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

FORM 10 - Q

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

For the quarterly period ended September 30, 2016

OR
□ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from: _____ to _____

000-30379
(Commission File Number)

Chembio Diagnostics, Inc.
(Exact name of registrant as specified in its charter)

Nevada	**88-0425691**
(State or other jurisdiction of incorporation)	*(IRS Employer Identification Number)*

3661 Horseblock Road
Medford, New York 11763
(Address of principal executive offices including zip code)
(631) 924-1135
(*Registrant's telephone number, including area code)*
N/A
(Former Name or Former Address, if Changed Since Last Report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes ☒ No □

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

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

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

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

As of November 7, 2016, the Registrant had 12,026,847 shares outstanding of its $.01 par value common stock.

Quarterly Report on FORM 10-Q
For The Quarterly Period Ended
September 30, 2016

Table of Contents

Chembio Diagnostics, Inc.

PART I
Item 1. FINANCIAL STATEMENTS

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

	September 30, 2016 (Unaudited)	December 31, 2015
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 12,171,954**	$ 5,376,931
Accounts receivable, net of allowance for doubtful accounts of $52,000 at September 30, 2016 and December 31, 2015, respectively	**4,208,232**	2,422,971
Inventories	**3,427,158**	3,578,025
Prepaid expenses and other current assets	**778,445**	1,256,879
TOTAL CURRENT ASSETS	**20,585,789**	12,634,806
FIXED ASSETS, net of accumulated depreciation	**1,847,317**	2,374,308
OTHER ASSETS:		
Deferred tax asset, net of valuation allowance	**-**	5,467,143
License agreements, net of current portion	**25,000**	100,000
Deposits on manufacturing equipment	**46,968**	30,918
Deposits and other assets	**179,788**	209,169
TOTAL ASSETS	**$ 22,684,862**	$ 20,816,344
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 2,588,393**	$ 2,801,432
Deferred revenue	**453,006**	353,406
TOTAL LIABILITIES	**3,041,399**	3,154,838
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock - 10,000,000 shares authorized; none outstanding	**-**	**-**
Common stock - $.01 par value; 100,000,000 shares authorized; 12,026,847 and 9,628,248 shares issued and outstanding for September 30, 2016 and December 31, 2015, respectively	**120,268**	96,282
Additional paid-in capital	**60,637,903**	47,890,642
Accumulated deficit	**(41,114,708)**	(30,325,418)
TOTAL STOCKHOLDERS' EQUITY	**19,643,463**	17,661,506
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 22,684,862**	$ 20,816,344

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	For the three months ended		For the nine months ended	
	September 30, 2016	**September 30, 2015**	**September 30, 2016**	**September 30, 2015**
REVENUES:				
Net product sales	**$ 2,502,097**	$ 6,209,625	**$ 10,453,188**	$ 18,145,864
License and royalty revenue	**77,754**	19,084	**133,850**	34,017
R&D, milestone and grant revenue	**1,166,610**	658,665	**3,026,927**	1,654,788
TOTAL REVENUES	**3,746,461**	6,887,374	**13,613,965**	19,834,669
Cost of product sales	**1,794,364**	3,976,840	**6,916,015**	11,218,385
GROSS MARGIN	**1,952,097**	2,910,534	**6,697,950**	8,616,284
OPERATING EXPENSES:				
Research and development expenses	**2,263,719**	1,570,044	**6,265,483**	4,911,587
Selling, general and administrative expenses	**1,832,451**	1,919,551	**5,430,668**	6,057,221
	4,096,170	3,489,595	**11,696,151**	10,968,808
LOSS FROM OPERATIONS	**(2,144,073)**	(579,061)	**(4,998,201)**	(2,352,524)
OTHER INCOME:				
Interest expense	-	(749)	-	(749)
Interest income	**5,855**	353	**9,729**	1,844
	5,855	(396)	**9,729**	1,095
LOSS BEFORE INCOME TAXES	**(2,138,218)**	(579,457)	**(4,988,472)**	(2,351,429)
Income tax provision (benefit)	-	(142,300)	**5,800,818**	(603,370)
NET LOSS	**$ (2,138,218)**	$ (437,157)	**$ (10,789,290)**	$ (1,748,059)
Basic loss per share	**$ (0.19)**	$ (0.05)	**$ (1.06)**	$ (0.18)
Diluted loss per share	**$ (0.19)**	$ (0.05)	**$ (1.06)**	$ (0.18)
Weighted average number of shares outstanding, basic	**11,142,090**	9,628,248	**10,150,737**	9,625,282
Weighted average number of shares outstanding, diluted	**11,142,090**	9,628,248	**10,150,737**	9,625,282

See accompanying notes to condensed consolidated financial statements

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

	September 30, 2016	September 30, 2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	**$ 11,928,304**	$ 18,468,607
Cash paid to suppliers and employees	**(17,614,106)**	(21,054,210)
Interest expense	**-**	(749)
Interest received	**9,729**	1,844
Net cash used in operating activities	**(5,676,073)**	(2,584,508)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of License	**-**	(450,000)
Acquisition of and deposits on fixed assets	**(79,877)**	(477,553)
Net cash used in investing activities	**(79,877)**	(927,553)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option exercises	**57,575**	**-**
Proceeds from line of credit	**-**	600,000
Payment of credit line	**-**	(600,000)
Proceeds from sale of common stock, net	**12,493,398**	-
Net cash provided by financing activities	**12,550,973**	**-**
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**6,795,023**	(3,512,061)
Cash and cash equivalents - beginning of the period	**5,376,931**	4,614,538
Cash and cash equivalents - end of the period	**$ 12,171,954**	$ 1,102,477
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net Loss	**$ (10,789,290)**	$ (1,748,059)
Adjustments:		
Depreciation and amortization	**876,103**	981,579
Deferred taxes	**5,800,818**	(603,370)
Share based compensation	**220,274**	267,850
Changes in assets and liabilities:		
Accounts receivable	**(1,785,261)**	(1,176,062)
Inventories	**150,867**	627,762
Prepaid expenses and other current assets	**(37,626)**	(249,915)
Deposits and other assets	**1,481**	**-**
Accounts payable and accrued liabilities	**(213,039)**	(494,293)
Customer deposits and deferred revenue	**99,600**	(190,000)
Net cash used in operating activities	**$ (5,676,073)**	$ (2,584,508)
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	**$ 49,590**	$ 20,017

See accompanying notes to condensed consolidated financial statements

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. (the "Company" or "Chembio") and its wholly-owned subsidiary, Chembio Diagnostic Systems Inc., develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company's main lateral flow products are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA in 2006; the third is sold for export only. In addition the Company has several products based on its patented Dual Path Platform (DPP®) technology, including a HIV test approved by the FDA in 2013 and CLIA-Waived in 2014. Lateral Flow Rapid HIV tests represented 54% of the Company's product revenues in the first nine months of 2016. The Company's products based on its DPP® platform represented approximately 43% of the Company's product revenues in the first nine months of 2016. The Company also has other rapid tests and components that together represented approximately 3% of product sales in the first nine months of 2016. The Company's products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments, both domestically and internationally. Chembio's products are sold under the Company's STAT PAK®, SURE CHECK®, STAT-VIEW® or DPP® registered trademarks, or under the private labels of its marketing partners. All of the Company's products that are currently being developed are based on its patented DPP®, which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology.

NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

a) Basis of Presentation:

The preceding (a) condensed consolidated balance sheet as of December 31, 2015, which has been derived from audited financial statements, and (b) the unaudited interim condensed consolidated financial statements as of September 30, 2016 and for the three and nine-month periods ended September 30, 2016 and 2015, 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, 2015, 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, 2016, its condensed consolidated results of operations for the three and nine-month periods ended September 30, 2016 and 2015, respectively, and its condensed consolidated cash flows for the nine-month periods ended September 30, 2016 and 2015, as applicable, have been made. The interim results of operations are not necessarily indicative of the operating results for the full fiscal year or any future periods.

