinical and Regulatory Affairs:				
Wages and related costs	\$ 410,136	\$ 417,542	\$ (7,406)	(1.77)%
Consulting	23,815	28,300	(4,485)	(15.85)%
Stock-based compensation	9,652	-	9,652	100.00%
Clinical trials	1,079,372	481,359	598,013	124.23%
Other	65,661	38,441	27,220	70.81%
Total Clinical and Regulatory Affairs	1,588,636	965,642	622,994	64.52%
R&D other than Clinical Regulatory Affairs:				
Wages and related costs	2,190,656	2,171,191	19,465	0.90%
Consulting	151,023	101,486	49,537	48.81%
Stock-based compensation	67,660	61,983	5,677	9.16%
Materials and supplies	1,565,111	2,607,179	(1,042,068)	(39.97)%
Other	471,649	358,002	113,647	31.74%
Total R&D other than Clinical Regulatory Affairs	4,446,099	5,299,841	(853,742)	(16.11)%
Total Research and Development	\$ 6,034,735	\$ 6,265,483	\$ (230,748)	(3.68)%

Expenses for Clinical & Regulatory Affairs for the nine months ended September 30, 2017 increased by \$623,000 as compared to the same period in 2016. This was primarily due to the increase in clinical trial expenses of \$598,000.

R&D expenses other than Clinical & Regulatory Affairs decreased by \$854,000 for the nine months ended September 30, 2017, as compared with the same period in 2016. The decreases were primarily related to a decrease in material and supplies, that resulted from the decrease in our sponsored research.

Selling, General and Administrative Expenses:

Selected expense lines:	For the nine months ended		\$ Change	% Change
	September 30, 2017	September 30, 2016		
Wages and related costs	\$ 2,807,297	\$ 2,408,996	\$ 398,301	16.53%
Consulting	123,433	124,192	(759)	(0.61)%
Commissions	651,316	553,931	97,385	17.58%
Stock-based compensation	185,204	158,296	26,908	17.00%
Marketing materials	202,305	301,302	(98,997)	(32.86)%
Investor relations/investment bankers	203,819	231,769	(27,950)	(12.06)%
Legal, accounting and compliance	1,010,591	731,492	279,099	38.15%
Travel, entertainment and trade shows	477,870	322,909	154,961	47.99%
Other	1,241,220	597,781	643,439	107.64%
Total S, G & A	\$ 6,903,055	\$ 5,430,668	\$ 1,472,387	27.11%

Selling, general and administrative expenses for the nine months ended September 30, 2017, increased by \$1,472,000 as compared with the same period in 2016, a 27.11% increase. This increase resulted primarily from increases in wages and related costs due to an increase in sales staff, professional fees, travel, entertainment and trade shows, increases in commissions, primarily due to increased sales to Brazil, stock-based compensation, and other expenses, primarily due to expenses from our Malaysian subsidiary, which were partially offset by decreases in marketing materials and decreases in investor relations expense.

Other Income:

	For the nine months ended		\$ Change	% Change
	September 30, 2017	September 30, 2016		
Interest income	\$ 24,956	\$ 9,729	\$ 15,227	156.51%
Total Other Income	\$ 24,956	\$ 9,729	\$ 15,227	156.51%

Other income for the nine months ended September 30, 2017 increased to \$ 24,956, from income of \$ 9,729 in the same period in 2016, primarily as a result of interest income received as a result of more cash to invest.

Income tax provision:

The Company recorded a full valuation allowance for the nine months ended September 30, 2017, on its deferred tax assets.

MATERIAL CHANGES IN FINANCIAL CONDITION

Selected Changes in Financial Condition	As of		\$ Change	% Change
	September 30, 2017	December 31, 2016		
Cash and cash equivalents	\$ 1,871,982	\$ 10,554,464	\$ (8,682,482)	-82.26%
Accounts receivable, net of allowance for doubtful accounts of \$52,000 at September 30, 2017 and December 31, 2016, respectively	5,768,920	3,383,729	2,385,191	70.49%
Inventories, net	5,235,164	3,335,188	1,899,976	56.97%
Fixed assets, net of accumulated depreciation	1,964,427	1,709,321	255,106	14.92%
Deposits on manufacturing equipment	243,755	31,900	211,855	664.12%
Deposits and other assets	146,789	720,489	(573,700)	-79.63%
Prepaid expenses and other current assets	842,532	840,145	2,387	0.28%
Goodwill	1,597,617	-	1,597,617	100.00%
Intangible assets, net	1,573,518	-	1,573,518	100.00%
Accounts payable and accrued liabilities	3,870,161	3,013,133	857,028	28.44%
Deferred revenue	-	392,517	(392,517)	-100.00%

Cash decreased by \$8,682,000 from December 31, 2016, primarily due to cash used in operating activities and cash used in investing activities, primarily for the acquisition of CDM, for the nine months of 2017. In addition, there were increases in accounts receivable of \$2,385,000 (primarily due to a large customer as described under "Liquidity And Capital Resources"), inventories of \$1,900,000, net fixed assets of \$255,000, deposits on manufacturing equipment of \$212,000, an increase in accounts payable and accrued liabilities of \$857,000, and increases in goodwill and intangible assets of \$1,598,000 and \$1,574,000, respectively due to the CDM acquisition. We experienced a decrease in deposits and other assets of \$574,000, primarily from reducing the deposit paid for the CDM acquisition, and a decrease in deferred revenue of \$393,000.

