CHEMBIO DIAGNOSTICS, INC.
Form 10-Q
August 11, 2016

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

_____

FORM 10 - Q

_____

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

For the quarterly period ended June 30, 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 August 8, 2016, the Registrant had 11,986,242 shares outstanding of its $.01 par value common stock.

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

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PART I
Item 1. FINANCIAL STATEMENTS
CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS
AS OF

	June 30, 2016 (Unaudited)	December 31, 2015
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	$1,439,869	$5,376,931
Accounts receivable, net of allowance for doubtful accounts of $52,000 at June 30, 2016 and December 31, 2015, respectively	4,579,553	2,422,971
Inventories	3,481,819	3,578,025
Prepaid expenses and other current assets	860,340	1,256,879
TOTAL CURRENT ASSETS	10,361,581	12,634,806
FIXED ASSETS, net of accumulated depreciation	2,035,666	2,374,308
OTHER ASSETS:		
Deferred tax asset, net of valuation allowance	-	5,467,143
License agreements, net of current portion	50,000	100,000
Deposits on manufacturing equipment	52,968	30,918
Deposits and other assets	189,064	209,169
TOTAL ASSETS	$12,689,279	$20,816,344
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$2,708,362	$2,801,432
Deferred revenue	818,848	353,406
TOTAL LIABILITIES	3,527,210	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; 9,686,242 and 9,628,248 shares issued and outstanding for June 30, 2016 and December 31, 2015, respectively	96,862	96,282
Additional paid-in capital	48,041,697	47,890,642
Accumulated deficit	(38,976,490)	(30,325,418)
TOTAL STOCKHOLDERS' EQUITY	9,162,069	17,661,506
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$12,689,279	$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 six months ended	
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
REVENUES:				
Net product sales	$2,034,072	$6,321,554	$7,951,091	$11,936,239
License and royalty revenue	33,895	7,882	56,096	14,933
R&D, milestone and grant revenue	1,198,438	386,722	1,860,317	996,123
TOTAL REVENUES	3,266,405	6,716,158	9,867,504	12,947,295
Cost of product sales	1,686,100	3,697,026	5,121,651	7,241,545
GROSS MARGIN	1,580,305	3,019,132	4,745,853	5,705,750
OPERATING EXPENSES:				
Research and development expenses	2,367,466	1,757,007	4,001,764	3,341,543
Selling, general and administrative expenses	1,598,813	2,160,096	3,598,217	4,137,670
	3,966,279	3,917,103	7,599,981	7,479,213
LOSS FROM OPERATIONS	(2,385,974)	(897,971)	(2,854,128)	(1,773,463)
OTHER INCOME:				
Interest income	1,310	316	3,874	1,491
	1,310	316	3,874	1,491
LOSS BEFORE INCOME TAXES	(2,384,664)	(897,655)	(2,850,254)	(1,771,972)
Income tax expense (benefit)	5,962,818	(233,570)	5,800,818	(461,070)
NET LOSS	$(8,347,482)	$(664,085)	$(8,651,072)	$(1,310,902)
Basic loss per share	$(0.86)	$(0.07)	$(0.90)	$(0.14)
Diluted loss per share	$(0.86)	$(0.07)	$(0.90)	$(0.14)
Weighted average number of shares outstanding, basic	9,667,543	9,627,951	9,649,612	9,623,773
Weighted average number of shares outstanding, diluted	9,667,543	9,627,951	9,649,612	9,623,773

See accompanying notes to condensed consolidated financial statements
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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE SIX MONTHS ENDED
(Unaudited)

	June 30, 2016	June 30, 2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	$8,176,364	$12,274,330
Cash paid to suppliers and employees	(12,036,793)	(14,441,822)
Interest received	3,874	1,491
Net cash used in operating activities	(3,856,555)	(2,166,001)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of License	-	(450,000)
Acquisition of and deposits on fixed assets	(85,877)	(434,466)
Net cash used in investing activities	(85,877)	(884,466)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option exercises	5,370	-
Net cash provided by financing activities	5,370	-
DECREASE IN CASH AND CASH EQUIVALENTS	(3,937,062)	(3,050,467)
Cash and cash equivalents - beginning of the period	5,376,931	4,614,538
Cash and cash equivalents - end of the period	$1,439,869	$1,564,071
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net Loss	$(8,651,072)	$(1,310,902)
Adjustments:		
Depreciation and amortization	580,159	665,672
Deferred taxes	5,800,818	(461,070)
Share based compensation	146,265	195,591
Changes in assets and liabilities:		
Accounts receivable	(2,156,582)	(528,642)
Inventories	96,206	(143,405)
Prepaid expenses and other current assets	(46,226)	(234,083)
Deposits and other assets	1,505	-
Accounts payable and accrued liabilities	(93,070)	(204,839)
Customer deposits and deferred revenue	465,442	(144,323)
Net cash used in operating activities	$(3,856,555)	$(2,166,001)
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	$43,590	$20,017