The Company currently has positive working capital; it has increased cash approximately $6.80 million for the nine months ended September 30, 2016. See Note 5. The Company closed on 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 $12.5 million. Approximately $2.68 million of the total $4.21 million of accounts receivable is comprised from one customer, and the Company has a high degree of confidence that the receivables are fairly stated and collectible from this customer.

b) Revenue Recognition:

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

For certain contracts, the Company recognizes revenue from non-milestone payments and grant revenues when earned. Grants are invoiced after expenses are incurred. Revenues from projects or grants funded in advance are deferred until earned. Deferred revenues not earned were $453,006 and $353,406 as of September 30, 2016 and December 31, 2015, 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, 2016	December 31, 2015
Raw materials	**$ 1,881,144**	$ 2,248,371
Work in process	**655,777**	370,340
Finished goods	**890,237**	959,314
	$ 3,427,158	$ 3,578,025

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, 2016 and 2015, have been included in the earnings per share computations:

	For the three months ended		For the nine months ended	
	September 30, 2016	**September 30, 2015**	**September 30, 2016**	**September 30, 2015**
Basic	11,142,090	9,628,248	10,150,737	9,625,282
Diluted	11,142,090	9,628,248	10,150,737	9,625,282

As there were losses for the three and nine months ended September 30, 2016 and 2015, no common share equivalents are included in the diluted per share computations.

There were 614,949 and 650,728 weighted-average number of options outstanding as of September 30, 2016 and 2015, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended September 30, 2016 and 2015 respectively. There were 677,050 and 661,570 weighted-average number of options outstanding as of September 30, 2016 and 2015, respectively, that were not included in the calculation of diluted per common share equivalent for the nine months ended September 30, 2016 and 2015, 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, 2016, there were 452,534 options exercised and 227,931 options outstanding under the SIP.

Effective June 19, 2014, the Company's stockholders voted to approve the 2014 Stock Incentive Plan ("2014-SIP"), with 800,000 shares of Common Stock available to be issued. Under the terms of the 2014-SIP, the Compensation Committee of the Company's Board has the discretion to select the persons to whom awards are to be granted and the number of shares of common stock to be covered by each grant. Awards can be incentive stock options, restricted stock and/or restricted stock units. The awards become vested at such times and under such conditions as determined by the Compensation Committee at the time of the initial stock option grant. As of September 30, 2016, there were no options exercised, 129,750 options outstanding and 670,250 options or shares still available to be issued under the 2014-SIP.

There were 106,875 stock options granted during the nine months ended September 30, 2016 and none for the nine months ended 2015. The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the nine months ended September 30, 2016, was $2.77 per share. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon the historical volatility of our stock. The expected term is based on historical information.

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

	For the three months ended		For the nine months ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Expected term (in years)	n/a	n/a	4.5 to 5.0	n/a
Expected volatility	n/a	n/a	43.00% to 48.66%	n/a
Expected dividend yield	n/a	n/a	0 %	n/a
Risk-free interest rate	n/a	n/a	0.90 % to 0.97%	n/a

The Company's results for the three-month periods ended September 30, 2016 and 2015 include share-based compensation expense, consisting solely of stock options, totaling $74,100 and $72,200, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within research and development ($27,300 and $14,800, respectively) and selling, general and administrative expenses ($46,800 and $57,400, respectively). The results for the nine-month periods ended September 30, 2016 and 2015 include share-based compensation expense, consisting solely of stock options, totaling approximately $220,300 and $267,900, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within research and development ($62,000 and $47,900, respectively) and selling, general and administrative expenses ($158,300 and $220,000, 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, 2016 and 2015 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, 2016:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2015	**649,478**	**$ 3.75**	**3.21 years**	**$ 1,032,362**
Granted	106,875	7.05		
Exercised	191,804	3.73		
Forfeited/expired/cancelled	-	-		
Outstanding at September 30, 2016	**564,549**	**$ 4.38**	**3.60 years**	**$ 1,773,657**
Exercisable at September 30, 2016	**255,549**	**$ 4.13**	**2.90 years**	**$ 850,302**

As of September 30, 2016, there was $372,716 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, 2016 and 2015 was approximately $237,095 and $332,500, respectively.

f) Geographic Information:

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

The Company produces only one group of similar products known collectively as "rapid medical tests". In addition, the Company generates revenue from R&D, milestone and grant revenue and from license and royalties, all of which are currently earned in the U.S. Management believes that it operates in a single business segment. Net product sales by geographic area are as follows:

	For the three months ended		For the nine months ended	
	September 30, 2016	**September 30, 2015**	**September 30, 2016**	**September 30, 2015**
Africa	**$ 577,108**	$ 341,520	**$ 1,686,327**	$ 3,049,257
Asia	**34,116**	37,569	**187,105**	147,722
Europe	**313,664**	474,164	**642,427**	696,998
North America	**903,327**	1,579,588	**3,953,469**	3,965,356
South America	**673,882**	3,776,784	**3,983,860**	10,286,531
	$ 2,502,097	$ 6,209,625	**$ 10,453,188**	$ 18,145,864

g) Accounts Payable and Accrued Liabilities:

Accounts payable and accrued liabilities consist of:

	September 30, 2016	**December 31, 2015**
Accounts payable – suppliers	**$ 1,179,884**	$ 1,260,520
Accrued commissions	**359,978**	129,192
Accrued royalties / license fees	**338,162**	732,301
Accrued payroll	**227,546**	146,962
Accrued vacation	**269,472**	244,810
Accrued bonuses	**-**	177,700
Accrued expenses – other	**213,351**	109,947
TOTAL	**$ 2,588,393**	$ 2,801,432

h) Recent Accounting Pronouncements Affecting the Company:

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, "Revenue from Contracts with Customers" ("ASU 2014-09"), which supersedes nearly all existing revenue recognition guidance under accounting principles generally accepted in United States ("U.S. GAAP"). The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 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 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 ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the method by which we will adopt the standard in 2018.

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 will be effective for Chembio beginning in 2018, with early adoption permitted. The Company does not believe this new accounting standard update will have a material impact on its consolidated financial statements.

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. The Company is currently assessing the impact on its consolidated financial position and results of operations.

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 is currently evaluating the impact of the provisions of ASU 2016-09.

NOTE 3 — COLLABORATIVE RESEARCH AND DEVELOPMENT ARRANGEMENTS:

a) RVR DPP® technology transfer agreement:

In February 2014, the Company entered into a technology transfer agreement with RVR Diagnostics Sdn Bhd for $1,500,000. The agreement was modified in September 2014. The Company did not earn revenues during the nine-month periods ended September 30, 2016 and 2015, respectively from this agreement. The Company earned $1,250,000 from this grant from inception through September 30, 2016. See Note 8, "SUBSEQUENT EVENT".

b) Dengue agreement:

In October 2014, the Company entered into a technology development agreement with a diagnostics company for $300,000. The Company earned none and $140,000 for the nine-month periods ended September 30, 2016 and 2015, respectively, from this agreement. The Company earned $300,000 from this grant from inception through September 30, 2016 and the development is completed.

c) Brain Injury agreement:

In January 2015, the Company entered into a technology development agreement with Perseus Science Group LLC for $946,000. The Company earned $180,381 and $300,000 for the nine-month periods ended September 30, 2016 and 2015, respectively, from this agreement. The Company earned $650,000 from this grant from inception through September 30, 2016.

d) Malaria agreements:

In January 2015, the Company was awarded a grant from the Bill & Melinda Gates Foundation for $307,000. The Company earned none and $307,000 for the nine-month periods ended September 30, 2016 and 2015, respectively, from this agreement. The Company earned $307,000 from this grant from inception through September 30, 2016 and the development is completed.
In April 2016, the Company was awarded a grant from the Bill & Melinda Gates Foundation for $678,000. The Company earned $224,938 for the nine-month period ended September 30, 2016 from this agreement, which is the total amount earned from this grant from inception through September 30, 2016.

e) Cancer agreement:

In October 2014, the Company entered into a technology development agreement with an international diagnostics company for $320,000. The Company earned $65,000 and $165,000 for the nine-month periods ended September 30, 2016 and 2015, respectively, from this agreement. The Company earned $270,000 from this grant from inception through September 30, 2016.

f) 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 $2,259,786 and none for the nine-month periods ended September 30, 2016 and 2015, respectively, from this agreement. The Company earned $2,668,265 from this grant from inception through September 30, 2016.

g) BARDA Zika agreement:

In August 2016, the Company was awarded a grant for 5,933,742 from BARDA, which is part of the U.S. Department of Health And Human Resources. The Company earned $221,563 for the nine-month period ended September 30, 2016 from this agreement. The Company earned $221,563 from this grant from inception through September 30, 2016.