LIQUIDITY AND CAPITAL RESOURCES

	For the nine months ended		\$ Change	% Change
	September 30, 2017	September 30, 2016		
Net cash used in operating activities	\$ (7,176,935)	\$ (5,676,073)	\$ (1,500,862)	26.44%
Net cash used in investing activities	(1,639,827)	(79,877)	(1,559,950)	1,952.94%
Net cash provided by financing activities	134,280	12,550,973	(12,416,693)	-98.93%
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	\$ (8,682,482)	\$ 6,795,023	\$ (15,477,505)	-227.78%

The Company's cash decreased as of September 30, 2017 by \$8,682,000 from December 31, 2016, primarily due to cash used in operating activities, and net cash used in investing activities, primarily for the CDM acquisition, for the first nine months of 2017.

The cash used in operations in the first nine months of 2017 was \$7,177,000, which consisted primarily of an increase in accounts receivable of \$2,385,000, an increase in prepaid expenses of \$115,000 (net of amortization), increase in inventories of \$1,900,000, a decrease in deferred revenue of \$393,000, and a net loss net of non-cash items of \$3,065,000, partially offset by cash provided by an increase in accounts payable and accrued liabilities of \$658,000. Net loss net of non-cash items includes loss before income taxes of \$4,373,000 reduced by non-cash expenses of \$1,011,000 in depreciation and amortization, and of \$297,000 in share-based non-cash compensation. The use of cash from investing activities is primarily due to the acquisition of CDM for \$1,400,000 in cash, of which \$850,000 was paid in the nine months ended September 30, 2017, and partially offset by reduction in deposit for the CDM investment of \$550,000 for a deposit paid in December of 2016.

The Company currently has positive working capital. It has used approximately \$8.7 million in cash for the nine months ended September 30, 2017, primarily due to cash used in operating activities. Approximately \$3.3 million of the total \$5.8 million of accounts receivable is related to one customer, and the Company has a high degree of confidence that this account receivable is collectible from this customer.

A fundamental principle of the preparation of financial statements in accordance with accounting principles generally accepted in the United States of America ("GAAP") is the assumption that an entity will continue in existence as a going concern, which contemplates continuity of operations and the realization of assets and settlement of liabilities occurring in the ordinary course of business. This principle is applicable to all entities except for entities in liquidation or entities for which liquidation appears imminent. In accordance with this requirement, the Company has prepared its consolidated financial statements on a going concern basis.

The Company has incurred significant operating losses in the previous three years as well as negative cash flow from operations. The Company currently has a working capital surplus of \$9.8 million. The Company's ability to continue as a going concern depends on its ability to execute its business plan, increase revenue and billings and reduce expenditures. During 2017, the Company began to focus on aligning its expense structure with revenue expectations which included tighter expense controls and overall operational efficiencies which better align the Company's current business plan on a run-rate basis. In addition, the Company recently increased its inventory in anticipation of orders which to date have not materialized and the plan includes reducing inventory levels to provide additional cash to fund operations. Another focus is on the Company's receivable balance which also increased over the nine months, partially due to increased product sales, and we are focusing on reducing days outstanding.

The Company entered into a Controlled Equity OfferingSM Sales Agreement with Cantor Fitzgerald & Co., as sales agent, pursuant to which the Company may offer and sell, from time to time, through Cantor Fitzgerald, shares of the Company's common stock, par value \$0.01 per share, having an aggregate offering price of up to \$21.2 million, and anticipates the ability to raise additional funding if needed through this vehicle. In addition, the Company may be able to raise additional funds through a private offering. With these options available and the steps outlined above, the Company expects it will be able to continue as a going concern into and beyond 2018. However, there can be no assurance that the Company will be able to obtain financing or that such financing will be on favorable terms. Any such financing would be dilutive to shareholders. Failure to generate sufficient revenue, control or further reduce expenditures and/or the inability to obtain financing will result in an inability of the Company to continue as a going concern.

Fixed Asset Commitments

As of September 30, 2017, the Company had \$243,755 in deposits on equipment, and \$462,989 in commitments for additional equipment purchase obligations.

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

During the third quarter of 2017, Chembio continued to execute its strategy and focus on three key areas: 1) strengthening the Company's core sexually transmitted disease business, 2) building a broad tropical and fever disease portfolio, and 3) establishing a global commercial organization.

Chembio believes there are significant opportunities in our core sexually transmitted disease business, including the commercialization of a U.S. version of the DPP® HIV-Syphilis Assay, as well as the DPP® HIV Self-Testing kits outside the U.S, specifically in Africa and Europe. The Company also believes large market opportunities can be addressed with its fever and tropical disease assays, including DPP® Malaria, DPP® Dengue, DPP® Zika, and the DPP® Fever Assays. Chembio's growing commercial organization includes experienced sales executives based in target regions, including the U.S., Latin America, Africa, Europe and Asia Pacific, and through this global sales infrastructure the Company's has had successes in each of these markets.

Sexually Transmitted Diseases Business

Within the sexually transmitted disease business, Chembio increased sales of its HIV Assays in multiple markets. The Company expects its DPP® HIV-Syphilis Assay to play an important role in combatting global concerns related to co-infection and mother-to-child transmission of both HIV and syphilis. The World Health Organization recommends screening all pregnant women for HIV and syphilis at the first antenatal care visit in nearly every country. Early diagnosis and treatment of both HIV and syphilis in pregnant women has proved effective in the prevention of both adverse outcomes of pregnancy and mother-to-child transmission. Additionally, there are other at-risk populations that may also benefit from improved HIV and syphilis screening coverage. Chembio's DPP® HIV-Syphilis Assay is currently available in Latin America, Europe and the Caribbean (except for Puerto Rico).