See accompanying notes to condensed consolidated financial statements

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2016
(UNAUDITED)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. (the "Company" or "Chembio") and its wholly-owned subsidiary, Chembio Diagnostic Systems Inc., develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company's main lateral flow products are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA in 2006; the third is sold for export only. In addition the Company has several products based on its patented Dual Path Platform (DPP®) technology, including a HIV test approved by the FDA in 2013 and CLIA-Waived in 2014. Lateral Flow Rapid HIV tests represented 53% of the Company's product revenues in the first six months of 2016. The Company's products based on its DPP® platform represented approximately 44% of the Company's product revenues in the first six months of 2016. The Company also has other rapid tests and components that together represented approximately 3% of product sales in the first six 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 June 30, 2016 and for the three and six-month periods ended June 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 June 30, 2016, its condensed consolidated results of operations for the three and six-month periods ended June 30, 2016 and 2015, respectively, and its condensed consolidated cash flows for the six-month periods ended June 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, however, it has used approximately $3.9 million in cash for the six months ended June 30, 2016, see Note 8. Approximately $3.4 million of the total $4.6 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 $818,848 and $353,406 as of June 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2016
(UNAUDITED)

c) Inventories:

Inventories consist of the following at:

	June 30, 2016	December 31, 2015
Raw materials	$2,004,357	$2,248,371
Work in process	609,548	370,340
Finished goods	867,914	959,314
	$3,481,819	$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 six-month periods ended June 30, 2016 and 2015, have been included in the earnings per share computations:

	For the three months ended		For the six months ended	
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
Basic	9,667,543	9,627,951	9,649,612	9,623,773
Diluted	9,667,543	9,627,951	9,649,612	9,623,773

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

There were 667,995 and 651,768 weighted-average number of options outstanding as of June 30, 2016 and 2015, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended June 30, 2016 and 2015 respectively. There were 708,514 and 667,082 weighted-average number of options outstanding as of June 30, 2016 and 2015, respectively, that were not included in the calculation of diluted per common share equivalent for the six months ended June 30, 2016 and 2015, respectively, because the effect would have been anti-dilutive as of June 30, 2016 and 2015, respectively.

e) Employee Stock Option Plans and Share-Based Compensation:

Effective June 3, 2008, the Company's stockholders voted to approve the 2008 Stock Incentive Plan ("SIP"), initially with 625,000 shares of Common Stock available to be issued. At the Annual Stockholder meeting on September 22, 2011, the Company's stockholders voted to approve an increase to the shares of Common Stock issuable under the SIP by 125,000 to 750,000. Under the terms of the SIP, the Compensation Committee of the Company's Board has the discretion to select the persons to whom awards are to be granted and the number of shares of common stock to be covered by each grant. Awards can be incentive stock options, restricted stock and/or restricted stock units. The awards become vested at such times and under such conditions as determined by the Compensation Committee at the time of the initial stock option grant. As of June 30, 2016, there were 411,929 options exercised and 286,806 options

outstanding under the SIP.

Effective June 19, 2014, the Company's stockholders voted to approve the 2014 Stock Incentive Plan ("2014-SIP"), with 800,000 shares of Common Stock available to be issued. Under the terms of the 2014-SIP, the Compensation Committee of the Company's Board has the discretion to select the persons to whom awards are to be granted and the number of shares of common stock to be covered by each grant. Awards can be incentive stock options, restricted stock and/or restricted stock units. The awards become vested at such times and under such conditions as determined by the Compensation Committee at the time of the initial stock option grant. As of June 30, 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 six months ended June 30, 2016 and none for the six months ended 2015. The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the six months ended June 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2016
(UNAUDITED)

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

The Company's results for the three-month periods ended June 30, 2016 and 2015 include share-based compensation expense, consisting solely of stock options, totaling $92,677 and $86,282, 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 ($65,400 and $71,400, respectively). The results for the six-month periods ended June 30, 2016 and 2015 include share-based compensation expense, consisting solely of stock options, totaling $146,265 and $195,591, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within research and development ($34,700 and $33,000, respectively) and selling, general and administrative expenses ($111,500 and $162,600, 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 six months ended June 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 six months ended June 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	132,929	4.01		
Forfeited/expired/cancelled	-	-		
Outstanding at June 30, 2016	623,424	$ 4.26	3.57 years	$2,481,356
Exercisable at June 30, 2016	305,049	$ 3.79	2.66 years	$1,343,516

As of June 30, 2016, there was $446,729 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 2.53 years. The total fair value of stock options vested during the six-month periods ended June 30, 2016 and 2015 was approximately $206,701 and $357,484, 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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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 six months ended	
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
Africa	$395,231	$1,131,684	$713,989	$2,707,738
Asia	88,984	59,340	64,005	110,153
Europe	205,667	157,689	123,096	222,835
North America	667,165	1,071,216	2,389,024	2,385,767
South America	677,025	3,901,625	4,660,977	6,509,746
	$2,034,072	$6,321,554	$7,951,091	$11,936,239

g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

	June 30, 2016	December 31, 2015
Accounts payable – suppliers	$1,319,683	$1,260,520
Accrued commissions	383,112	129,192
Accrued royalties / license fees	358,462	732,301
Accrued payroll	149,803	146,962
Accrued vacation	301,703	244,810
Accrued bonuses	-	177,700
Accrued expenses – other	195,599	109,947
TOTAL	$2,708,362	$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, 2016, 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2016
(UNAUDITED)

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 for $1,500,000. The agreement was modified in September 2014. The Company did not earn revenues during the six-month periods ended June 30, 2016 and 2015, respectively from this agreement. The Company earned $1,250,000 from this grant from inception through June 30, 2016.

b) Dengue agreement:

In October 2014, the Company entered into a technology development agreement with a diagnostics company for $300,000. The Company earned $- and $140,000 for the six-month periods ended June 30, 2016 and 2015, respectively from this agreement. The Company earned $300,000 from this grant from inception through June 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 $188,098 and $252,500 for the six-month periods ended June 30, 2016 and 2015, respectively from this agreement. The Company earned $657,716 from this grant from inception through June 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 $- and $258,900 for the six-month periods ended June 30, 2016 and 2015, respectively from this agreement. The Company earned $307,000 from this grant from inception through June 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 $25,866 for the six-month periods ended June 30, 2016 from this agreement. The Company earned $25,866 from this grant from inception through June 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 $50,000 and $75,000 for the six-month periods ended June 30, 2016 and 2015, respectively from this agreement. The Company earned $255,000 from this grant from inception through June 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 $1,559,500 and $- for the six-month periods ended June 30, 2016 and 2015, respectively from this agreement. The Company earned $1,968,000 from this grant from inception through June 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2016
(UNAUDITED)

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 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 60,000 incentive and non-incentive stock options to purchase 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 the Company had to each customer that purchased in excess of 10% of the Company's net product sales for the periods indicated:

	For the three months ended				For the six months ended				Accounts Receivable as of	
	June 30, 2016		June 30, 2015		June 30, 2016		June 30, 2015		June 30, 2016	June 30, 2015
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales		
Customer 1	$666,765	33	$3,882,161	61	$3,256,170	41	$6,344,032	53	$3,389,505	$7,362,622

Customer 2	-	-	708,311	11	1,796,477	23	1,725,300	14	-	307,125
Customer 3	*	*	*	*	*	*	1,750,722	15 %	*	114,999

(*) 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2016
(UNAUDITED)

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

	For the three months ended				For the six months ended				Accounts Payable as of	
	June 30, 2016		June 30, 2015		June 30, 2016		June 30, 2015		June 30, 2016	June 30, 2015
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	$203,020	12	$*	*	$425,922	13	$*	*	$60,935	$*
Vendor 2	*	*	332,273	17	*	*	794,536	11	*	147,795

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

The Company currently buys materials which are purchased under intellectual property rights agreements and are important components in its products. Management believes that other suppliers could provide similar materials on comparable terms as the vendors shown in this table. A change in suppliers, however, could cause a delay in manufacturing and a possible loss of sales, which could adversely affect operating results.

b) Governmental Regulation:

All of the Company's existing and proposed diagnostic products are regulated by the United States Food and Drug Administration, United States Department of Agriculture, certain U.S., state and local agencies, and/or comparable regulatory bodies in other countries. Most aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and record keeping, are subject to review. After marketing approval has been granted, Chembio must continue to comply with governmental regulations. Failure to comply with these regulations can result in significant penalties.

c) Employment Agreements:

The Company has employment contracts with three key employees. 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, 250,000 options to purchase common 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, 5,000 options to purchase common stock, with one-half vesting on each of the first and second anniversaries of the grant. In connection with the Esfandiari contract that expires in March 2019, the Company issued, in March 2016, 60,000 options to purchase 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 six months ended June 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:

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 estimated offering expenses payable by the Company, was approximately $12,484,000. The Company intends to use the net proceeds for business expansion and working capital, including product development, operational improvements, clinical trials, and sales and marketing.

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 six months ended June 30, 2016 increased to $1.86 million from $1.00 million in the prior-year period, which was primarily the result of increased R&D project revenues in 2016. Some projects are based on a milestone basis for which revenue cannot be recognized until the milestone is achieved, while expenses incurred to reach that milestone are expensed in the period incurred.

R&D expenses in the six months ended June 30, 2016 were $4.00 million, compared with $3.34 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 for commercial use by the Brazilian regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA). The DPP® HIV-Syphilis Assay is the only test cleared for commercialization in Brazil for rapid, POC detection of both HIV 1/2 and syphilis. We are developing a U.S. version of the DPP® HIV-Syphilis Assay, designed to meet the performance requirements for the "reverse" algorithm that is currently in clinical use for syphilis testing in the United States. We have completed our pre-clinical studies for this product with encouraging results, and initiated the clinical trial in the U.S. during first quarter of 2016.

Fever Disease

- DPP® Malaria Assay: The DPP® Malaria Assay is a rapid, POC, multiplex test for the simultaneous detection of plasmodium falciparum and other plasmodium infections. In January 2015, we received a grant from the Bill & Melinda Gates Foundation to expedite the development and feasibility testing of a POC DPP® Malaria Assay. The Company recently completed this project, which compared the new DPP® Malaria Assay to the world's leading currently-available POC malaria assay. Based on initial testing, the new DPP® Malaria Assay met the major objective of the feasibility project: a ten-fold improvement in sensitivity. Given these results, 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.

- 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 development, including the addition of Zika, by the end 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). During the third and fourth quarters of 2015, we sold DPP® Ebola and DPP® Malaria-Ebola Assays to the Centers for Disease Control & Prevention (CDC) for field studies in West Africa, which is ongoing.

- DPP® Dengue Fever Assay: The DPP® Dengue Fever Assay is a rapid, POC, multiplex test for the detection of IgG/IgM and NS1 antigens. We are currently conducting verification and validation studies, and we anticipate the production of pilot lots, to support preclinical studies. During the second quarter of 2016, we initiated registration to begin initial commercialization, which we anticipate in the second half of 2016. This program is fully funded by a partner. However, under the terms of our agreement, Chembio's partner is not being disclosed.