NOTE 4 — 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 5 — COMMON STOCK, WARRANTS AND OPTIONS:

The Company closed on 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 $12,493,398. 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.

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 "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 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 Employment Agreement was entered into. The exercise price for these options was to be 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 6 — COMMITMENTS, CONTINGENCIES, AND CONCENTRATIONS:

a) Economic Dependency:

The following table discloses product sales and accounts receivable that 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, 2016		September 30, 2015		September 30, 2016		September 30, 2015		September 30, 2016	September 30, 2015
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales		
Customer 1	$ 662,841	26	$ 3,749,480	60	$ 3,919,011	37	$ 10,093,512	56	$ 2,683,910	$ 7,871,679
Customer 2	*	*	1,116,504	18	1,796,477	17	2,841,803	16	-	563,385
Customer 3	*	*	*	*	*	*	1,750,722	10	*	189,472

(*) 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, 2016		September 30, 2015		September 30, 2016		September 30, 2015		September 30, 2016	September 30, 2015
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	$ 132,122	11	$ *	*	$ 558,044	12	$ *	*	$ 53,682	$ *
Vendor 2	*	*	167,670	9	*	*	654,253	12	*	46,866

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

The Company currently buys materials which are purchased under intellectual property rights agreements and are important components in its products. Management believes that other suppliers could provide similar materials on comparable terms as the vendors shown in this table. A change in suppliers, however, could cause a delay in manufacturing, 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 three key employees: CEO John J. Sperzel II; COO Sharon Klugewicz; and CSTO Javan Esfandiari. The contracts call for salaries presently aggregating $975,000 per year. The Sperzel contract expires in March 2017, the Klugewicz contract expires in May 2017, and the Esfandiari contract expires in March 2019. In connection with the Sperzel contract that expires in March 2017, the Company issued, in March 2014, options to purchase 250,000 common shares of stock, with 1/5 vesting on each of the first five anniversaries of the grant. In connection with the Klugewicz contract that expires in May 2017, no options were issued; however in connection with the prior Klugewicz contract that expired in May 2015, the Company issued, in May 2013, options to purchase 5,000 shares of common stock, with one-half vesting on each of the first and second anniversaries of the grant. In connection with the Esfandiari contract that expires in March 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.

NOTE 7 — INCOME TAXES:

The Company recorded a full valuation allowance during the nine months ended September 30, 2016, on its deferred tax assets. Changes in expectations since the filing of our Form 10-K for 2015 and our Form 10-Q for the three months ended March 31, 2016 resulted in a different conclusion and now the Company believes that the valuation allowance is necessary as it is more likely than not that the deferred tax asset will not be realized in the foreseeable future based on information available at this time. This conclusion was reached because of uncertainties related to future taxable income, in terms of both its timing and its sufficiency, which would enable the Company to realize the deferred tax assets.

NOTE 8 — SUBSEQUENT EVENTS:

On November 4, 2016, Chembio entered into an agreement with the two shareholders of RVR Diagnostics Sdn Bhd (RVR), a Malaysia company for Chembio to acquire all the stock and any other equity interests in RVR. The agreement includes the following provisions:

(i) The purchase price at closing shall consist of $1.4 million cash; $1.85 million in Chembio's stock (based on a 15-day volume weighted average trading price ("VWAP")); and Chembio's forgiveness of a $250,000 contingent obligation from RVR to Chembio;

(ii) The two sellers of the RVR stock also will be entitled to receive milestone payments of an aggregate total of up to $100,000 in cash and $150,000 in Chembio's common stock (calculated with the same 15-day VWAP) in increasing amounts up to the $250,000 maximum aggregate milestone payment to the extent that RVR's sales for 2017 exceed $2.25 million;

(iii) Each of the two sellers will be employed by RVR for one year after closing at a salary of $10,000 per month;

(iv) The Company will be entitled to undertake due diligence after signing of the Stock Purchase Agreement;

(v) Each of the two sellers will indemnify the Company for any undisclosed liabilities;

(vi) The Company, immediately after signing the Agreement and as soon as RVR has provided the Company with the RVR financial statements needed for the filing, will file a registration statement with the SEC to register the issuance of the shares to the sellers, and the closing will occur within a few days after the registration statement becomes effective with the SEC;

(vii) Closing of the transaction is subject to a number of other conditions that can be waived by the party for whom the condition is to be satisfied; and

(viii) Upon closing of the acquisition, the directors of RVR will be Magentiren Vajuram, Avijit Roy, Katherine Davis, John Sperzel, and Rich Larkin. Messrs. Vajuram and Roy are the selling stockholders and also the current management of RVR.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The terms "Chembio", "Company,", "we", "us", and "our" refer to Chembio Diagnostics, Inc. and its subsidiary as a consolidated entity, unless the context suggests otherwise.

Overview

This discussion and analysis should be read in conjunction with the accompanying Condensed Consolidated Financial Statements and related notes. The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of any contingent liabilities at the financial statement date, and reported amounts of revenue and expenses during the reporting period. On an ongoing basis, we review our estimates and assumptions. Our estimates are based on our historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results are likely to differ from those estimates under different assumptions or conditions, but we do not believe such differences will materially affect our financial position or results of operations. Our critical accounting policies, the policies we believe are most important to the presentation of our financial statements and require the most difficult, subjective and complex judgments, are outlined below in "Critical Accounting Policies," and have not changed significantly from December 31, 2015.

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, RVR and Bio-Rad.

Research and development ("R&D"), milestone, and grant revenues for the nine months ended September 30, 2016 increased to $3.03 million from $1.65 million in the prior-year period, which was primarily the result of increased R&D project revenues in 2016.

R&D expenses in the nine months ended September 30, 2016 were $6.27 million, compared with $4.91 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.

Research & Development Activities

Sexually Transmitted Disease

- DPP® HIV-Syphilis Assay: The DPP® HIV-Syphilis Assay is a rapid, point-of-care (POC), multiplex test for the simultaneous detection of antibodies to HIV and to Treponema Pallidum (TP) bacteria (the causative agent of syphilis). This novel combination assay was developed to address the growing concern among public health officials regarding the rising co-infection rates of HIV and syphilis as well as mother-to-child transmission (MTCT) of HIV and syphilis. The product was successfully launched in Mexico during 2014, and received approval in 2015 for commercial use by the Brazilian regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA). The DPP® HIV-Syphilis Assay is the only test cleared for commercialization in Brazil for rapid, POC detection of both HIV 1/2 and syphilis. We are developing a U.S. version of the DPP® HIV-Syphilis Assay, designed to meet the performance requirements for the "reverse" algorithm that is currently in clinical use for syphilis testing in the United States. The DPP® HIV-SYP Assay clinical trial is on schedule; initiated in the first quarter of 2016 and, at the current enrollment rate, we expect to complete the trial in the first quarter of 2017.