In March 2017, the FDA requested that the Company undertake further studies of its DPP® HIV-Syphilis Assay, in addition to the clinical studies recently completed, which are in progress and expected to be complete during the fourth quarter of 2017, in preparation for the Company's filing the Premarket Approval Application for its DPP® HIV-Syphilis Assay.

Another important factor in the U.S. market is the fact that Chembio won multiple HIV rapid test procurement awards in recent quarters. The Company has been supplying HIV products pursuant to these awards in 2017, and expects to continue doing so during 2018.

Outside the U.S., Chembio's DPP® Syphilis Screen & Confirm Assay, which is CE Marked, is now available. The DPP® Syphilis Screen & Confirm Assay has been successfully used in several pilot programs in Africa, and to the Company's knowledge is the only rapid test that can detect both active and past-treated syphilis infections with the same test. We believe this product represents a paradigm shift in syphilis confirmatory testing outside of the U.S.

Chembio's HIV Self-Testing products continue to record sales growth in the EU. We believe the market for HIV Self-Testing, especially in Africa and Europe, offers significant growth potential and we believe our HIV products are well-suited to penetrate these markets.

During the third quarter, Chembio continued to fulfill the \$5.8 million order received in May 2017 for the production of DPP® HIV 1/2 Assays, both blood and oral fluid, in Brazil. The Company shipped \$0.9 million during the second quarter of 2017, \$3.2 million in the third quarter of 2017, and anticipates shipping the remaining \$1.6 million during the fourth quarter of 2017.

Tropical and Fever Disease Business

One of Chembio's key goals is the commercialization of multiple tropical and fever disease products during 2017. We are pleased to confirm that during the third quarter of 2017 the Company initiated sales of its DPP® Dengue Assay and DPP® Zika Assay, and initiated a pilot program with the Centers for Disease Control and Prevention (CDC) for the Company's DPP® Dengue/Zika/Chikungunya Assay in India, Peru, Haiti and Guatemala.

Also during the third quarter of 2017, Chembio received approval for its DPP® Micro Reader from Agência Nacional de Vigilância Sanitária (ANVISA), the Brazilian health regulatory agency, in collaboration with Bio-Manguinhos/Fiocruz. The DPP® Zika IgM/IgG Assay detects antibodies using a tiny (10uL) drop of blood from the fingertip and provides quantitative results in 15 minutes, when used with the handheld, battery-operated DPP® Micro Reader. With this approval, Chembio's DPP® Zika System, which includes the DPP® Zika IgM/IgG Assay and DPP® Micro Reader, is now approved for commercial use in Brazil.

Another significant milestone during the third quarter of 2017 was Chembio's receipt of U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for its DPP® Zika System. The DPP® Zika System is the first and only rapid Zika test to receive an FDA EUA. The test is authorized for the presumptive detection of Zika virus IgM antibodies in fingerstick whole blood, EDTA venous whole blood, EDTA plasma (each collected alongside a patient-matched serum specimen) or serum (plain or separation gel) specimens collected from individuals meeting CDC Zika virus clinical and/or epidemiological criteria, from 8 days of on-set and up to 12 weeks. The Company believes its DPP® Zika System will be an important contributor to future sales.

The Company continues to pursue additional regulatory approvals for its DPP® Zika System, including the World Health Organization Emergency Use Assessment and Listing. We remain optimistic regarding these authorizations, given the performance of our DPP® Zika System.

Beyond the products that we are currently marketing, Chembio continues to work with collaborators toward the development of the Company's next generation of tropical and fever disease products, including: DPP® Fever Panel – Africa, DPP® Fever Panel – Asia, DPP® Malaria Assay and, DPP® Zika/Dengue/Chikungunya Assay, among others. It is important to note that nearly all of the Company's tropical and fever disease products are being developed through collaborations and/or funding from world-leading health organizations, including the Bill & Melinda Gates Foundation, the Paul G. Allen Family Foundation, the CDC, FIND, and BARDA.

Global Commercialization

In mid-2014, Chembio made a strategic decision to transform from a product supply organization to an integrated commercial organization. The Company then terminated its distribution agreements with a former U.S. exclusive distributor in 2014 and 2016, respectively. Subsequently, Chembio began building a sales and marketing team in the U.S market.

During the fourth quarter of 2016, we strengthened our commercial leadership, appointing seasoned executives to lead the Americas region, as well as the European, Middle East and Africa regions and Asia Pacific region. And, during the first quarter of 2017, we added experienced diagnostics sales executives in Latin America, Africa and Asia Pacific. We believe that this infrastructure positions the Company for commercial success, globally.

Additionally, Chembio has integrated our newly-acquired facility in Malaysia to execute upon our global commercialization strategy, which includes the manufacture of tests locally, in high growth regions where product performance and competitive pricing is key. In Medford, NY the Company has also made investments in automation of its DPP® manufacturing line to produce high quality, reliable, products that can be scaled up quickly. Also, importantly, the Company hired David Gyorke, Chembio's Vice President of Operations, in January 2017 to drive manufacturing strategy to support growth.