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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. In March, Chembio announced collaboration with Bio-Manguinhos for the development and commercialization of DPP® Zika and DPP® Dengue/Chikungunya/Zika 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. The Company has completed development and field testing of the DPP® Zika IgM/IgG Assay, including testing of more than 1,000 clinical specimens, including samples from over 600 pregnant women in the U.S. and Mexico, required to file 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. The Company expects some revenue from the sales of its DPP® Zika IgM/IgG Assay in 2016.

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 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 several hospitals and began conducting initial studies of the DPP® Traumatic Brain Injury Assay using patient samples.

- DPP® FLU Immunostatus Assay: The DPP® FLU Immunostatus Assay is a rapid, POC, multiplex influenza immunity test. In November 2014, we entered into a follow-on, milestone-based development agreement with a contracting organization, acting on behalf of the U.S. government, for a multiplex POC influenza immunity test utilizing our patented DPP® technology. We successfully completed the product development of a 7-band multiplex DPP® Flu Immunostatus Assay with a digital reader during the first quarter of 2015 and subsequently applied for additional funding in response to a new request for proposal (RFP) from the U.S. Government, for which we expect a response in the third quarter of 2016.

Regulatory Activities

DPP® HIV-Syphilis Assay: In December 2015, the application by way of technical file was submitted to the Notified Body for CE Mark consideration to commercialize within the European Union.

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.

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.

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

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 estimated offering expenses payable by the Company, was approximately $12,484,000. The Company intends to use the net proceeds for business expansion and working capital, including product development, operational improvements, clinical trials, and sales and marketing.

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

Income:

For the three months ended June 30, 2016, Loss before income taxes was $2,385,000 compared to $898,000 for the three months ended June 30, 2015. Net Loss for the 2016 period was $8,347,000 as compared to $664,000 for 2015. The increase in Net Loss is primarily attributable to decreased product revenues and decreased product gross margin, partially offset by increased R&D revenues of $812,000 which also includes recording of a full valuation of approximately $5,963,000 on our Deferred Tax Asset (DTA) in the 2016 period. Product gross margin decreased in the three months ended June 30, 2016, as compared with the three months ended June 30, 2015, by $2,277,000 or 86.74%.

Revenues:

Selected Product Categories:	For the three months ended June 30, 2016	June 30, 2015	$ Change	% Change
Lateral Flow HIV Tests and Components	$1,168,759	$2,226,094	$(1,057,335)	-47.50 %
DPP® Tests and Components	834,561	3,980,726	(3,146,165)	-79.03 %
Other	30,752	114,734	(83,982)	-73.20 %
Net Product Sales	2,034,072	6,321,554	(4,287,482)	-67.82 %
License and royalty revenue	33,895	7,882	26,013	330.03 %
R&D, milestone and grant revenue	1,198,438	386,722	811,716	209.90 %
Total Revenues	$3,266,405	$6,716,158	$(3,449,753)	-51.36 %

Revenues for our lateral flow HIV tests and related components during the three months ended June 30, 2016 decreased by approximately $1,057,000 from the same period in 2015. This was primarily attributable to decreased sales to Africa of approximately $736,000 and to North America of approximately $410,000, partially offset by increased sales to Europe, of approximately $48,000 and Asia of approximately $30,000. Revenues for our DPP® products during the three months ended June 30, 2016 decreased by approximately $3,146,000 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. Some projects are based on a milestone basis for which revenue cannot be recognized until the milestone is achieved, while expenses incurred to reach that milestone are expensed in the period incurred.

Gross Margin:

	For the three months ended June 30, 2016	June 30, 2015	$ Change	% Change
Gross Margin per Statement of Operations	$1,580,305	$3,019,132	$(1,438,827)	-47.66 %
Less: R&D, milestone, grant, license and royalty revenues	1,232,333	394,604	837,729	212.30 %

Gross Margin from Net Product Sales	$347,972	$2,624,528	$(2,276,556)	-86.74 %
Product Gross Margin %	17.11 %	41.52 %		

The overall gross margin dollar decrease of $1,439,000 included a $2,277,000 decrease in gross margin from product sales and was partially offset by a $838,000 increase in non-product revenues. The decrease in net product sales gross margin of $2,277,000 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 $4,287,000, which, at the 41.5% margin percentage for June 30, 2015, contributed $1,780,000 to the decrease, and the other is the decreased change in margin percentage of 24.4%, which contributed $497,000 to the balance of the decrease in our net product sales gross margin. Part of the reduction in the margin percentage was due to a vendor quality issue of approximately $119,000. The issue has been resolved.

Research and Development:

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

Selected expense lines:	For the three months ended June 30, 2016	June 30, 2015	$ Change	% Change
Clinical and Regulatory Affairs:				
Wages and related costs	$131,472	$131,290	$182	0.14 %
Consulting	12,055	14,104	(2,049)	-14.53 %
Clinical trials	106,746	244,110	(137,364)	-56.27 %
Other	9,723	20,163	(10,440)	-51.78 %
Total Regulatory	259,996	409,667	(149,671)	-36.53 %
R&D Other than Regulatory:				
Wages and related costs	698,385	745,996	(47,611)	-6.38 %
Consulting	37,115	28,110	9,005	32.03 %
Stock-based compensation	27,263	14,834	12,429	83.79 %
Materials and supplies	1,244,803	417,756	827,047	197.97 %
Other	99,904	140,644	(40,740)	-28.97 %
Total other than Regulatory	2,107,470	1,347,340	760,130	56.42 %
Total Research and Development	$2,367,466	$1,757,007	$610,459	34.74 %

Expenses for Clinical & Regulatory Affairs for the three months ended June 30, 2016 decreased by $150,000 as compared to the same period in 2015. This was primarily due to the decrease in clinical trial expenses of $137,000.

R&D expenses other than Clinical & Regulatory Affairs increased by $760,000 in the three months ended June 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 June 30, 2016	June 30, 2015	$ Change	% Change
Wages and related costs	$750,624	$849,002	$(98,378)	-11.59 %
Consulting	56,479	73,500	(17,021)	-23.16 %
Commissions	90,299	468,033	(377,734)	-80.71 %
Stock-based compensation	65,414	71,448	(6,034)	-8.45 %
Marketing materials	97,704	71,048	26,656	37.52 %
Investor relations/investment bankers	81,236	39,965	41,271	103.27 %
Legal, accounting and compliance	149,247	209,974	(60,727)	-28.92 %
Travel, entertainment and trade shows	116,725	122,904	(6,179)	-5.03 %
Other	191,085	254,222	(63,137)	-24.84 %
Total S, G &A	$1,598,813	$2,160,096	$(561,283)	-25.98 %

Selling, general and administrative expenses for the three months ended June 30, 2016, decreased by $561,000 as compared with the same period in 2015, a (26.0%) decrease. This decrease resulted primarily from decreases in wages and related costs due to a transition period while sales staff were replaced, stock-based compensation, commissions, travel, entertainment and trade shows, consulting, and professional fees, which were partially offset by increases in marketing materials, and investor relations expenses.

Other Income:

	For the three months ended June 30, 2016	June 30, 2015	$ Change	% Change
Interest income	$1,310	$316	$ 994	314.56%
Total Other Income	$1,310	$316	$ 994	314.56%

Other income for the three months ended June 30, 2016 increased to $1,300, from an income of $300 in the same period in 2015, 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 three months ended June 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 three months ended June 30, 2016 the Company recognized a $5,963,000 income tax expense and decreased its deferred tax assets.

RESULTS OF OPERATIONS FOR THE SIX MONTHS ENDED JUNE 30, 2016 AS COMPARED WITH THE SIX MONTHS ENDED JUNE 30, 2015

Income:

For the six months ended June 30, 2016, Loss before income taxes was $2,850,000 compared to $1,772,000 for the six months ended June 30, 2015. Net Loss for the 2016 period was $8,651,000 as compared to $1,311,000 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 six months ended June 30, 2016, as compared with the six months ended June 30, 2015, by $960,000, or (16.8)%.

Revenues:

Selected Product Categories:	For the six months ended June 30, 2016	June 30, 2015	$ Change	% Change
Lateral Flow HIV Tests and Components	$4,225,287	$5,116,631	$(891,344)	-17.42 %
DPP® Tests and Components	3,492,446	6,443,828	(2,951,382)	-45.80 %
Other	233,358	375,780	(142,422)	-37.90 %
Net Product Sales	7,951,091	11,936,239	(3,985,148)	-33.39 %
License and royalty revenue	56,096	14,933	41,163	275.65 %
R&D, milestone and grant revenue	1,860,317	996,123	864,194	86.76 %
Total Revenues	$9,867,504	$12,947,295	$(3,079,791)	-23.79 %

Revenues for our lateral flow HIV tests and related components during the six months ended June 30, 2016 decreased by approximately $891,000 from the same period in 2015. This was primarily attributable to decreased sales to Africa,

of approximately $1,599,000 partially offset by increased sales to North America of approximately $543,000, increased sales to Europe of approximately $106,000, and increased sales to Asia of approximately $43,000. Revenues for our DPP® products during the six months ended June 30, 2016 decreased by approximately $2,951,000 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. Some projects are based on a milestone basis for which revenue cannot be recognized until the milestone is achieved, while expenses incurred to reach that milestone are expensed in the period incurred.

Gross Margin:

	For the six months ended			
	June 30, 2016	June 30, 2015	$ Change	% Change
Gross Margin per Statement of Operations	$4,745,853	$5,705,750	$(959,897)	-16.82 %
Less: R&D, milestone, grant, license and royalty revenues	1,916,413	1,011,056	905,357	89.55 %
Gross Margin from Net Product Sales	$2,829,440	$4,694,694	$(1,865,254)	-39.73 %
Product Gross Margin %	35.59 %	39.33 %		

The overall gross margin dollar decrease of $960,000 included a $1,865,000 decrease in gross margin from product sales and was partially offset by a $905,000 increase in non-product revenues. The decrease in net product sales gross margin of $1,865,000 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 $3,985,000, which, at the 39.3% margin percentage for June 30, 2015, contributed $1,567,000 to the decrease, and the other is the decreased change in margin percentage of 3.8%, which contributed $298,000 to the balance of the decrease in our net product sales gross margin. Part of the reduction in the margin percentage was due to a vendor quality issue of approximately $119,000. The issue has been resolved.

Research and Development:

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

Selected expense lines:	For the six months ended June 30, 2016	June 30, 2015	$ Change	% Change
Clinical and Regulatory Affairs:				
Wages and related costs	$264,042	$253,975	$10,067	3.96 %
Consulting	16,451	22,361	(5,910)	-26.43 %
Clinical trials	158,841	356,140	(197,299)	100.00 %
Other	23,423	43,165	(19,742)	-55.40 %
Total Regulatory	462,757	675,641	(212,884)	-45.74 %
				-31.51 %
R&D Other than Regulatory:				
Wages and related costs	1,438,416	1,510,001	(71,585)	-4.74 %
Consulting	42,775	38,043	4,732	12.44 %
Stock-based compensation	34,720	33,041	1,679	5.08 %
Materials and supplies	1,805,036	820,888	984,148	119.89 %
Other	218,060	263,929	(45,869)	-17.38 %
Total other than Regulatory	3,539,007	2,665,902	873,105	32.75 %
Total Research and Development	$4,001,764	$3,341,543	$660,221	19.76 %

Expenses for Clinical & Regulatory Affairs for the six months ended June 30, 2016 decreased by $213,000 as compared to the same period in 2015. This was primarily due to the decrease in clinical trial expenses of $197,000.

R&D expenses other than Clinical & Regulatory Affairs increased by $873,000 in the six months ended June 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 six months ended June 30, 2016	June 30, 2015	$ Change	% Change
Wages and related costs	$$1,564,873	$$1,722,799	$($157,926)	-9.17 %
Consulting	118,223	115,106	3,117	2.71 %
Commissions	406,279	804,905	(398,626)	-49.52 %
Stock-based compensation	111,545	162,551	(51,006)	-31.38 %
Marketing materials	147,837	107,371	40,466	37.69 %
Investor relations/investment bankers	164,162	84,079	80,083	95.25 %
Legal, accounting and compliance	481,363	446,910	34,453	7.71 %
Travel, entertainment and trade shows	207,209	217,663	(10,454)	-4.80 %
Other	396,726	476,286	(79,560)	-16.70 %
Total S, G &A	$$3,598,217	$$4,137,670	$($539,453)	-13.04 %

Selling, general and administrative expenses for the six months ended June 30, 2016, decreased by $539,000 as compared with the same period in 2015, a (13.0)% decrease. This decrease resulted primarily from decreases in wages and related costs due to a transition period while sales staff were replaced, commissions, stock-based compensation and travel, entertainment and trade shows, which were partially offset by increases in consulting, marketing materials, investor relations expenses and professional fees.

Other Income:

	For the six months ended June 30, 2016	June 30, 2015	$ Change	% Change
Interest income	$3,874	$1,491	$2,383	159.83%
Total Other Income	$3,874	$1,491	$2,383	159.83%

Other income for the six months ended June 30, 2016 increased to $3,900, from an income of $1,500 in the same period in 2015, as a result of interest income received as a result of more cash to inves.

Income tax expense:

The Company recorded a full valuation allowance during the six months ended June 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 six months ended June 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 June 30, 2016	December 31, 2015	$ Change	% Change
Cash and cash equivalents	$1,439,869	$5,376,931	$(3,937,062)	-73.22 %
Accounts receivable, net of allowance for doubtful accounts of $52,000 at June 30, 2016 and December 31, 2015, respectively	4,579,553	2,422,971	2,156,582	89.01 %
Inventories	3,481,819	3,578,025	(96,206)	-2.69 %
Prepaid expenses and other current assets	860,340	1,256,879	(396,539)	-31.55 %
Fixed assets, net of accumulated depreciation	2,035,666	2,374,308	(338,642)	-14.26 %
Deferred tax asset, net of valuation allowance	-	5,467,143	(5,467,143)	-100.00%
Deferred revenue	818,848	353,406	465,442	131.70 %
Accounts payable and accrued liabilities	2,708,362	2,801,432	(93,070)	-3.32 %

Cash decreased by $3,937,000 from December 31, 2015, primarily due to net cash used in operating activities for the six months of 2016. In addition there were increases in accounts receivable of $2,157,000 (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 $465,000. We experienced a decrease in inventories of $96,000, prepaid expenses of $397,000, fixed assets of $339,000 and accounts payable and accrued liabilities of $93,000.

LIQUIDITY AND CAPITAL RESOURCES

	For the six months ended June 30, 2016	June 30, 2015	$ Change	% Change
Net cash used in operating activities	$(3,856,555)	$(2,166,001)	$(1,690,554)	78.05 %
Net cash used in investing activities	(85,877)	(884,466)	798,589	-90.29 %
Net cash provided by financing activities	5,370	-	5,370	100.00 %
Decrease in cash and cash equivalents	$(3,937,062)	$(3,050,467)	$(886,595)	29.06 %

The Company's cash decreased as of June 30, 2016 by $3,937,000 from December 31, 2015, primarily due to net cash used in operating activities and net cash used in investing activities for the six months of 2016.

The cash used in operations in 2016 was $3,857,000, which consisted primarily of an increase in accounts receivable of $2,157,000, an increase in prepaid expenses of $46,000 (net of amortization), a decrease in accounts payable and accrued liabilities of $93,000 and a net loss net of non-cash items of $2,124,000, partially offset by cash provided by a decrease in inventories of $96,000, deposits and other assets of $2,000 and an increase in deferred revenue of $465,000. Net loss net of non-cash items includes loss before income taxes of $2,850,000 reduced by non-cash expenses of $580,000 in depreciation and amortization, and of $146,000 in share-based compensation. The use of cash from investing activities is primarily due to the purchase of fixed assets of $86,000.

The Company currently has positive working capital, however, it has used approximately $3.9 million in cash for the six months ended June 30, 2016. Approximately $3.4 million of the total $4.6 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 June 30, 2016, the Company had $52,968 in deposits on equipment. The Company had $12,700 in commitments for additional equipment purchase obligations.

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

During the second quarter of 2016, Chembio further strengthened its three business areas. The Company expanded its fever disease business by adding a new program which is funded by the Gates Foundation, and made important advances with its Bio-Manguinhos/Fiocruz partnership in Brazil. To support the development of a suite of fever disease assays, Chembio sold 2,300,000 shares of common stock, raising $13.8 million before expenses, for a net funding of approximately $12.5 million, in a registered offering that closed on August 3, 2016. While the majority of Chembio's current fever disease programs are funded by partners, proceeds from this financing will allow the Company, among other things, to improve and expand production capacity, as well as those needs that we may have to commercialize our products and/or to license new technologies to address the considerable and growing need in this area.

In the sexually transmitted disease business, the Company made progress with its ongoing clinical trial for the DPP® HIV-Syphilis Assay for the U.S. market, expanded its Chembio-branded pipeline, and established a new pricing platform to make all of the Company's HIV assays increasingly accessible to the populations in greatest need. The Company also made progress with multiple technology collaborations, including the first regulatory approval for the DPP® Micro Reader.

Sexually Transmitted Disease

Chembio's sexually transmitted disease product sales decreased during the second quarter of 2016, due to the discontinuation of sales to the Company's former U.S. distributor following termination of their distribution agreement, as well as decreased sales of its DPP® HIV and DPP® Syphilis products in Brazil and HIV products in Africa during the quarter. The decrease in 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 the anticipated launch of the DPP® Zika IgM/IgG Assay and DPP® Micro Reader, which are discussed below, will be important new products in this region.

During the quarter, the Company took steps to strengthen its Chembio-branded product pipeline and its leadership position in the U.S. market. In June 2016, the Company launched U.S. sales of its Chembio-branded SURE CHECK® HIV 1/2 Assay. The SURE CHECK® HIV 1/2 Assay had previously been sold in the U.S. exclusively by a distributor under the name Clearview Complete® HIV 1/2. In conjunction with this launch, the Company implemented a new pricing program for its POC HIV products for the U.S. public health market with the goal of increasing testing frequency and reducing rates of HIV infection. Through this new program, the Company is selling its HIV tests in the U.S. public health market at a price of five dollars ($5.00) per test, which represents a significant discount from prior pricing. Products offered under this new pricing initiative include Chembio's three FDA-approved, CLIA-Waived HIV assays: DPP® HIV 1/2, SURE CHECK® HIV 1/2, and HIV 1/2 STAT-PAK®. This product portfolio provides customers with multiple POC HIV testing options, as well as the ability to use either fingerstick or venous whole blood, or oral fluid samples.

Despite lighter sales in the U.S. and Brazil, during the second quarter of 2016, the Company recorded a 50% increase in sales to Asia and a 30% increase in sales to Europe, as compared to the second quarter of 2015. We believe both of these regions will represent growing markets for Chembio's products.

Also during the second quarter, the Company continued to advance the clinical trial for its DPP® HIV-Syphilis Assay for the U.S. market. 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 successfully marketing a DPP®

HIV-Syphilis combo assay in Latin America, regulatory standards require additional enhancements for the U.S. market and completion of a clinical trial. We are 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.

Fever Disease

During the second quarter of 2016, Chembio expanded its fever disease business by adding a new program, and made significant progress with an existing partnership.

The new program, which is funded by the Bill & Melinda Gates Foundation, will 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. Worldwide total market POC diagnostic tests to detect malaria, orders have grown from 46 million in 2008 to 314 million in 2015, and are an increasingly important tool in the diagnosis and treatment of malaria. Given our success with our initial malaria program to demonstrate significant improvement in sensitivity as compared to the world's leading POC malaria test, which was also funded by the Bill & Melinda Gates Foundation, as well as the fact that we have already developed and received FDA approval and CLIA Waiver for an oral fluid HIV Assay, we are optimistic that we will be successful with this program.

During the quarter, the Company also made important advances toward the development of the DPP® Zika IgM/IgG Assay, under initial funding from The Paul G. Allen Family Foundation, which the Company received in February 2016. In March 2016, the Company announced a collaboration with Bio-Manguinhos/Fiocruz to develop the DPP® Zika IgM/IgG Assay for the Ministry of Health in Brazil, and in May 2016 the Bio-Manguinhos/Fiocruz collaboration was expanded to include the following products: DPP® Dengue IgM/IgG Assay, DPP® Chikungunya IgM/IgG Assay, DPP® Zika/Chikungunya/Dengue IgM/IgG Combination Assay, and DPP® Micro Reader. Though this collaboration was only initiated in March 2016, the Company has made rapid progress, successfully developing a DPP® Zika IgM/IgG Assay. The Company has also collected over 1,000 data points for the DPP® Zika IgM/IgG Assay. Including these two programs, Chembio is actively developing nine POC DPP® fever assays, with the majority of these programs being supported and funded by leading health organizations, including the Bill & Melinda Gates Foundation and The Paul G. Allen Family Foundation.

Concurrent with this important development work, Chembio is moving expeditiously to complete the 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 the 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, excluding Puerto Rico. Chembio expects initial sales of the system to these countries in the second half of 2016. In the first half of 2016, the Company made multiple other regulatory filings for the DPP® Zika IgM/IgG Assay, including a submission with Agência Nacional de Vigilância Sanitária (ANVISA) in Brazil, 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 four ongoing technology collaborations: DPP® Cancer Assay for a specific form of cancer, DPP® Flu Immunostatus Assay, DPP® Traumatic Brain Injury Assay, and DPP® Micro Reader. We are pleased to report that we made progress with each of these programs in the second 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 second 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.

We are awaiting response on a multi-year grant proposal for completion of the DPP® Flu Immunostatus Assay, a multiplex assay to monitor nine different seasonal and pandemic flu viruses. While there is no guarantee that we will receive this grant, Chembio was the only company to receive the previous grants associated with the program.

Our fourth technology collaboration is with opTricon, a leading developer of mobile analysis devices for rapid diagnostic tests. Through our exclusive agreement, Chembio will launch the DPP® Micro Reader to complement a number of our proprietary assays for sexually transmitted diseases, certain fever diseases, and a specific form of cancer. As stated above, the Company has recently obtained a CE Mark that will allow it to commercialize its DPP® Zika IgM/IgG System, which includes an assay utilizing the patented DPP® technology, as well as the DPP® Micro Reader, in 17 European countries, and a majority of Caribbean nations, excluding Puerto Rico. Commercialization of this system, which is expected to begin in the second half of 2016, will mark the first launch of the Chembio DPP® Micro Reader.

Using a state-of-the-art camera system, the DPP® Micro Reader is designed to provide definitive diagnostic results for low analyte concentrations, which may otherwise result in faint or ambiguous test results. In addition, the DPP® Micro Reader will provide customers with various options to capture, record, transmit and store test results. Because the DPP® Micro Reader is simple, fast, palm-sized, battery-operated and cost-effective compared to traditional POC assay readers, it is unique in its attractiveness and utility, and we believe it will be well-received by the market. We are working to develop other DPP® Assay-Reader kits, and we look forward to further commercializing these innovative diagnostic systems.

Revenues during the second quarter of 2016 reflect the Company's deliberate move to fully control its product pipeline by not attempting to renew the expiration of its agreement with its former U.S. exclusive distributor of its SURE CHECK® HIV 1/2 assay. It further demonstrates the Company's refusal to accept unfavorable economics in any market. While these steps resulted in a decline in sales for the period, we believe they will significantly strengthen Chembio in the years to come. On the development side, the Company believes its patented DPP® technology is unique due to its inherent characteristics such as enhanced sensitivity, the ability to detect multiple diseases with a single patient sample, and the ability to use multiple specimen types, such as oral fluid or blood. Considering the progress made in each of Chembio's three business areas during the quarter, the versatility and utility of this technology has never been more evident. In the sexually transmitted disease business, the clinical trial for our DPP® HIV-Syphilis Assay for the U.S. market is advancing well, and we anticipate completion by the end of the first quarter of 2017. Fever disease advances in the second quarter include initiating development of the world's first oral fluid/saliva POC diagnostic test to detect all species of malaria, which is being funded by the Bill & Melinda Gates Foundation. This is the second POC Malaria grant that Chembio has received from the Bill & Melinda Gates Foundation and we are proud to be called upon again to work with this leading organization on this critical project. We also made significant progress toward the development of the DPP® Zika IgM/IgG Assay, under initial funding from The Paul G. Allen Family Foundation, which the Company received in February 2016. The progress with this program has been rapid and results have been highly encouraging. We are hopeful that this product will receive approval following submissions to numerous regulatory agencies, providing health organizations around the world with an important tool to combat the further spread of Zika virus. And just two weeks ago, a CE mark was obtained for the commercialization of the DPP® Zika IgM/IgG System in 17 European countries as well as the Caribbean region. As this system includes a DPP® Zika IgM/IgG Assay in combination with the DPP® Micro Reader, launch of this system will be the first of the Company's technology collaboration products to be commercialized - another significant milestone for Chembio and our DPP® platform. And also, in August 2016, Chembio successfully raised the funds to support this expanding work and to apply to building the global infrastructure to drive sales of new and existing products. Chembio is proud of its progress toward expanding its product portfolio in the second quarter of 2016 and our continued work to make much-needed POC diagnostics available to battle the spread of HIV, Syphilis, Zika, Dengue, Malaria and other life-threatening diseases.

ITEM 4. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures. Under the supervision and with the participation of our senior management, consisting of our chief executive officer and our chief financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this report (the "Evaluation Date"). Based on that evaluation, the Company's management, including our chief executive officer and chief financial officer, concluded that as of the Evaluation Date our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our Exchange Act reports is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

(b) Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 under the Exchange Act that occurred during the Company's first six months of fiscal 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

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.

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SIGNATURES

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

Chembio Diagnostics, Inc.

Date: August 11, 2016 By: /s/ John J. Sperzel III
John J. Sperzel III
Chief Executive Officer
(Principal Executive Officer)

Date: August 11, 2016 By: /s / Richard J. Larkin
Richard J. Larkin
Chief Financial Officer
(Principal Financial and Accounting Officer)