Fever Disease

- **DPP® Malaria Assay:** The DPP® Malaria Assay is a rapid, POC, multiplex test for the simultaneous detection of plasmodium falciparum and other plasmodium infections. In January 2015, we received a grant from the Bill & Melinda Gates Foundation to expedite the development and feasibility testing of a POC DPP® Malaria Assay. The Company 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. Given these results, we plan to develop and commercialize a family of DPP® Malaria Assays. In April 2016, we received a 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 plan to complete the assay development by the end of 2016 and provide tests to a third party, selected by the Bill & Melinda Gates Foundation, during the first quarter of 2017, to verify performance of the DPP® Malaria Assay.

- **DPP® Fever Panel Assay:** The DPP® Fever Panel Assay 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 and a follow-on grant to add a test for the detection of Zika virus. We plan to complete the assay development, including the addition of Zika, by the end of 2016 and plan to initiate field testing during the first quarter of 2017 in collaboration with FIND.

- **DPP® Dengue Fever Assay:** The DPP® Dengue Fever Assay is a rapid, POC, multiplex test for the detection of IgG/IgM antibodies and NS1 antigens. We completed verification and validation studies, and production of pilot lots, to support preclinical studies. During the second quarter of 2016, we initiated registration to begin initial commercialization in Southeast Asia, which we anticipate in the fourth quarter of 2016.

- **DPP® Zika Assays:** The DPP® Zika Assay is a rapid POC stand-alone test for the simultaneous detection of IgM/IgG antibodies, and the DPP® Dengue/Chikungunya/Zika Assay is a rapid, POC, multiplex test for the simultaneous detection of IgM/IgG antibodies. In February 2016, we received a $550,000 grant from The Paul G. Allen Family Foundation to develop the DPP® Zika Assays. Between March and May 2016, Chembio announced collaborations with Bio-Manguinhos for the development and commercialization of DPP® Zika, DPP® Dengue, DPP® Chikungunya and DPP® Zika/Dengue/Chikungunya Assays. Bio-Manguinhos is 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. In August 2016, we received an award from the U.S. Government (HHS/ASPR/BARDA), for a grant of up to $13.2 million ($5.9 million to develop DPP® Zika Assay and obtain U.S. regulatory approval, and an option for $7.3 million to develop DPP® Zika/Dengue/Chikungunya Assay and obtain U.S. regulatory approval. In September 2016, we received a $330,000 contract award from CDC to initiate a Zika, Dengue and Chikungunya surveillance program in India, Peru, Guatemala and Haiti. We filed the following regulatory submissions: U.S. Food and Drug Administration Emergency Use Authorization (EUA), World Health Organization EUA, Brazil's regulatory agency ANVISA, Mexico's regulatory agency Cofepris, and CE Mark. In late October 2016, we received ANVISA approval (Brazil) and we previously had obtained a CE Mark. As a result, we expect revenue from the sales of our DPP® Zika IgM/IgG Assay in the 4th Quarter of 2016.

- **DPP® Ebola Assay and DPP® Malaria-Ebola Assay:** The DPP® Ebola Assay is a rapid POC test for the detection of Ebola, and the DPP® Malaria-Ebola Assay is a rapid, POC, multiplex test for the simultaneous detection of Malaria and Ebola. In October 2014, we announced plans to develop, validate, and commercialize POC DPP® Assays for Ebola and Febrile Illness. We completed the development of the DPP® Ebola Assay and submitted 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 are 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 a 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 of the DPP® Cancer Assay, which development and verification is 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. We recently finalized institutional review board (IRB) agreements with multiple hospitals and began conducting 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 will be 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 will be developed in collaboration with National Animal Disease Center (NADC) and Infectious Disease Research Institute (IDRI). Under the two-year grant, Chembio will use 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 will be 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 approval of the DPP® HIV-Syphilis Assay was initiated during first quarter of 2016 and is expected to be completed in the first quarter of 2017. We are also pursuing CE Mark for the DPP® HIV-SYP Assay and believe we have sufficient data to obtain CE Mark, which we anticipate in Q1 2017.

DPP® Zika IgM/IgG System: In July of 2016, Chembio obtained a CE Mark for the DPP® Zika IgM/IgG Assay. The DPP® Zika IgM/IgG System, which includes an assay utilizing the patented DPP® technology as well as a digital reader (DPP® Micro reader), are now cleared for commercialization in European countries as well as the majority of the Caribbean nations, not including U.S. territories. In late October of 2016, we received approval from ANVISA, Brazil's regulatory Agency. We have also filed regulatory submissions to U.S. Food and Drug Administration, the World Health Organization, and 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, and income taxes. For a summary of our significant accounting policies, which have not changed from December 31, 2015, see our Annual Report on Form 10-K for the twelve months ended December 31, 2015, which was filed with the SEC on March 8, 2016.

Recent Events

See "Agreement to Acquire RVR Diagnostics Sbn Bhd" under "RECENT DEVELOPMENTS AND CHEMBIO'S PLAN OF OPERATIONS FOR THE NEXT TWELVE MONTHS".

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2016 AS COMPARED WITH THE THREE MONTHS ENDED SEPTEMBER 30, 2015

Income:

For the three months ended September 30, 2016, Loss before income taxes was $2,138,000 compared to $579,000 for the three months ended September 30, 2015. Net Loss for the 2016 period was $2,138,000 as compared to $437,000 for 2015. The increase in Net Loss is primarily attributable to decreased product revenues, decreased product gross margin, and decrease in income tax benefit, partially offset by increased R&D revenues of $508,000. Product gross margin decreased in the three months ended September 30, 2016, as compared with the three months ended September 30, 2015, by $1,525,000 or 68.30%.

Revenues:

Selected Product Categories:	For the three months ended			
	September 30, 2016	September 30, 2015	**$ Change**	**% Change**
Lateral Flow HIV Tests and Components	$ 1,471,458	$ 2,286,629	$ (815,171)	-35.65%
DPP® Tests and Components	997,768	3,783,581	(2,785,813)	-73.63%
Other	32,871	139,415	(106,544)	-76.42%
Net Product Sales	2,502,097	6,209,625	(3,707,528)	-59.71%
License and royalty revenue	77,754	19,084	58,670	307.43%
R&D, milestone and grant revenue	1,166,610	658,665	507,945	77.12%
Total Revenues	$ 3,746,461	$ 6,887,374	$ (3,140,913)	-45.60%

Revenues for our lateral flow HIV tests and related components during the three months ended September 30, 2016 decreased by approximately $815,000 from the same period in 2015. This was primarily attributable to decreased sales to North America of approximately $791,000, decreased sales to Europe of approximately $150,000, decreased sales to South America of approximately $13,000 and Asia of approximately $5,000, partially offset by increased sales to Africa of approximately $145,000. Revenues for our DPP® products during the three months ended September 30, 2016 decreased by approximately $2,786,000 over the same period in 2015, primarily due to decreased sales in Brazil. The increase in R&D, and in milestone and grant revenue, was primarily due to increased R&D project revenues in 2016.

Gross Margin:

	For the three months ended			
	September 30, 2016	September 30, 2015	**$ Change**	**% Change**
Gross Margin per Statement of Operations	$ 1,952,097	$ 2,910,534	$ (958,437)	-32.93%
Less: R&D, milestone, grant, license and royalty revenues	1,244,364	677,749	566,615	83.60%
Gross Margin from Net Product Sales	$ 707,733	$ 2,232,785	$ (1,525,052)	-68.30%
Product Gross Margin %	28.29%	35.96%		

The overall gross margin dollar decrease of $958,000 included a $1,525,000 decrease in gross margin from product sales and was partially offset by a $567,000 increase in non-product revenues. The decrease in net product sales gross margin of $1,525,000 is primarily attributable to the reduction in sales compared to 2015. The net product sales gross margin decrease is primarily affected by two components, one is the decrease in product sales of $3,708,000, which, at the 36.0% margin percentage for September 30, 2015, contributed $1,333,000 to the decrease, and the other is the decreased change in margin percentage of 7.7%, which contributed $192,000 to the balance of the decrease in our net product sales gross margin.