Key Personnel:

During the third quarter, Chembio announced the addition of Gail Page to the Company's Board of Directors. Ms. Page has spent her entire career in health care with a focus on diagnostics and emerging technologies. In January 2013, Ms. Page founded Vineyard Investment Advisors (VIA), through which she works with entrepreneurs, businesses, and universities to transform their ideas into products and services. Prior to VIA, Ms. Page served as the President, CEO and a Director of Vermillion, Inc., a healthcare company focused on developing and commercializing novel diagnostic blood tests. As President and CEO, Ms. Page directed Vermillion's repositioning to highlight the progressive nature of its pipeline, successfully raised over \$100M in funding, developed and commercially launched the OVA1® Test, which was the first FDA-cleared blood test to help diagnose ovarian cancer, and engaged Quest Diagnostics as an equity and commercial partner. In the years preceding Vermillion, Ms. Page served as Executive Vice President and Chief Operating Officer at Luminex, and as Sr. Vice President at Roche Biomedical / Laboratory Corporation of America (LabCorp), during which time her team launched approximately 300 innovative tests, including a suite of HIV and infectious disease assays. Ms. Page's current board appointments include Sword Diagnostics, Inc., Consortia Health Holdings (Chair and Co-founder), and NxPrenatal, Inc., for which she serves as Executive Chair.

In other personnel news, Richard J. Larkin, Chembio's Executive Vice President and Chief Financial Officer (CFO), has recently announced his intent to retire by December 31, 2017. An external search for a new Company CFO has commenced. To ensure an orderly transition, Mr. Larkin is expected to continue to serve as the Company's CFO and remain an officer of the Company until the earlier of December 31, 2017 or until a successor is found. Mr. Larkin has been a dedicated and valuable member of the Chembio team for fourteen years. We wish him well as he transitions into retirement.

Also recently, John Sperzel, Chembio's President and Chief Executive Officer (CEO), returned from medical leave to resume his full responsibilities. During Mr. Sperzel's recovery from heart transplant surgery, he remained engaged in corporate activities and decisions. In his absence, Sharon Klugewicz, President of the Americas, assumed the role of acting CEO, and provided expert leadership in advancing the Company's strategy.

Overview of Chembio's Global Sales:

During the third quarter of 2017, Chembio achieved total revenue of \$7.6 million, which represents a 102% increase over the prior-year period. Product sales during the third quarter of 2017 were \$6.1 million, which represents a 144% increase over the prior-year period. This increase was driven primarily by product sales growth within certain target regions compared to the prior-year period, including: 386% increase in Latin America, 100% increase in Africa, 32% increase in the U.S., and 27% increase in Europe.

The increase in product revenue during the third quarter can be attributed to the efforts of our expanding sales and marketing organization. In Latin America, we achieved sales in excess of \$3.5 million in large part led by strong DPP® sales. In the U.S., the Company achieved over \$1.1 million in sales, as we evolve from a product supply organization to direct sales of our three FDA- PMA-approved, CLIA-waived HIV rapid tests, serving both public health and the professional market. And, we expect the recent EUA for our DPP® Zika System to strengthen U.S. sales in the coming quarters. In Africa, we achieved sales of nearly \$1.0 million, and in Europe, we recognized revenue of approximately \$0.4 million, driven primarily by HIV sales for self-testing.

Conclusion:

The third quarter of 2017 was a strong one for Chembio. During the period, sales increased over 100% as compared to the prior-year period. In our sexually transmitted disease business, the Company advanced a pivotal clinical trial for our DPP® HIV-Syphilis Assay, and we plan to file a PMA for this assay during the fourth quarter of 2017, moving the product closer to U.S. commercialization.

Two key regulatory approvals during the third quarter have the potential to impact future sales in our tropical and fever disease business. With ANVISA approval of the DPP® Zika System in Brazil and with the FDA EUA for the DPP® Zika System in the U.S. market, Chembio has the opportunity to establish itself as the leader in rapid testing for this growing health concern.

In both the tropical and fever disease business, as well as other areas of interest, Chembio remains actively engaged with multiple funding collaborators, working toward the development of new assays that we expect to fill our product pipeline in the future.

Supporting our near-term and future growth is the global commercial team that we've built over the last year. With strong sales experience and leadership in target regions around the world, combined with high-quality and much needed products, we are confident in Chembio's future.

- (a) **Disclosure Controls and Procedures.** Under the supervision and with the participation of our senior management, consisting of our principal executive officer and our principal 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. Based on this evaluation, our management, including our principal executive officer and principal financial officer, concluded that as of September 30, 2017 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. On January 9, 2017, the Company acquired all the outstanding stock of Chembio Diagnostics Malaysia Sdn Bhd ("CDM") (formally known as RVR Diagnostics Sdn Bhd), which became a wholly-owned subsidiary of the Company as a result of the acquisition. This report on controls does not include controls and procedures concerning CDM.
- (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 nine months ended September 30, 2017, except for CDM, 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	Bylaws and Bylaw Amendments. (2)
3.3	Certificate of Designation of Series D Preferred Stock (13)
4.1	2008 Stock Incentive Plan, as amended. (3)
4.2	Form of Option, for 2008 Stock Incentive Plan (4)
4.3	2014 Stock Incentive Plan (5)
4.4	Form of Option, for 2014 Stock Incentive Plan (6)
4.5	Rights Agreement, dated as of March 8, 2016 (7)
4.6	Form of Warrant (to be filed by amendment)
10.1*	Employment Agreement dated effective as of March 13, 2017 with John J. Sperzel III (15)
10.2*	Employment Agreement dated March 5, 2016 with Javan Esfandiari (8)
10.3*	Employment Agreement effective May 22, 2017 with Sharon Klugewicz
10.4	Sales Agreement dated as of June 27, 2017, between Chembio Diagnostics, Inc. and Cantor Fitzgerald & Co. (9)
10.5*	Employment Agreement dated January 9, 2017 with Magentiren Vajuram (15)
10.6*	Employment Agreement dated January 9, 2017 with Avijit Roy (15)
10.7	HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Alere and StatSure. (10)
10.8	HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (10)
10.9	Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (10)
10.10	Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (10)
10.11	2015 Omnibus Agreement (11)
10.12	Amended And Restated Stock Purchase Agreement, dated as of December 7, 2016, by and among Chembio Diagnostics, Inc., RVR Diagnostics Sdn Bhd, Avijit Roy and Magentiren Vajuram (14)
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 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 April 7, 2016.
8 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on March 14, 2016.
9 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 27, 2017.
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.
13 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on April 7, 2016.
14 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on January 10, 2017.
15 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on May 9, 2017.