Research and Development:

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

Selected expense lines:	For the three months ended			
	September 30, 2016	September 30, 2015	**$ Change**	**% Change**
Clinical and Regulatory Affairs:				
Wages and related costs	$ 153,500	$ 111,948	$ 41,552	37.12%
Consulting	11,849	3,189	8,660	271.56%
Clinical trials	322,518	9,329	313,189	3,357.16%
Other	15,018	23,177	(8,159)	-35.20%
Total Regulatory	502,885	147,643	355,242	240.61%
R&D Other than Regulatory:				
Wages and related costs	732,775	671,950	60,825	9.05%
Consulting	58,711	31,436	27,275	86.76%
Stock-based compensation	27,263	14,838	12,425	83.74%
Materials and supplies	802,144	566,558	235,586	41.58%
Other	139,941	137,619	2,322	1.69%
Total other than Regulatory	1,760,834	1,422,401	338,433	23.79%
Total Research and Development	$ 2,263,719	$ 1,570,044	$ 693,675	44.18%

Expenses for Clinical & Regulatory Affairs for the three months ended September 30, 2016 increased by $355,000 as compared to the same period in 2015. This was primarily due to the increase in clinical trial expenses of $313,000.

R&D expenses other than Clinical & Regulatory Affairs increased by $338,000 in the three months ended September 30, 2016, as compared with the same period in 2015. The increases were primarily related to an increase in material and supplies, in order to support the increase in our sponsored research.

Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended			
	September 30, 2016	September 30, 2015	**$ Change**	**% Change**
Wages and related costs	$ 844,123	$ 632,308	$ 211,815	33.50%
Consulting	5,969	77,367	(71,398)	-92.28%
Commissions	147,652	476,850	(329,198)	-69.04%
Stock-based compensation	46,750	57,420	(10,670)	-18.58%
Marketing materials	153,465	46,895	106,570	227.25%
Investor relations/investment bankers	67,607	54,977	12,630	22.97%
Legal, accounting and compliance	250,129	179,223	70,906	39.56%
Travel, entertainment and trade shows	115,701	146,309	(30,608)	-20.92%
Other	201,055	248,202	(47,147)	-19.00%
Total S, G &A	$ 1,832,451	$ 1,919,551	$ (87,100)	-4.54%

Selling, general and administrative expenses for the three months ended September 30, 2016, decreased by $87,000 as compared with the same period in 2015, a 4.5% decrease. This decrease resulted primarily from decreases in commissions, primarily due to decreased sales to Brazil, decreases in consulting, travel, entertainment and trade shows, stock-based compensation, and other expense which were partially offset by increases in wages and related costs due to a transition period while sales staff were replaced, professional fees, marketing materials, and investor relations expenses.

Other Income:

	For the three months ended			
	September 30, 2016	September 30, 2015	**$ Change**	**% Change**
Interest income	$ 5,855	$ 353	$ 5,502	1,558.64%
Interest expense	-	(749)	749	-100.00%
Total Other Income	$ 5,855	$ (396)	$ 6,251	-1,578.54%

Other income for the three months ended September 30, 2016 increased to $5,855, from an expense of $396 in the same period in 2015, primarily as a result of interest income received as a result of more cash to invest.

RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2016 AS COMPARED WITH THE NINE MONTHS ENDED SEPTEMBER 30, 2015

Income:

For the nine months ended September 30, 2016, Loss before income taxes was $4,988,000 compared to $2,351,000 for the nine months ended September 30, 2015. Net Loss for the 2016 period was $10,789,000 as compared to $1,748,000 for 2015. The increase in Net Loss is primarily attributable to decreased product revenues and decreased product gross margin and the recording of a $5,801,000 full valuation on our DTA in the 2016 period. Gross margin decreased for the nine months ended September 30, 2016, as compared with the nine months ended September 30, 2015, by $1,918,000, or 22.3%.

Revenues:

Selected Product Categories:	For the nine months ended			
	September 30, 2016	September 30, 2015	**$ Change**	**% Change**
Lateral Flow HIV Tests and Components	$ 5,696,745	$ 7,403,260	$ (1,706,515)	-23.05%
DPP® Tests and Components	4,490,214	10,227,409	(5,737,195)	-56.10%
Other	266,229	515,195	(248,966)	-48.32%
Net Product Sales	10,453,188	18,145,864	(7,692,676)	-42.39%
License and royalty revenue	133,850	34,017	99,833	293.48%
R&D, milestone and grant revenue	3,026,927	1,654,788	1,372,139	82.92%
Total Revenues	$ 13,613,965	$ 19,834,669	$ (6,220,704)	-31.36%

Revenues for our lateral flow HIV tests and related components during the nine months ended September 30, 2016 decreased by approximately $1,707,000 from the same period in 2015. This was primarily attributable to decreased sales to Africa, of approximately $1,476,000, decreased sales to North America of approximately $253,000 and decreased sales to Europe of approximately $21,000, and partially offset by increased sales to Asia of approximately $47,000. Revenues for our DPP® products during the nine months ended September 30, 2016 decreased by approximately $5,737,000 over the same period in 2015, primarily due to decreased sales in Brazil. The increase in R&D, and in milestone and grant revenue, was primarily due to increased R&D project revenues in 2016.

Gross Margin:

	For the nine months ended			
	September 30, 2016	September 30, 2015	**$ Change**	**% Change**
Gross Margin per Statement of Operations	$ 6,697,950	$ 8,616,284	$ (1,918,334)	-22.26%
Less: R&D, milestone, grant, license and royalty revenues	3,160,777	1,688,805	1,471,972	87.16%
Gross Margin from Net Product Sales	$ 3,537,173	$ 6,927,479	$ (3,390,306)	-48.94%
Product Gross Margin %	33.84%	38.18%		

The overall gross margin dollar decrease of $1,918,000 included a $3,390,000 decrease in gross margin from product sales and was partially offset by a $1,472,000 increase in non-product revenues. The decrease in net product sales gross margin of $3,390,000 is primarily attributable to the reduced sales compared to 2015. The net product sales gross margin decrease is primarily affected by two components, one is the decrease in product sales of $7,693,000, which, at the 38.2% margin percentage for September 30, 2015, contributed $2,937,000 to the decrease, and the other is the decreased change in margin percentage of 4.3%, which contributed $453,000 to the balance of the decrease in our net product sales gross margin.

Research and Development:

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

Selected expense lines:	For the nine months ended			
	September 30, 2016	September 30, 2015	**$ Change**	**% Change**
Clinical and Regulatory Affairs:				
Wages and related costs	$ 417,542	$ 365,923	$ 51,619	14.11%
Consulting	28,300	25,550	2,750	10.76%
Clinical trials	481,359	365,469	115,890	31.71%
Other	38,441	66,342	(27,901)	-42.06%
Total Regulatory	965,642	823,284	142,358	17.29%
R&D Other than Regulatory:				
Wages and related costs	2,171,191	2,181,951	(10,760)	-0.49%
Consulting	101,486	69,479	32,007	46.07%
Stock-based compensation	61,983	47,879	14,104	29.46%
Materials and supplies	2,607,179	1,387,446	1,219,733	87.91%
Other	358,002	401,548	(43,546)	-10.84%
Total other than Regulatory	5,299,841	4,088,303	1,211,538	29.63%
Total Research and Development	$ 6,265,483	$ 4,911,587	$ 1,353,896	27.57%

Expenses for Clinical & Regulatory Affairs for the nine months ended September 30, 2016 increased by $142,000 as compared to the same period in 2015. This was primarily due to the increase in clinical trial expenses of $116,000.

R&D expenses other than Clinical & Regulatory Affairs increased by $1,212,000 in the nine months ended September 30, 2016, as compared with the same period in 2015. The increases were primarily related to an increase in material and supplies, in order to support the increase in our sponsored research.

Selling, General and Administrative Expenses:

Selected expense lines:	For the nine months ended			
	September 30, 2016	September 30, 2015	**$ Change**	**% Change**
Wages and related costs	$ $2,408,996	$ $2,355,107	$ $53,889	2.29%
Consulting	124,192	192,473	(68,281)	-35.48%
Commissions	553,931	1,281,754	(727,823)	-56.78%
Stock-based compensation	158,296	219,971	(61,675)	-28.04%
Marketing materials	301,302	154,267	147,035	95.31%
Investor relations/investment bankers	231,769	139,057	92,712	66.67%
Legal, accounting and compliance	731,492	626,133	105,359	16.83%
Travel, entertainment and trade shows	322,909	363,972	(41,063)	-11.28%
Other	597,781	724,487	(126,706)	-17.49%
Total S, G &A	$ $5,430,668	$ $6,057,221	$ ($626,553)	-10.34%

Selling, general and administrative expenses for the nine months ended September 30, 2016, decreased by $627,000 as compared with the same period in 2015, a 10.3% decrease. This decrease resulted primarily from decreases in commissions, primarily due to reduced sales in Brazil, stock-based compensation, travel, entertainment and trade shows and other expenses, which were partially offset by increases in wages and related costs, consulting, marketing materials, investor relations expenses and professional fees.

Other Income:

	For the nine months ended			
	September 30, 2016	September 30, 2015	**$ Change**	**% Change**
Interest income	$ 9,729	$ 1,844	$ 7,885	427.60%
Interest expense	-	(749)	749	-100.00%
Total Other Income	$ 9,729	$ 1,095	$ 8,634	788.49%

Other income for the nine months ended September 30, 2016 increased to $9,729, from an income of $1,095 in the same period in 2015, primarily as a result of interest income received as a result of more cash to invest.

Income tax expense:

The Company recorded a full valuation allowance during the nine months ended September 30, 2016, on its deferred tax assets. Changes in expectations since the filing of our Form 10-K for 2015 and our Form 10-Q for the three months ended March 31, 2016 resulted in a different conclusion, and now the Company believes that the valuation allowance is necessary as it is more likely than not that the deferred tax asset will not be realized in the foreseeable future based on information available at this time. This conclusion was reached because of uncertainties related to future taxable income, in terms of both its timing and its sufficiency, which would enable the Company to realize the deferred tax assets. For the nine months ended September 30, 2016 the Company recognized a $5,801,000 income tax expense and decreased its deferred tax assets.

MATERIAL CHANGES IN FINANCIAL CONDITION

Selected Changes in Financial Condition	As of			
	September 30, 2016	December 31, 2015	**$ Change**	**% Change**
Cash and cash equivalents	$ 12,171,954	$ 5,376,931	$ 6,795,023	126.37%
Accounts receivable, net of allowance for doubtful accounts of $52,000 at September 30, 2016 and December 31, 2015, respectively	4,208,232	2,422,971	1,785,261	73.68%
Inventories	3,427,158	3,578,025	(150,867)	-4.22%
Prepaid expenses and other current assets	778,445	1,256,879	(478,434)	-38.07%
Fixed assets, net of accumulated depreciation	1,847,317	2,374,308	(526,991)	-22.20%
Deferred tax asset, net of valuation allowance	-	5,467,143	(5,467,143)	-100.00%
Deferred revenue	453,006	353,406	99,600	28.18%
Accounts payable and accrued liabilities	2,588,393	2,801,432	(213,039)	-7.60%

Cash increased by $6,795,000 from December 31, 2015, primarily due to net cash provided by financing activities, primarily from cash raised in the sale of common stock, partially offset by cash used in operating activities for the nine months of 2016. In addition there were increases in accounts receivable of $1,785,000 (primarily due to a large customer as described under "Liquidity And Capital Resources"), in non-current deferred tax asset of $5,467,000 and an increase in deferred revenue of $100,000. We experienced a decrease in inventories of $151,000, prepaid expenses of $478,000, fixed assets of $527,000 and accounts payable and accrued liabilities of $213,000.

LIQUIDITY AND CAPITAL RESOURCES

	For the nine months ended			
	September 30, 2016	September 30, 2015	**$ Change**	**% Change**
Net cash used in operating activities	$ (5,676,073)	$ (2,584,508)	$ (3,091,565)	119.62%
Net cash used in investing activities	(79,877)	(927,553)	847,676	-91.39%
Net cash provided by financing activities	12,550,973	-	12,550,973	100.00%
Decrease in cash and cash equivalents	$ 6,795,023	$ (3,512,061)	$ 10,307,084	-293.48%

The Company's cash increased as of September 30, 2016 by $6,795,000 from December 31, 2015, primarily due to net cash provided by financing activities, primarily from cash raised in the sale of common stock, partially offset by cash used in operating activities for the nine months of 2016.

The cash used in operations in the first nine months of 2016 was $5,676,000, which consisted primarily of an increase in accounts receivable of $1,785,000, an increase in prepaid expenses of $38,000 (net of amortization), a decrease in accounts payable and accrued liabilities of $213,000 and a net loss net of non-cash items of $3,892,000, partially offset by cash provided by a decrease in inventories of $151,000, deposits and other assets of $1,000 and an increase in deferred revenue of $100,000. Net loss net of non-cash items includes loss before income taxes of $4,988,000 reduced by non-cash expenses of $876,000 in depreciation and amortization, and of $220,000 in share-based non-cash compensation. The use of cash from investing activities is primarily due to the purchase of fixed assets of $80,000.

The Company currently has positive working capital. It has added approximately $6.8 million in cash for the nine months ended September 30, 2016, primarily due to cash raised in the sale of common stock. Approximately $2.7 million of the total $4.2 million of accounts receivable is related to one customer, and the Company has a high degree of confidence that the receivable is collectible from this customer.

Fixed Asset Commitments

As of September 30, 2016, the Company had $46,968 in deposits on equipment, and $9,400 in commitments for additional equipment purchase obligations.

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

Since June 30, 2016, during the third quarter of 2016, Chembio received several grants to support product development, achieved important regulatory milestones, and significantly strengthened its sales and marketing platform, including the expansion of its distribution network and appointing new leadership to guide the Company's worldwide commercialization effort.

In the fever disease business, Chembio received a contract award from the Centers for Disease Control and Prevention (CDC), and a multi-million dollar grant from the U.S. Department of Health and Human Services (HHS); Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), for the development of rapid POC Zika-related products. On the regulatory front, the Company received CE Mark for its DPP® Zika IgM/IgG Assay during the quarter, and expanded its commercial distribution throughout the Caribbean and in late October 2016, the Company received ANVISA approval.

In the sexually transmitted disease business, the Company continued to make progress with its ongoing clinical trial for the DPP® HIV-Syphilis Assay for the U.S. market, which is expected to be completed during the first quarter of 2017, and also expanded product distribution in the Caribbean region. In other areas, the Company made progress with multiple technology collaborations, and received a grant from the U.S. Department of Agriculture to develop a POC diagnostic test for bovine tuberculosis.

To support the expansion of Chembio's sales and marketing effort, to establish operations in the growing Asian market, to ensure ongoing development of each of Chembio's programs, and to strengthen the Company's balance sheet, Chembio recently executed two important transactions. In August 2016, Chembio closed a public offering of approximately 2.3 million common shares, including the exercise of the underwriter's full allotment, which raised approximately $13.8 million, before expenses. And, in November 2016, Chembio entered into an agreement for the acquisition of RVR Diagnostics Sdn Bhd (RVR), a Malaysia-based, privately-held manufacturer and distributor of POC diagnostic tests for infectious diseases. Subject to satisfaction of the conditions for closing, the acquisition of RVR will provide Chembio with a source of additional revenue, as well as a strategically located and cost-effective manufacturing facility that is anticipated to be important in serving a number of global markets, including the rapidly growing Asian markets. See "Agreement to Acquire RVR Diagnostics Sdn Bhd", below.