(*) 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.

Chembio Diagnostics, Inc.

Date: November 8, 2017

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

Date: November 8, 2017

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 8, 2017

/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 8, 2017

/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, 2017, 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 undersigned's knowledge and belief:

(1) This Form 10-Q for the quarter ended September 30, 2017 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, 2017 fairly presents, in all material respects, the financial condition and results of operations of Chembio Diagnostics, Inc. for the periods presented therein.

Dated: November 8, 2017 /s/ John J. Sperzel III
John J. Sperzel III
Chief Executive Officer

Dated: November 8, 2017 /s/ Richard J. Larkin
Richard J. Larkin
Chief Financial Officer

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is entered into as of the 14th day of September, 2017 (the "Effective Date"), by and between Chembio Diagnostics, Inc., a Nevada corporation (the "Company"), and Sharon Klugewicz ("Employee"). Employee and the Company are sometimes referred to individually as a "Party" and collectively as the "Parties".

In consideration of the mutual covenants, promises and agreements herein contained, the Company and Employee hereby covenant, promise and agree to and with each other as follows:

1. Employment. The Company shall employ Employee and Employee shall perform services for and on behalf of the Company upon the terms and conditions set forth in this Agreement.
2. Positions and Duties of Employment. Employee shall be required to devote her full energy, skill and best efforts as required to the furtherance of her managerial duties with the Company as the Company's President, Americas Region. While serving in such capacities, Employee shall have the responsibilities, duties, obligations, rights, benefits and requisite authority as is customary for her position and as may be determined by the Company's Board of Directors (the "Board").

Employee understands that her employment as President, Americas Region of the Company involves a high degree of trust and confidence, that she is employed for the purpose of furthering the Company's reputation and improving the Company's operations and profitability, and that in executing this Agreement she undertakes the obligations set forth herein to accomplish such objectives. Employee agrees that she shall serve the Company fully, diligently, competently and to the best of her ability. Employee certifies that she fully understands her right to discuss this Agreement with her attorney, that she has availed herself of this right to the extent that she desires, that she has carefully read and fully understands this entire Agreement, and that she is voluntarily entering into this Agreement.

3. Duties. Employee shall perform the following services for the Company:
 - (a) Employee shall serve as President, Americas Region of the Company, or in such other position as determined by the Board, and in those capacities shall work with the Company to pursue the Company's plans as directed by the Board.
 - (b) Employee shall perform duties with the functions of an officer of the Company, subject to the direction of the Board.
 - (c) During the Term (as defined in Section 4 below) of this Agreement, Employee shall devote substantially all of Employee's business time to the performance of Employee's duties under this Agreement. Without limiting the foregoing, Employee shall perform services on behalf of the Company for at least forty hours per week, and Employee shall be reasonably available at the request of the Company at other times, including weekends and holidays, to meet the needs and requests of the Company's customers.
 - (d) During the Term, Employee will not engage in any other activities or undertake any other commitments that conflict with or take priority over Employee's responsibilities and obligations to the Company and the Company's customers, including without limitation those responsibilities and obligations incurred pursuant to this Agreement.

4. Term. Unless terminated earlier as provided for in this Agreement, the term of this Agreement shall be for one year, commencing on the Effective Date and ending on the first anniversary of the Effective Date (the "Term"). If the employment relationship is terminated by either Party, Employee agrees to cooperate with the Company and with the Company's new management with respect to the transition of the new management in the operations previously performed by Employee. Upon Employee's termination, Employee agrees to return to the Company all Company documents (and all copies thereof), any other Company property in Employee's possession or control, and any materials of any kind that contain or embody any proprietary or confidential material of the Company.

5. Compensation. As compensation for the services to be performed by Employee during the Term, Company shall pay Employee the following a compensation:

(a) A base salary at an annual rate of \$280,000, subject to periodic review by the Board or the Compensation Committee of the Board (the "Committee"), payable in accordance with the Company's customary payroll practices (the "Base Salary").

(b) A performance-based bonus (the "Performance Bonus") of up to 37.5% of the Base Salary, to be comprised of the same components in the same ratios as for the Company's other executive officers.

6. Certain Additional Provisions Relating to Compensation and Other Employee Benefits.

(a) If Employee is eligible, the Company shall include Employee in any profit sharing plan, executive stock option plan, long term incentive program, pension plan, retirement plan, medical and/or hospitalization plan, and/or any and all other benefit plans, except for disability and life insurance, which may be placed in effect by the Company for the benefit of the Company's executive officers during the Term. Except for the fact that the Company at all times shall provide employee with all or at least a portion of Employee's medical and/or hospitalization insurance, which shall not be less than that afforded to the Company's other executive officers, nothing in this Agreement shall limit (i) the Company's ability to exercise the discretion provided to it under any such benefit plan, or (ii) the Company's discretion to adopt, not adopt, amend or terminate any such benefit plan at any time.