Sexually Transmitted Disease

Chembio's sexually transmitted disease product sales decreased during the third quarter of 2016, due primarily to the termination, effective May 31, 2016, of our distribution agreement with the former U.S. distributor of our SURE CHECK® HIV 1/2 Assay, as well as decreased sales of our DPP® HIV and DPP® Syphilis products in Brazil. The decrease in HIV and Syphilis product sales in Brazil was primarily due to the Company's loss of ongoing business as a result of a previously disclosed tender offer in Brazil having been awarded to a competitor at an extremely low price point. Despite the loss of this tender, Chembio continues to supply other DPP® products to Bio-Manguinhos/Fiocruz, and the Ministry of Health in Brazil, as well as other organizations in Latin America, and we believe this region will continue to be a strong market for Chembio. In particular, we believe our ongoing DPP® HIV Confirmatory and DPP® Leishmania Assays, as well as the anticipated launch of the DPP® Zika IgM/IgG Assay and DPP® Micro Reader, which are discussed below, will be important new products in Brazil.

In other regions during the third quarter of 2016, the Company recorded decreases in sales in both Asia and Europe as compared to the third quarter of 2015, due primarily to HIV products. During the same period, the Company recorded a 69% increase in sales to Africa, as compared to the third quarter of 2015.

In the development area, the Company continued to advance the clinical trial for its DPP® HIV-Syphilis Assay for the U.S. market in the third quarter of 2016, which is expected to be completed in the first quarter of 2017. As we've stated previously, it is an important corporate priority to be the first-to-market in the U.S. with an HIV-Syphilis combination test. While the Company is already marketing a DPP® HIV-Syphilis combo assay in Latin America, regulatory standards require additional enhancements for the U.S. market and completion of a clinical trial.

On the sales and marketing front during the third quarter, Chembio entered into exclusive distribution agreements with Isla Lab Caribbean, a leader in the distribution of innovative technology for clinical laboratories, hospitals and other healthcare institutions, for the distribution of Chembio products in more than twenty-five Caribbean nations including Puerto Rico and the U.S. Virgin Islands. The agreements initially cover those sexually transmitted disease products, which have met regulatory requirements to be marketed and sold in the Caribbean region, including: DPP® HIV 1/2 Assay, DPP® HIV/Syphilis Assay (except Puerto Rico and the U.S. Virgin Islands), HIV 1/2 STAT-PAK® Assay, STAT-VIEW® HIV 1/2 Assay (except Puerto Rico and the U.S. Virgin Islands) as well as the fever disease DPP® ZIKA IgM/IgG Assay (except Puerto Rico and the U.S. Virgin Islands). The agreement also includes future Chembio products, which are pending regulatory approval or in development, and which will be discussed in the fever disease section. Chembio is also in the process of submitting the technical dossier for CE Mark which, if obtained, will allow us to commercialize the DPP® HIV-Syphilis Assay in Europe.

In addition to building its distribution network, Chembio recently appointed two senior executives to direct the expansion of the Company's global commercial operations. Robert Passas, Ph.D., joined the Company in October 2016 as President, EMEA and APAC regions, with responsibility for commercial operations in Europe, Middle East, Africa, and Asia. Prior to joining the Company, Mr. Passas held positions of increasing responsibility at Abbott, Quidel, The Binding Site, and Trinity Biotech. In his most recent position, he was responsible for worldwide marketing and international sales at Trinity Biotech. Dr. Passas holds a B.S. in medical biochemistry and a Ph.D. in analytical chemistry from the University of Surrey, U.K.

Sharon Klugewicz, who most recently served as the Company's Chief Operating Officer, was promoted to President, Americas region in October 2016, with responsibility for commercial operations in the United States, Latin America, and Canada. In Ms. Klugewicz's new role as President of Chembio's Americas region, she will be responsible for sales, marketing, customer support, clinical and regulatory affairs, and quality systems in the Americas, and will be tasked with leading the U.S. commercial team and expanding commercial operations throughout Latin America, the U.S. and Canada. Prior to joining the Company, she spent 20 years at Pall Corporation where she held positions of increasing responsibility, including Senior Vice President, Scientific and Laboratory Services. Ms. Klugewicz received a B.S. in Neurobiology from Stony Brook University and a M.S. in Biochemistry from Adelphi University.

Fever Disease

During the third quarter of 2016, Chembio received two important grants supporting the Company's fever disease programs. In August 2016, Chembio was awarded a contract for up to $13.2 million in total funding from BARDA for the development and commercialization of the Company's rapid POC Zika test and Zika-related products. The award includes an initial commitment of $5.9 million allocated specifically to the DPP® Zika IgM/IgG Assay and DPP® Micro Reader, as well as an option for an additional $7.3 million to fund the development, clinical trial and regulatory submissions related to the Company's DPP® Zika/Chikungunya/Dengue IgM/IgG Combination Assay.

Through this grant, the Company is working to develop a much-needed alternative to currently available molecular tests for the Zika virus that have limited utility as they are accurate only during a narrow window of time between initial Zika virus exposure and the patient's development of detectable antibodies to the virus, a process known as seroconversion. Following seroconversion, antibody tests are recommended to accurately identify Zika virus infections. The DPP® Zika IgM/IgG Assay will provide timely results, during the patient consultation. The DPP® Zika System, which includes the DPP® Zika IgM/IgG Assay and DPP® Micro Reader, detects both IgM and IgG antibodies, uses a 10uL fingerstick blood sample and provides semi-quantitative results in 15 minutes.

In September 2016, Chembio was awarded a $330,000 contract for the purchase by the CDC from Chembio of POC surveillance diagnostic assays for Zika, Dengue and Chikungunya. Under the terms of the 12-month contract, Chembio will provide its DPP® Zika IgM/IgG Assay, DPP® Zika/Chikungunya/Dengue IgM/IgG Combination Assay, and DPP® Micro Reader to the CDC, for a surveillance testing pilot program in India, Peru, Guatemala and Haiti.

Including these programs, Chembio is actively developing numerous POC DPP® fever assays, with the majority of these programs being supported and funded by leading health organizations, including the Bill & Melinda Gates Foundation, The Paul G. Allen Family Foundation, HHS/ASPR/BARDA and the CDC.

Concurrent with this important development work, Chembio is moving expeditiously to complete regulatory filings that will ultimately determine the availability of our products to the regions in need. In July 2016, a CE Mark was obtained that will allow the Company to begin commercializing the DPP® Zika IgM/IgG System, which includes an assay utilizing our patented DPP® technology, as well as a digital reader, the DPP® Micro Reader, in 17 European countries, including the United Kingdom, Germany, and France, as well as a majority of the Caribbean nations. Chembio expects initial sales of the system to these countries in the fourth quarter of 2016.

As discussed previously, during the third quarter, Chembio entered into exclusive distribution agreements with Isla Lab Caribbean for the distribution of Chembio products in more than twenty-five Caribbean nations, as well as Puerto Rico and the U.S. Virgin Islands. In addition to certain of the Company's sexually transmitted disease products, the distribution agreements cover those fever disease products, which have met regulatory requirements to be marketed and sold in the Caribbean region, including: DPP® Zika IgM/IgG Assay and DPP® Micro Reader. Additional regulatory requirements will need to be satisfied before sales may be made in Puerto Rico and the U.S. Virgin Islands.

In late October 2016, the Company received approval for commercial use of its DPP® Zika IgM/IgG Assay by the Brazilian health regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA). Brazil has been hard hit by the Zika virus, where it is estimated that 1.5 million people have been infected with Zika virus and 2,000 babies have been born with microcephaly, a devastating birth defect linked to the Zika virus. For this reason the Company is particularly pleased to receive approval from Brazil's health regulatory agency, and we look forward to initiating sales of our DPP® Zika IgM/IgG Assay, which we expect to occur following successful INCQS evaluation of the DPP® Zika IgM/IgG Assay and ANVISA approval of the DPP® Micro Reader. Chembio is currently involved with INCQS, Brazil's National Institute for Quality Control in Health, and ANVISA to accomplish these final steps.

Beyond these approvals, the Company has made multiple other regulatory filings during 2016 for the DPP® Zika IgM/IgG Assay, including an Emergency Use Authorization (EUA) submission with the U.S. Food and Drug Administration (FDA), an EUA application with the World Health Organization (WHO), and a submission with Cofepris in Mexico. Supplementing these filings, the Company is engaged fully with these agencies in the hope of facilitating the earliest possible approvals.

Technology Collaborations

Chembio currently has the following ongoing technology collaborations: DPP® Cancer Assay for a specific form of cancer, DPP® Traumatic Brain Injury Assay, and DPP® BovidTB Assay. We are pleased to report that we made progress with each of these programs in the third quarter of 2016.

The DPP® Cancer Assay, which is funded by an undisclosed entity, targets a specific form of cancer. During 2015, we successfully completed the feasibility phase of the program and moved into the product development stage, which is also funded by the undisclosed entity. The results to-date with this program have been highly encouraging. With success, we are hopeful that we'll be able to find additional applications for our DPP® technology in the broader oncology market.

We also made important advances with our DPP® Traumatic Brain Injury Assay program during the third quarter of 2016. This project, which is funded by Perseus Science Group, LLC, is in the feasibility phase. We recently finalized institutional review board (IRB) agreements with several hospitals and began conducting initial studies of the DPP® Traumatic Brain Injury Assay using patient samples.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. Under the two-year grant, Chembio will use 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 will be designed to provide results within 20 minutes, thereby significantly improving on the time-consuming, tedious and inadequate diagnostic methods currently in use.

In addition to the ongoing progress that Chembio made with each of its development programs, the Company made important advances in three critical areas during the third quarter of 2016. The first area is commercial infrastructure. Despite reporting a decrease in product sales for both the second and third quarters of 2016, a quarter-over-quarter analysis shows sales growth with total revenues for the third quarter of 2016 up 15% from the second quarter 2016, and product sales up 23% in the third quarter of 2016 compared to the second quarter of 2016. This quarter-over-quarter growth provides evidence that our commercialization strategy is effectively responding to prior market challenges. And during the quarter we strengthened our sales and marketing organization by expanding our distribution network throughout the Caribbean and appointing seasoned executives to direct the expansion of our commercialization efforts in Europe, the Middle East, Africa, Asia, North America and Latin America.

The second area of advancement is regulatory approvals. In July 2016, a CE Mark was obtained that will allow the Company to begin commercializing the DPP® Zika IgM/IgG and Micro Reader System, in 17 European countries, including the United Kingdom, Germany, and France, as well as a majority of the Caribbean nations. Chembio expects initial sales of the system to these countries in the fourth quarter of 2016. And in late October 2016, the Company received approval for commercial use of its DPP® Zika IgM/IgG Assay by the Brazilian health regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA). The Company expects to initiate sales following successful INCQS evaluation of the DPP® Zika IgM/IgG Assay and ANVISA approval of the DPP® Micro Reader. The Company believes that these regulatory approvals – in conjunction with Chembio's expanded Caribbean distribution network and new global sales leadership – will open new channels to several large and important markets in the coming months.

Lastly, the third area of achievement for Chembio was the execution two important corporate transactions. The first was the fundraising that provided the Company with gross proceeds of approximately $13.8 million. This offering provides Chembio the funds to continue to advance its development programs and invest in the sales and operational infrastructure needed to support sustained growth. And subsequent to the quarter-end, the Company set a path to further expand the organization through the signing of an agreement for the acquisition of RVR Diagnostics Sdn Bhd in Malaysia. Completion of this transaction is subject to certain closing conditions. If consummated, we believe this acquisition would provide Chembio with an additional source of revenue, state-of-the art production capacity, and an operational base in Asia that is anticipated to allow the Company to manufacture at a competitive price point in the region.

Through the Company's achievements in strengthening commercial infrastructure, securing regulatory approvals, improving its balance sheet and establishing operations in the growing Asian market, we believe Chembio has established a truly global operation and a path for continued growth.

Agreement to Acquire RVR Diagnostics Sdn Bhd

On November 4, 2016, Chembio entered into an agreement with the two shareholders of RVR Diagnostics Sdn Bhd (RVR), a Malaysia company for Chembio to acquire all the stock and any other equity interests in RVR. The agreement includes the following provisions:

(i) The purchase price at closing shall consist of US $1.4 million cash; US$1.85 million in Chembio's stock (based on a 15-day volume weighted average trading price ("VWAP")); and Chembio's forgiveness of a US$250,000 contingent obligation from RVR to Chembio;

(ii) The two sellers of the RVR stock also will be entitled to receive milestone payments of an aggregate total of up to US$100,000 in cash and US$150,000 in Chembio's common stock (calculated with the same 15-day VWAP) in increasing amounts up to the US$250,000 maximum aggregate milestone payment to the extent that RVR's sales for 2017 exceed US$2.25 million;

(iii) Each of the two sellers will be employed by RVR for one year after closing at a salary of US$10,000 per month;

(iv) The Company will be entitled to undertake due diligence after signing of the Stock Purchase Agreement;

(v) Each of the two sellers will indemnify the Company for any undisclosed liabilities;

(vi) The Company, immediately after signing the Agreement and as soon as RVR has provided the Company with the RVR financial statements needed for the filing, will file a registration statement with the SEC to register the issuance of the shares to the sellers, and the closing will occur within a few days after the registration statement becomes effective with the SEC;

(vii) Closing of the transaction is subject to a number of other conditions that can be waived by the party for whom the condition is to be satisfied; and

(viii) Upon closing of the acquisition, the directors of RVR will be Magentiren Vajuram, Avijit Roy, Katherine Davis, John Sperzel, and Rich Larkin. Messrs. Vajuram and Roy are the selling stockholders and also the current management of RVR.

ITEM 4. CONTROLS AND PROCEDURES

(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, 2016 our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our Exchange Act reports is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

(b) Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 under the Exchange Act that occurred during the three months ended September 30, 2016 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 March 13, 2014 with John J. Sperzel III (4)
10.2*	Employment Agreement dated March 5, 2016 with Javan Esfandiari (8)
10.3*	Employment Agreement dated June 12, 2015 with Sharon Klugewicz (9)
10.4	HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Alere and StatSure. (10)
10.5	HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (10)
10.6	Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (10)
10.7	Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (10)
10.8	2015 Omnibus Agreement (11)
14.1	Ethics Policy (12)
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Definition Linkbase Document
101.LAB	XBRL Taxonomy Label Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document

1	Incorporated by reference to the Registrant's 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 17, 2015.
10	Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.
11	Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Commission on March 5, 2015.
12	Incorporated by reference to the Registrant's Annual Report on Form 10-KSB filed with the Commission on March 30, 2006.
13	Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on April 7, 2016.

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

SIGNATURES

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

Chembio Diagnostics, Inc.

Date: November 10, 2016

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

Date: November 10, 2016

By: /s / Richard J. Larkin
Richard J. Larkin
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

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 10, 2016 /s/ John J. Sperzel III
John J. Sperzel III, Chief Executive Officer

EXHIBIT 31.2

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 10, 2016 /s/ Richard J. Larkin

Richard J. Larkin, Chief Financial Officer

EXHIBIT 32

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, 2016, each of the undersigned John J. Sperzel III, the Chief Executive Officer of the Company, and Richard J. Larkin, the Chief Financial Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of the undersigneds' knowledge and belief:

(1) This Form 10-Q for the quarter ended September 30, 2016 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, 2016 fairly presents, in all material respects, the financial condition and results of operations of Chembio Diagnostics, Inc. for the periods presented therein.

Dated: November 10, 2016 /s/ John J. Sperzel III
John J. Sperzel III
Chief Executive Officer

Dated: November 10, 2016 /s/ Richard J. Larkin
Richard J. Larkin
Chief Financial Officer