(b) Employee shall be entitled to four (4) weeks vacation leave for each year of the Term, as well as sick leave, medical insurance coverage and any other benefits consistent with the Company's plans and policies in effect for the Company's executives from time to time. The Company may modify in its sole and absolute discretion such benefits from time to time as it considers necessary or appropriate.

(c) During the Term, Employee shall be reimbursed for reasonable expenses that are authorized by the Company and that are incurred by Employee for the benefit of the Company in accordance with the standard reimbursement practices of the Company. Any direct payment or reimbursement of expenses shall be made only upon presentation of an itemized accounting conforming in form and content to standards prescribed by the Internal Revenue Service relative to the substantiation of the deductibility of business expenses.

(d) Any payments which the Company shall make to Employee pursuant to this Agreement shall be reduced by standard withholding and other applicable payroll deductions, including, without limitation, federal, state or local income or other taxes, social security and medicare taxes, state unemployment insurance deductions, state disability insurance deductions, and any other applicable tax or deduction (collectively, any withheld taxes and deductions, "Deductions").

7. Confidentiality.

(a) Employee hereby warrants, covenants and agrees that, without the prior express written consent of the Company, and unless required by law, court order or similar process, Employee shall hold in the strictest confidence, and shall not disclose to any person, firm, corporation or other entity, any and all of the Company's information, including, for example, and without limitation, any data related to (i) drawings, sketches, plans or other documents concerning the Company's business or development plans, customers or suppliers, and research and development efforts; (ii) the Company's development, design, construction or sales and marketing methods or techniques; or (iii) the Company's trade secrets and other "know-how" or information not of a public nature, regardless of how such information came to the custody of Employee (collectively, subsections (i), (ii) and (iii) of this Section 7(a), "Information"). For purposes of this Agreement, such Information shall include, but not be limited to, any information regarding a formula, pattern, compilation, program, device, method, technique or process that (A) derives independent economic value, present or potential, not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (B) is the subject of Company efforts.

(b) In the event Employee is required by law, court order or similar process to disclose any Information, Employee shall provide immediate notice of such obligatory disclosure prior to such disclosure, so that the Company, at its sole option, may attempt to seek a protective order or other appropriate remedy to preclude such disclosure.

(c) The warranties, covenants and agreements set forth in this Section 8 shall not expire, shall survive this Agreement, and shall be binding upon Employee without regard to the passage of time or any other event.

8. Company's Right To Inventions and Discoveries

(a) "Inventions" means all improvements, discoveries, inventions, works of authorship, mask works, computer programs, source and object codes, writings, formulas, ideas, processes, techniques, know-how and data, made or conceived or reduced to practice or developed by Employee, either alone or jointly with others as a result of employment at the Company. "Proprietary Rights" means all trade secret, patent, copyright, trademark, trade name, service mark, and other intellectual property rights throughout the world. Inventions and Proprietary Rights do not include inventions that the Employee developed entirely on

Employee's own time without using the Company's equipment, supplies, facilities, or Information except for those inventions that either relate to the Company's actual or anticipated business, research or development or that result from work performed by the Employee for the Company.

(b) Employee hereby assigns and agrees to assign in the future to the Company all of Employee's right, title and interest in and to any and all Inventions and all Proprietary Rights, whether or not subject to protection under the patent, copyright, trademark or industrial design laws, made or conceived or reduced to practice or learned by Employee (solely or jointly with others) during Employee's employment with the Company (including, without limitation such employment prior to the Effective Date) and for a one-year period after Employee's termination of employment with the Company (collectively "Assigned Intellectual Property"). Employee further agrees that all Assigned Intellectual Property is the sole property of the Company.

(c) Employee agrees to promptly notify and fully disclose to the Company all Assigned Intellectual Property, and will take such steps as are deemed necessary to maintain complete and current records of same. Employee will, at the Company's request and expense, whether during or after employment, take such steps as are reasonably necessary to assist the Company in securing, maintaining, defending or enforcing any title and right to Assigned Intellectual Property.

9. Non-Compete. Employee acknowledges and recognizes the highly competitive nature of the Company's business and that Employee's duties hereunder justify restricting Employee's further employment following any termination of employment. Employee further acknowledges and understands that the Company recognizes Employee's importance and value to the Company and thus has provided Employee with the overall compensation package described hereunder in order to induce Employee to enter into this Agreement. Accordingly, Employee agrees that so long as Employee is employed by the Company, and (i) for a period of two (2) years following the termination of this Agreement, Employee shall not induce or attempt to induce any employee of the Company to leave the employ of the Company, or in any way interfere with the relationship between the Company and any other employee; (ii) for a period of one (1) year following the termination of this Agreement, Employee, except when acting at the request of the Company on behalf of or for the benefit of the Company, shall not induce customers, agents or other sources of distribution of the Company's business under contract or doing business with the Company to terminate, reduce, alter or divert business with or from the Company; and (iii) for a period of one (1) year following the termination of this Agreement, Employee shall not, directly or indirectly, either as a principal, agent, employee, employer, consultant, partner, member or manager of a limited liability company, shareholder of a company that does not have securities registered under the Securities Exchange Act of 1934 (the "1934 Act"), or a shareholder in excess of one (1%) percent of a company that has securities registered under the 1934 Act, corporate officer or director, or in any other individual or representative capacity, engage or otherwise participate in any manner or fashion in any business that directly competes with the business activities of the Company in or about any market in which the Company is, or has publicly announced a plan for doing business. Employee further covenants and agrees that the restrictive covenants set forth in this paragraph are reasonable as to duration, terms, and geographical area and that the same protects the legitimate interests of the Company, imposes no undue hardship on Employee, and is not injurious to the public. The covenant set forth under (iii) above shall not apply if Employee's employment is terminated within twelve (12) months of a Change in Control. Ownership by Employee, for investment purposes only, of less than one (1%) percent of any class of securities of a corporation if said securities are listed on a national securities exchange or registered under the 1934 Act shall not constitute a breach of the covenant set forth under (iii) above. Employee acknowledges and understands that, by virtue of her position with the Company, she will have exposure to various entities with which the Company does business or is in discussions to do business. Accordingly, Employee hereby covenants and agrees that, so long as she is employed by the Company, she will not, except with the prior written consent of the Company, solicit or enter into any discussions for a position of employment with any such entities. It is the desire and intent of the Parties that the provisions of this paragraph be enforced to the fullest extent permissible under the laws and public policies applied in each jurisdiction in which enforcement is sought. Accordingly, if any particular portion of this paragraph shall be adjudicated to be invalid or enforceable, this paragraph shall be deemed amended to apply in the broadest allowable manner and to delete therefrom the portion adjudicated to be invalid or unenforceable, such amendment and deletion to apply only with respect to the operation of this paragraph in the particular jurisdiction in which that adjudication is made.

10. Internal Revenue Code Section 409A ("409A") Matters. this Agreement is intended to comply with 409A any ambiguous provisions will be construed in a manner that is compliant with or exempt from the application of 409A. If a provision of the Agreement would result in the imposition of an applicable tax under 409A, the parties agree that such provision shall be reformed to avoid imposition of the applicable tax, with such reformation effected in a manner that has the most favorable result to Employee.

(a) For purposes of 409A, each payment or amount due under this Agreement shall be considered a separate payment, and Employee's entitlement to a series of payments under this Agreement is to be treated as an entitlement to a series of separate payments.

(b) If (x) Employee is a "specified employee," as such term is defined in 409A and determined as described below in this Paragraph 10(b), and (y) any payment due under this Agreement is subject to 409A and is required to be delayed under 409A because Employee is a specified employee, that payment shall be payable on the earlier of (A) the first business day that is six months after Employee's separation from service, as such term is defined in 409A, (B) the date of Employee's death, or (C) the date that otherwise complies with the requirements of 409A. this Paragraph 10(b) shall be applied by accumulating all payments that otherwise would have been paid within six months of Employee's separation and paying such accumulated amounts on the earliest business day which complies with the requirements of 409A. For purposes of determining the identity of specified employees, the Board may establish procedures as it deems appropriate in accordance with 409A.

11. Termination.

(a) If Employee's employment is terminated by the Company without Cause, or if Employee terminates her employment for Reasonable Basis (as defined below), then the Company shall, in exchange for Employee's execution of a general release and waiver of claims against the Company as of the termination date in a form reasonably acceptable to the Company, continue to pay as severance Employee's Base Salary for a period of six months following the date such general release and waiver of claims is executed. Such payments shall be made in accordance with the Company's customary payroll practices, and shall be subject to all applicable Deductions. In the event of any such termination set forth in this Section 11(a), Employee will not be entitled to any additional cash compensation or benefits beyond what is provided in the first sentence of this Section 12(a).

(i) For purposes of this Agreement, "Cause" shall mean that the Board, acting in good faith based upon the information then known to the Company, determines that Employee has engaged in or committed any of the following: (A) willful misconduct, gross negligence, theft, fraud, or other illegal conduct; (B) refusal or unwillingness to perform Employee's duties; (C) performance by Employee of Employee's duties determined by the Board to be inadequate in a material respect; (D) breach of any applicable non-competition provision, confidentiality provision or other proprietary information or inventions agreement between Employee and the Company; (E) inappropriate conflict of interest; (F) insubordination; (G) failure to follow the directions of the Board or any committee thereof; (H) any other material breach of this Agreement. In addition, an indictment or conviction of any felony, or any entry of a plea of nolo contendere, under the laws of the United States or any State shall be considered "Cause" hereunder. "Cause" shall be specified in a notice of termination to be delivered by the Company to Employee no later than the date as of which termination is effective.

(ii) For purposes of this Agreement, "Reasonable Basis" shall mean (A) a material breach of this Agreement by the Company, provided, however, that Employee shall provide written notice to the Company of any alleged material breach, and any alleged material breach will only be considered a material breach if the Company fails to cure such breach within thirty days after receiving notice of such breach; (B) termination of Employee's employment by the Company without Cause during the term hereof; (C) a reduction in Employee's salary, except to the extent that a majority of the other executive officers of the Company incur reductions of salary that average no less than the percentage reduction incurred by Employee; (D) without Employee's consent, a material reduction in Employee's title, duties, or responsibilities; or (E) termination of Employee's employment by Employee within six (6) months after a "Change of Control," which is defined as any of the following:

- (1) any consolidation or merger of the Company in which the Company is not the continuing or surviving corporation, other than a merger of the Company in which the holders of the Company's voting common stock immediately prior to the merger own a majority of the voting common stock of the surviving corporation immediately after the merger;
- (2) any sale, lease, exchange or other transfer (in one transaction or a series of related transactions) of all or substantially all the assets of the Company;
- (3) any approval by the stockholders of the Company of any plan or proposal for the liquidation or dissolution of the Company;
- (4) the acquisition by any person or entity, or any group of persons and/or entities of a majority of the stock entitled to elect a majority of the directors of the Company; or
- (5) subject to applicable law, in a Chapter 11 bankruptcy proceeding, the appointment of a trustee or the conversion of a case involving the Company to a case under a Chapter 7 bankruptcy proceeding.

(b) In the event that Employee's employment with the Company is terminated for Cause, by reason of Employee's death or disability, or due to Employee's resignation or voluntary termination (other than for a Reasonable Basis), then all compensation (including, without limitation, any Base Salary, and the right to receive a Performance Bonus, and benefits, and the vesting of any unvested Restricted Options, will cease as of the effective date of such termination, and Employee shall receive no severance benefits, or any other compensation; provided that Employee shall be entitled to receive all compensation earned and all benefits and reimbursements due through the effective date of termination.

(c) Employee agrees that the payments contemplated by this Agreement shall constitute the exclusive and sole remedy for any termination of employment, and Employee covenants not to assert or pursue any other remedies, at law or in equity, with respect to any termination of employment.

(d) Any Party terminating this Agreement shall give prompt written notice to the other Party hereto advising such other Party of the termination of this Agreement stating in reasonable detail the basis for such termination (the "Notice of Termination"). The Notice of Termination shall indicate whether termination is being made for Cause (if the Company has terminated the Agreement) or for a Reasonable Basis (if Employee has terminated the Agreement).

12. Remedies. If there is a breach or threatened breach of any provision of Section 7, 8, 9, or 11 of this Agreement, the Company will suffer irreparable harm and shall be entitled to an injunction restraining Employee from such breach. Nothing herein shall be construed as prohibiting the Company from pursuing any other remedies for such breach or threatened breach.

13. Severability. It is the clear intention of the Parties to this Agreement that no term, provision or clause of this Agreement shall be deemed to be invalid, illegal or unenforceable in any respect, unless such term, provision or clause cannot be otherwise construed, interpreted, or modified to give effect to the intent of the Parties and to be valid, legal or enforceable. The Parties specifically charge the trier of fact to give effect to the intent of the Parties, even if in doing so, invalidation of a specific provision of this Agreement is required to make the Agreement consistent with the foregoing stated intent. In the event that a term, provision, or clause cannot be so construed, interpreted or modified, the validity, legality and enforceability of the remaining provisions contained herein and other application(s) thereof shall not in any way be affected or impaired thereby and shall remain in full force and effect.

14. Waiver of Breach. The waiver by the Company or Employee of the breach of any provision of this Agreement by the other Party shall not operate or be construed as a waiver of any subsequent breach by that Party.

15. Entire Agreement. this document contains the entire agreement between the Parties and supersedes all prior oral or written agreements, if any, concerning the subject matter hereof or otherwise concerning Employee's employment by the Company (except with respect to shares, and options to purchase shares, of the Company's Common Stock previously granted to Employee). this Agreement may not be changed orally, but only by a written agreement signed by both Parties.

16. Governing Law. this Agreement, its validity, interpretation and enforcement, shall be governed by the laws of the State of New York, excluding conflict of laws principles. Employee hereby expressly consents to personal jurisdiction in the state and federal courts located in Suffolk County, NY for any lawsuit filed there against him by the Company arising from or relating to this Agreement.

17. Notices. Any notice pursuant to this Agreement shall be validly given or served if that notice is made in writing and delivered personally or sent by certified mail or registered, return receipt requested, postage prepaid, to the following addresses:

If to Company: Chembio Diagnostics, Inc.

3661 Horseblock Road, Suite A

Medford, NY 11763

Attention: Chief Executive Officer

If to Employee: To the address for Employee
set forth below her signature.

All notices so given shall be deemed effective upon personal delivery or, if sent by certified or registered mail, five business days after date of mailing or, if sent by overnight courier, one business day after dispatch. Either Party, by notice so given, may change the address to which her or its future notices shall be sent.

18. Assignment and Binding Effect. this Agreement shall be binding upon Employee and the Company and shall benefit the Company and its successors and assigns. this Agreement shall not be assignable by Employee.

19. Headings. The headings in this Agreement are for convenience only; they form no part of this Agreement and shall not affect its interpretation.

20. Construction. Employee represents she has (a) read and completely understands this Agreement and (b) had an opportunity to consult with such legal and other advisers as she has desired in connection with this Agreement. This Agreement shall not be construed against any one of the Parties.

21. Directors' and Officers' Insurance. The Company is to maintain directors' and officers' insurance in an amount reasonably determined by the Board.

22. Key Man Insurance. The Company has purchased, or may purchase, one or more "key man" insurance policies on Employee's life, each of which will be payable to and owned by the Company. The Company, in its sole discretion, may select the amount and type of key man life insurance purchased, and Employee will have no interest in any such policies. Employee will cooperate with the Company in securing and maintaining this key man insurance by submitting to all required medical examinations, supplying all information and executing all documents required in order for the Company to secure and maintain the insurance.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed on the respective dates set forth below to be effective as of May 22, 2015.

Employee:

Sharon Klugewicz, Individually

3661 Hoseblock Road
Medford, NY 11763

Date:

Company:

Chembio Diagnostics, Inc.

By:

John J. Sperzel III, Chief Executive Officer

Date: