

CHEMBIO DIAGNOSTICS, INC.  
Form 10-Q  
May 12, 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 March 31, 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

Edgar Filing: CHEMBIO DIAGNOSTICS, INC. - Form 10-Q

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 March 10, 2016, the Registrant had 0 shares outstanding of its \$.01 par value common stock.

---

Quarterly Report on FORM 10-Q  
For The Quarterly Period Ended  
March 31, 2016

Table of Contents

Chembio Diagnostics, Inc.

	Page
<b>Part I. FINANCIAL INFORMATION:</b>	
Item 1. Financial Statements:	
Condensed Consolidated Balance Sheets as of March 31, 2016 (unaudited) and December 31, 2015	2
Condensed Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2016 and 2015	3
Condensed Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2016 and 2015	4
Notes to Condensed Consolidated Financial Statements (unaudited)	5
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 4. Controls and Procedures	21
<b>Part II. OTHER INFORMATION:</b>	
Item 6. Exhibits	22
<b>SIGNATURES</b>	<b>23</b>
<b>EXHIBITS</b>	

---

## PART I

## Item 1. FINANCIAL STATEMENTS

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

## - ASSETS -

	March 31, 2016 (Unaudited)	December 31, 2015
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$2,657,914	\$5,376,931
Accounts receivable, net of allowance for doubtful accounts of \$52,000 at March 31, 2016 and December 31, 2015, respectively	4,896,609	2,422,971
Inventories	3,383,273	3,578,025
Prepaid expenses and other current assets	1,109,410	1,256,879
<b>TOTAL CURRENT ASSETS</b>	<b>12,047,206</b>	<b>12,634,806</b>
FIXED ASSETS, net of accumulated depreciation	2,202,373	2,374,308
<b>OTHER ASSETS:</b>		
Deferred tax asset, net of valuation allowance	5,619,143	5,467,143
License agreements, net of current portion	75,000	100,000
Deposits on manufacturing equipment	28,473	30,918
Deposits and other assets	200,016	209,169
<b>TOTAL ASSETS</b>	<b>\$20,172,211</b>	<b>\$20,816,344</b>
<b>- LIABILITIES AND STOCKHOLDERS' EQUITY -</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$2,416,122	\$2,801,432
Deferred revenue	344,585	353,406
<b>TOTAL LIABILITIES</b>	<b>2,760,707</b>	<b>3,154,838</b>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock – 10,000,000 shares authorized; none outstanding	-	-
Common stock - \$.01 par value; 100,000,000 shares authorized; 9,650,707 and 9,628,248 shares issued and outstanding for March 31, 2016 and December 31, 2015, respectively	96,507	96,282
Additional paid-in capital	47,944,005	47,890,642
Accumulated deficit	(30,629,008)	(30,325,418)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>17,411,504</b>	<b>17,661,506</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$20,172,211</b>	<b>\$20,816,344</b>

See accompanying notes to condensed consolidated financial statements

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

	For the three months ended	
	March 31, 2016	March 31, 2015
REVENUES:		
Net product sales	\$5,917,019	\$5,614,685
License and royalty revenue	22,201	7,051
R&D, milestone and grant revenue	661,879	609,401
TOTAL REVENUES	6,601,099	6,231,137
Cost of product sales	3,435,551	3,544,519
GROSS MARGIN	3,165,548	2,686,618
OPERATING EXPENSES:		
Research and development expenses	1,634,298	1,584,536
Selling, general and administrative expenses	1,999,404	1,977,574
	3,633,702	3,562,110
LOSS FROM OPERATIONS	(468,154 )	(875,492 )
OTHER INCOME:		
Interest income	2,564	1,175
	2,564	1,175
LOSS BEFORE INCOME TAXES	(465,590 )	(874,317 )
Income tax benefit	(162,000 )	(227,500 )
NET LOSS	\$(303,590 )	\$(646,817 )
Basic loss per share	\$(0.03 )	\$(0.07 )
Diluted loss per share	\$(0.03 )	\$(0.07 )
Weighted average number of shares outstanding, basic	9,631,686	9,624,691
Weighted average number of shares outstanding, diluted	9,631,686	9,624,691

See accompanying notes to condensed consolidated financial statements

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

	March 31, 2016	March 31, 2015
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Cash received from customers and grants	\$4,118,640	\$6,465,602
Cash paid to suppliers and employees	(6,811,814)	(7,408,585)
Interest received	2,564	1,175
Net cash used in operating activities	(2,690,610)	(941,808 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of License	-	(450,000 )
Acquisition of and deposits on fixed assets	(28,407 )	(406,968 )
Net cash used in investing activities	(28,407 )	(856,968 )
<b>DECREASE IN CASH AND CASH EQUIVALENTS</b>		
Cash and cash equivalents - beginning of the period	(2,719,017)	(1,798,776)
	5,376,931	4,614,538
Cash and cash equivalents - end of the period	\$2,657,914	\$2,815,762
<b>RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:</b>		
Net Loss	\$(303,590 )	\$(646,817 )
Adjustments:		
Depreciation and amortization	291,632	345,731
Deferred taxes	(162,000 )	(227,500 )
Share based compensation	53,588	109,309
Changes in assets and liabilities:		
Accounts receivable	(2,473,638)	78,788
Inventories	194,752	(60,324 )
Prepaid expenses and other current assets	102,924	(140,424 )
Deposits and other assets	(147 )	(162 )
Accounts payable and accrued liabilities	(385,310 )	(556,086 )
Customer deposits and deferred revenue	(8,821 )	155,677
Net cash used in operating activities	\$(2,690,610)	\$(941,808 )
<b>Supplemental disclosures for non-cash investing and financing activities:</b>		
Deposits on manufacturing equipment transferred to fixed assets	\$15,118	\$20,017

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 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 52 % of the Company's product revenues in the first three months of 2016. The Company's products based on its DPP® platform represented approximately 45 % of the Company's product revenues in the first three months of 2016. The Company also has other rapid tests and components that together represented approximately 3 % of product sales in the first three 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 March 31, 2016 and for the three-month periods ended March 31, 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 March 31, 2016, its condensed consolidated results of operations for the three-month periods ended March 31, 2016 and 2015, respectively, and its condensed consolidated cash flows for the three-month periods ended March 31, 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.

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 \$345,000 and \$353,000 as of March 31, 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  
MARCH 31, 2016

(UNAUDITED)

c) Inventories:

Inventories consist of the following at:

	March 31, 2016	December 31, 2015
Raw materials	\$2,066,123	\$2,248,371
Work in process	495,502	370,340
Finished goods	821,648	959,314
	\$3,383,273	\$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-month periods ended March 31, 2016 and 2015, have been included in the earnings per share computations:

	For the three months ended	
	March 31, 2016	March 31, 2015
Basic	9,631,686	9,624,691
Diluted	9,631,686	9,624,691

No additional securities, are presented on a common share equivalent basis for the three-month periods ended March 31, 2016 and 2015, as each period has a loss and any additional shares would be anti-dilutive.

There were 655,672 and 671,868 options outstanding as of March 31, 2016 and 2015, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended March 31, 2016 and 2015, respectively, because the effect would have been anti-dilutive as of March 31, 2016 and 2015, respectively.

e) Employee Stock Option Plan:

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, non-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. As of March 31, 2016, there were 472,478 options exercised, 327,046 options outstanding and 46,560 options or shares still available to be issued under the SIP.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2016

(UNAUDITED)

Effective June 19, 2014, the Company's stockholders voted to approve the 2014 Stock Incentive Plan ("2014-SIP"), with 800,000 shares of Common Stock available to be issued. Under the terms of the 2014-SIP, the Compensation Committee of the Company's Board has the discretion to select the persons to whom awards are to be granted and the number of shares of common stock to be covered by each grant. Awards can be incentive stock options, restricted stock and/or restricted stock units. The awards become vested at such times and under such conditions as determined by the Compensation Committee at the time of the initial stock option grant. As of March 31, 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.

The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the three-month period ended March 31, 2016, was \$5.64 per share. The Company did not grant any options during the three months ended March 31, 2015. 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	
	March 31, 2016	March 31, 2015
Expected term (in years)	5.0	n/a
Expected volatility	48.66 %	n/a
Expected dividend yield	0 %	n/a
Risk-free interest rate	0.90 %	n/a

The Company's results for the three-month periods ended March 31, 2016 and 2015 include share-based compensation expense totaling \$53,600 and \$109,300, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within research and development (\$7,500 and \$18,200, respectively), and selling, general and administrative expenses (\$46,100 and \$91,100, respectively). The income tax benefit has been recognized in the statement of operations for share-based compensation arrangements.

Stock option compensation expense for the three-month periods ended March 31, 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, except for those that vested immediately and for which the estimated fair value was expensed immediately.

The following table provides stock option activity for the three months ended March 31, 2016:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Stock Options Outstanding at December 31, 2015	649,478	\$ 3.75	3.21 years	\$1,032,362
Granted	60,000	5.64		
Exercised	45,814	2.82		

Edgar Filing: CHEMBIO DIAGNOSTICS, INC. - Form 10-Q

Forfeited/expired/cancelled	-	-		
Outstanding at March 31, 2016	663,664	\$ 3.98	3.31 years	\$1,331,294
Exercisable at March 31, 2016	373,414	\$ 4.00	2.37 years	\$743,691

As of March 31, 2016, there was \$387,433 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 2.32 years. The total fair value of stock options vested during the three-month periods ended March 31, 2016 and 2015 was approximately \$174,371 and \$357,484, respectively.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2016

(UNAUDITED)

## f) Geographic Information:

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

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

	For the three months ended	
	March 31, 2016	<u>March 31,</u> <u>2015</u>
Africa	\$713,989	\$1,576,054
Asia	64,005	50,813
Europe	123,096	65,146
North America	2,389,024	1,319,002
South America	2,626,905	2,603,670
	\$5,917,019	\$5,614,685

## g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

	March 31, 2016	December 31, 2015
Accounts payable – suppliers	\$1,162,164	\$1,260,520
Accrued commissions	320,753	129,192
Accrued royalties / license fees	269,309	732,301
Accrued payroll	197,682	146,962
Accrued vacation	270,569	244,810
Accrued bonuses	-	177,700
Accrued expenses – other	195,645	109,947
TOTAL	\$2,416,122	\$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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2016

(UNAUDITED)

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.

**NOTE3 — COLLABORATIVE RESEARCH AND DEVELOPMENT ARRANGEMENTS:**

a) Battelle/CDC DPP® Influenza Immunity Test:

The Company has a milestone-based development agreement of an amount up to an additional \$1,268,000, based on Chembio's previous successful initial development of a multiplex rapid point-of-care ("POC") influenza immunity test utilizing its patented Dual Path Platform (DPP®) technology. The Company earned \$- and \$221,000 for the three-month periods ended March 31, 2016 and 2015, respectively from this agreement. The Company earned \$1,257,000 from this grant from inception through March 31, 2016. As of June 30, 2015, we have successfully completed the product development, and the final report is being evaluated by the contracting entity.

b) RVR DPP® technology transfer agreement:

In February 2014, the Company entered into a technology transfer agreement with RVR Diagnostics for \$1,500,000. The agreement was modified in September 2014. The Company did not earn revenues during the three-month periods ended March 31, 2016 and 2015, respectively from this agreement. The Company earned \$1,250,000 from this grant from inception through March 31, 2016.

c) Dengue agreement:

In October 2014, the Company entered into a technology development agreement with a diagnostics company for \$300,000. The Company earned \$- and \$90,000 for the three-month periods ended March 31, 2016 and 2015, respectively from this agreement. The Company earned \$300,000 from this grant from inception through March 31,

2016 and the development is completed.

9

---

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2016

(UNAUDITED)

d) 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 \$61,500 and \$127,500 for the three-month periods ended March 31, 2016 and 2015, respectively from this agreement. The Company earned \$531,150 from this grant from inception through March 31, 2016.

e) Malaria agreement:

In January 2015, the Company was awarded a grant from the Bill & Melinda Gates Foundation for \$307,000. The Company earned \$- and \$133,900 for the three-month periods ended March 31, 2016 and 2015, respectively from this agreement. The Company earned \$307,000 from this grant from inception through March 31, 2016 and the development is completed.

f) Cancer agreement:

In October 2014, the Company entered into a technology development agreement with an international diagnostics company for \$320,000. The Company earned \$- and \$75,000 for the three-month periods ended March 31, 2016 and 2015, respectively from this agreement. The Company earned \$205,000 from this grant from inception through March 31, 2016.

g) Fever Panel agreement:

In October 2015, the Company entered into a technology development agreement with the Paul G. Allen Ebola Program for \$2,118,265 and a follow-on agreement in February 2016 for \$550,135. The Company earned \$572,300 and \$- for the three-month periods ended March 31, 2016 and 2015, respectively from this agreement. The Company earned \$980,800 from this grant from inception through March 31, 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").



CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2016

(UNAUDITED)

## 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 trading 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 (the date on which the Agreement was entered into), 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				Accounts Receivable as of	
	March 31, 2016		March 31, 2015		March 31, 2016	March 31, 2015
	Sales	% of Sales	Sales	% of Sales		
Customer 1	\$2,589,405	44	% \$2,461,871	44	% \$2,694,495	\$6,097,611
Customer 2	1,796,477	30	% 1,016,989	18	% 860,420	345,502
Customer 3	*	*	1,386,183	25	% 461,594	1,134,327

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

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

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

	For the three months ended				Accounts Payable as of	
	March 31, 2016		March 31, 2015		March 31, 2016	March 31, 2015
	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	\$222,902	14	% * *		\$-	*

(\*) 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2016

(UNAUDITED)

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 one-fifth vesting on each of the first five anniversaries of the grant. In connection with the Klugewicz contract that expires in May 2017, no options were issued; however in connection with the prior Klugewicz contract that expired in May 2015, the Company issued, in May 2013, 5,000 options to purchase common stock, with one-half vesting on each of the first and second anniversaries of the grant. In connection with the Esfandiari contract that expires in March 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's interim benefit for income taxes is estimated based on our calculated effective tax rate expected to be applied for the full year. This estimate is used to determine the income tax (benefit) on a year-to-date basis and may change in subsequent interim periods. Our effective tax rate for the three months ended March 31, 2016 was a benefit of 34.8 %. The calculated benefit of \$(162,000) increased the carrying value of the deferred tax asset for the three months ended March 31, 2016. The 34.8 % benefit rate is slightly more than the 26.0 % provision rate used for the three months ended March 31, 2015. There are several factors that go into the estimated effective tax rate, some of which include estimated year-end income or loss, timing differences and permanent differences. Some of these estimates can change over time and likewise the estimated effective rate can change as was the case in 2015, for which the year-end 2015 estimated rate was 32.05 %.

## 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), 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 three months ended March 31, 2016 increased to \$0.66 million from \$0.61 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 three months ended March 31, 2016 were \$1.63 million, compared with \$1.58 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. We anticipate starting pre-clinical studies and initiating registration to begin initial commercialization in the second quarter of 2016. This program is fully funded by a

partner. However, under the terms of our agreement, Chembio's partner is not being disclosed.

DPP® Zika Assays: The DPP® Zika Assay is a rapid POC stand-alone test for the simultaneous detection of IgG/IgM antibodies, and the DPP® Dengue/Chikungunya/Zika Assay is a rapid, POC, multiplex test for the simultaneous detection of IgG/IgM 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, including testing clinical specimens from over 600 pregnant women, of the DPP® Zika Assay required to file the following regulatory submissions: U.S. Food and Drug Administration Emergency Use Authorization (EUA), World Health Organization EUA, and Brazil's regulatory agency ANVISA. The Company expects significant revenue from the sales outside the U.S. of its DPP® Zika 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. In May 2015, an Informational Meeting was conducted at the FDA to present the technology and intended use, as well to initiate dialogue regarding the regulatory pathway for this product. The DPP® Traumatic Brain Injury Assay is in the feasibility stage. We are currently working with several hospitals to finalize institutional review board (IRB) agreements and we expect to begin conducting initial studies of the DPP® Traumatic Brain Injury Assay using patient samples in the second half of 2016.

**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 second 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 FDA approval of the DPP HIV-Syphilis Assay was initiated during first quarter of 2016.

There can be no assurance that any of the aforementioned Research & Development and/or regulatory products or activities will result in any product approvals or commercialization, nor that any of the existing research and development activities, or any new potential development programs or collaborations will materialize or that they will meet regulatory or any other technical requirements and specifications, and/or that if continued, will result in completed products, or that such products, if they are successfully completed, can or will be successfully commercialized.

## Critical Accounting Policies and Estimates



We believe that there are several accounting policies that are critical to understanding our historical and future performance, as these policies affect the reported amounts of revenue and the more significant areas involving management's judgments and estimates. These significant accounting policies relate to revenue recognition, research and development costs, valuation of inventory, valuation of long-lived assets, and income taxes. For a summary of our significant accounting policies, which have not changed from December 31, 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.

## RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2016 AS COMPARED WITH THE THREE MONTHS ENDED MARCH 31, 2015

Income:

For the three months ended March 31, 2016, Loss before income taxes was \$(466,000) compared to \$(874,000) for the three months ended March 31, 2015. Net Loss for the 2016 period was \$(304,000) as compared to \$(647,000) for 2015. The decrease in Net Loss is primarily attributable to increased gross margin, partially offset by increased operating expenses of \$72,000. Gross margin increased in the three months ended March 31, 2016, as compared with the three months ended March 31, 2015, by \$479,000, or 17.8%.

Revenues:

Selected Product Categories:	For the three months ended			
	March 31, 2016	March 31, 2015	\$ Change	% Change
Lateral Flow HIV Tests and Components	\$3,056,531	\$2,894,988	\$161,543	5.58 %
DPP® Tests and Components	2,657,884	2,463,102	194,782	7.91 %
Other	202,604	256,595	(53,991)	-21.04 %
Net Product Sales	5,917,019	5,614,685	302,334	5.38 %
License and royalty revenue	22,201	7,051	15,150	214.86 %
R&D, milestone and grant revenue	661,879	609,401	52,478	8.61 %
Total Revenues	\$6,601,099	\$6,231,137	\$369,962	5.94 %

Revenues for our lateral flow HIV tests and related components during the three months ended March 31, 2016 increased by approximately \$162,000 from the same period in 2015. This was primarily attributable to increased sales to North America of approximately \$1,070,000 and Europe of approximately \$58,000, partially offset by decreased sales to Africa, of approximately \$862,000 and South America of approximately \$106,000. Revenues for our DPP® products during the three months ended March 31, 2016 increased by approximately \$195,000 over the same period in 2015, primarily due to increased 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			
	March 31, 2016	March 31, 2015	\$ Change	% Change
Gross Margin per Statement of Operations	\$3,165,548	\$2,686,618	\$478,930	17.83 %
Less: R&D, milestone, grant, license and royalty revenues	684,080	616,452	67,628	10.97 %
Gross Margin from Net Product Sales	\$2,481,468	\$2,070,166	\$411,302	19.87 %
Product Gross Margin %	41.94 %	36.87 %		

The overall gross margin dollar increase of \$479,000 included a \$411,000 increase in gross margin from product sales and a \$68,000 increase in non-product revenues. The increase in net product sales gross margin of \$411,000 is primarily attributable to the product mix of sales compared to 2015. The net product sales gross margin increase is

primarily affected by two components, one is the increase in product sales of \$302,000, which, at the 36.9% margin percentage for March 31, 2015, contributed \$111,000 to the increase, and the other is the increased change in margin percentage of 5.1%, which contributed \$300,000 to the balance of the increase in our net product sales gross margin.

Research and Development:

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

Selected expense lines:	For the three months ended		\$ Change	% Change	
	March 31, 2016	March 31, 2015			
<b>Clinical and Regulatory Affairs:</b>					
Wages and related costs	\$ 132,569	\$ 122,686	\$ 9,883	8.06	%
Consulting	4,396	8,257	(3,861 )	-46.76	%
Clinical trials	52,095	112,030	(59,935 )	-53.50	%
Other	13,700	23,002	(9,302 )	-40.44	%
Total Regulatory	202,760	265,975	(63,215 )	-23.77	%
<b>R&amp;D Other than Regulatory:</b>					
Wages and related costs	740,031	764,005	(23,974 )	-3.14	%
Consulting	5,660	9,933	(4,273 )	-43.02	%
Stock-based compensation	7,457	18,207	(10,750 )	-59.04	%
Materials and supplies	560,232	403,132	157,100	38.97	%
Other	118,158	123,284	(5,126 )	-4.16	%
Total other than Regulatory	1,431,538	1,318,561	112,977	8.57	%
<b>Total Research and Development</b>	<b>\$ 1,634,298</b>	<b>\$ 1,584,536</b>	<b>\$ 49,762</b>	<b>3.14</b>	<b>%</b>

Expenses for Clinical & Regulatory Affairs for the three months ended March 31, 2016 decreased by \$63,000 as compared to the same period in 2015. This was primarily due to the decrease in clinical trial expenses of \$60,000.

R&D expenses other than Clinical & Regulatory Affairs increased by \$113,000 in the three months ended March 31, 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		\$ Change	% Change	
	March 31, 2016	March 31, 2015			
Wages and related costs	\$ 814,249	\$ 873,798	\$ (59,549)	-6.81	%
Consulting	61,744	41,606	20,138	48.40	%
Commissions	315,980	336,872	(20,892)	-6.20	%
Stock-based compensation	46,132	91,102	(44,970)	-49.36	%
Marketing materials	50,133	36,323	13,810	38.02	%
Investor relations/investment bankers	82,926	44,114	38,812	87.98	%
Legal, accounting and compliance	332,117	236,936	95,181	40.17	%

Edgar Filing: CHEMBIO DIAGNOSTICS, INC. - Form 10-Q

Travel, entertainment and trade shows	90,484	94,760	(4,276 )	-4.51	%
Other	205,639	222,063	(16,424)	-7.40	%
Total S, G &A	\$ 1,999,404	\$ 1,977,574	\$ 21,830	1.10	%

Selling, general and administrative expenses for the three months ended March 31, 2016, increased by \$22,000 as compared with the same period in 2015, a 1% increase. This increase resulted primarily from increases in consulting, marketing materials, investor relations expenses and professional fees, which were partially offset by decreases in wages and related costs, travel, entertainment and trade shows, stock-based compensation, and commissions.

17

---

Other Income:

	For the three months ended			
	March 31, 2016	March 31, 2015	\$ Change	% Change
Interest income	\$2,564	\$1,175	\$ 1,389	118.21 %
Total Other Income	\$2,564	\$1,175	\$ 1,389	118.21 %

Other income for the three months ended March 31, 2016 increased \$1,400, from an income of \$1,200 in the same period in 2015, as a result of more cash to invest.

Income tax benefit:

For the three months ended March 31, 2016 the Company recognized a \$162,000 income tax benefit and increased its deferred tax asset. For the three months ended March 31, 2015, the Company recognized a \$227,500 income tax benefit. The Company maintains a full valuation allowance on research and development tax credits. There are several factors that go into the estimated effective tax rate, some of which include estimated year-end income or loss, timing differences and permanent differences.

## MATERIAL CHANGES IN FINANCIAL CONDITION

Selected Changes in Financial Condition	As of		\$ Change	% Change
	March 31, 2016	December 31, 2015		
Cash and cash equivalents	\$2,657,914	\$5,376,931	\$ (2,719,017)	-50.57 %
Accounts receivable, net of allowance for doubtful accounts of \$52,000 at March 31, 2016 and December 31, 2015, respectively	4,896,609	2,422,971	2,473,638	102.09 %
Inventories	3,383,273	3,578,025	(194,752 )	-5.44 %
Prepaid expenses and other current assets	1,109,410	1,256,879	(147,469 )	-11.73 %
Fixed assets, net of accumulated depreciation	2,202,373	2,374,308	(171,935 )	-7.24 %
Deferred tax asset, net of valuation allowance	5,619,143	5,467,143	152,000	2.78 %
Accounts payable and accrued liabilities	2,416,122	2,801,432	(385,310 )	-13.75 %

Cash decreased by \$2,719,000 from December 31, 2015, primarily due to net cash used in operating activities for the three months of 2016. In addition there were increases in accounts receivable of \$2,474,000 (primarily due to a large customer as described under "Liquidity And Capital Resources"), and in non-current deferred tax asset of \$152,000. We experienced a decrease in inventories of \$195,000, prepaid expenses of \$147,000, fixed assets of \$172,000 and accounts payable and accrued liabilities of \$385,000.

## LIQUIDITY AND CAPITAL RESOURCES

	For the three months ended			
	March 31, 2016	March 31, 2015	\$ Change	% Change
Net cash used in operating activities	\$ (2,690,610)	\$ (941,808 )	\$ (1,748,802)	185.69 %
Net cash used in investing activities	(28,407 )	(856,968 )	828,561	-96.69 %
Net cash provided by financing activities	-	-	-	100.00 %
Decrease in cash and cash equivalents	\$ (2,719,017)	\$ (1,798,776)	\$ (920,241 )	51.16 %

The Company's cash decreased as of March 31, 2016 by \$2,719,000 from December 31, 2015, primarily due to net cash used in operating activities and net cash used in investing activities for the three months of 2016.

The cash used in operations in 2016 was \$2,719,000, which consisted primarily of an increase in accounts receivable of \$2,474,000, a decrease in accounts payable and accrued liabilities of \$385,000 and a net loss net of non-cash items of \$120,000, partially offset by cash provided by a decrease in inventories of \$195,000 and prepaid expenses of \$103,000. Net loss net of non-cash items includes net loss of \$304,000, which includes \$162,000 in benefit for income taxes, partially offset by non-cash expenses for \$292,000 in depreciation and amortization, and by \$54,000 in share-based compensation. The use of cash from investing activities is primarily due to the purchase of fixed assets of \$28,000.

The Company currently has positive working capital, however, it has used approximately \$2.7 million in cash for the three months ended March 31, 2016. Approximately \$2.7 million of the total \$4.9 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 March 31, 2016, the Company had \$28,473 in deposits on equipment. The Company had \$31,600 in commitments for additional equipment purchase obligations.

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

Each of Chembio's three business segments made important advances during the first few months of 2016. During the period, Chembio entered into three new development collaborations expanding the company's fever disease business. In the sexually transmitted disease segment, Chembio initiated a critical clinical trial, achieved sales growth in multiple regions, and prepared to expand the product commercialization effort for this business. And lastly, the company made progress with a number of its technology collaborations.

### Sexually Transmitted Disease

In the first quarter of 2016, Chembio's sexually transmitted disease product sales in North America, South America, Asia and Europe increased 29% quarter-over-quarter as compared to the prior year period.

Notably, in the U.S., we saw an increase in sales of approximately \$1.0 million, an increase of approximately 78% compared to the first quarter of 2015. We are pleased with the demand for our HIV products in the U.S., and look forward to adding the SURE CHECK® HIV 1/2 Assay to our U.S. commercial efforts, effective June 1, 2016, following the end of our current distribution agreement. Associated with the increase in sales, we've recorded an increase in accounts receivable of approximately \$2.5 million, resulting in total receivables of \$4.9 million. We are confident in our ability to collect these receivables, which will significantly increase our cash balance.

Though we saw a decrease in lateral flow product sales to Africa and South America during the first quarter of 2016, revenues for our DPP® products during the three months ended March 31, 2016 increased by approximately \$195,000 over the same period in 2015, primarily due to increased sales in Brazil. Chembio continues to have strong relationships with the Ministry of Health and Bio-Manguinhos/Fiocruz in Brazil as evidenced by our recent fever disease collaboration, as well as other groups throughout Latin America, and we believe this region will continue to be a strong market for Chembio.

On the clinical development side, we made an important advance with our DPP® HIV-Syphilis Assay for the U.S. market during the first quarter of 2016. 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 pleased to report that this clinical trial was initiated on time, during the first quarter of 2016. We are also in the process of submitting the technical dossier for CE Mark which will allow us to commercialize the DPP® HIV-Syphilis Assay in Europe.

### Fever Disease

During the first quarter of 2016, Chembio expanded its fever disease business by entering into two new collaborations with world-leading healthcare research and funding organizations for the development of point-of-care (POC) diagnostics intended to contain the spread of fever diseases through accurate and early diagnosis. The company entered into a third such partnership in April 2016. New products to be developed under these agreements are as follows:

· The DPP® Zika Assay, which has received initial funding from the Paul G. Allen Family Foundation.

· The DPP® Zika IgM/IgG Assay for the Ministry of Health in Brazil, to be developed in collaboration with Bio-Manguinhos/Fiocruz.



The world's first oral fluid/saliva POC diagnostic test to simply and accurately identify individuals infected with all species of malaria, which has initial funding from the Bill & Melinda Gates Foundation.

Since announcing the initiation of our new Zika program during the first quarter of 2016, we have made rapid and significant progress. To date, we have developed a DPP® Zika IgM/IgG Assay and have collected over 1,000 data points for the stand-alone test, which have yielded highly encouraging results. Our latest collaboration, the oral fluid/saliva POC malaria test, is in early stages. However, given our success with our initial malaria program, 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.

With the addition of these three programs, Chembio is actively developing nine POC DPP® fever assays, with the majority of these programs being supported and funded by leading health research and funding organizations. It is important to note that a number of these organizations are returning to Chembio to initiate new programs after having prior experience with the company's DPP® technology. We believe that these discerning return collaborators, such as the Bill & Melinda Gates Foundation and the Paul G. Allen Family Foundation, offer critical validation for the DPP® technology, as well as our team of scientists and developers.

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. Since the beginning of the first quarter of 2016, for the DPP® Zika IgM/IgG Assay, the company filed 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), and plans to submit an EUA application with the World Health Organization (WHO) during May 2016. 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 first 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 quarter of 2016. This project, which is funded by Perseus Science Group, LLC, is in the feasibility phase. We are currently working with several hospitals to finalize institutional review board (IRB) agreements and develop the plan for conducting initial studies of the DPP® Traumatic Brain Injury Assay using patient samples.

We are awaiting response on the most recent 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. We are particularly excited about offering this technology in combination with our assays. 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 a suite of DPP® Assay-Reader kits, and we look forward to commercialization of these innovative and versatile diagnostic systems.

The first quarter of 2016 was exceptional for Chembio, with meaningful advancements in each of our business segments. In our sexually transmitted disease business, we achieved sales growth in North America, South America, Europe and Asia during the quarter of 2016, with a significant increase in U.S. sales as compared to the first quarter of 2015. In our fever disease business, driven by the serious threat posed by both Malaria and now by Zika virus, and through collaborations with leading health research and funding organizations, Chembio is working to leverage its patented DPP® technology into products that may allow healthcare workers to change current testing paradigms and contain the spread of life-threatening diseases. During the period, we received a grant from the Paul G. Allen Family Foundation to initiate development of a DPP® Zika Assay. Less than three months later, we announced our filing with Brazil's regulatory agency and plans to introduce the DPP® Zika IgM/IgG Assay in Brazil through our partner Bio-Manguinhos/Fiocruz, who is responsible for supplying diagnostics to Brazil's Ministry of Health. And, in April, we received a grant from the Bill and Melinda Gates Foundation to complete feasibility on our DPP® technology platform, to develop the world's first POC Malaria assay using oral fluid/saliva. We are honored by the confidence of our partners in these endeavors and committed to delivering these much-needed POC diagnostic tools.

#### 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 three months of fiscal 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

21

---

ITEM 6. EXHIBITS

EXHIBITS INDEX

Number Description

- 3.1 Articles of Incorporation, as amended. (1)
- 3.2 Amended and Restated Bylaws. (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

Edgar Filing: CHEMBIO DIAGNOSTICS, INC. - Form 10-Q

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: May 12, 2016 By: /s/ John J. Sperzel III  
John J. Sperzel III  
Chief Executive Officer  
(Principal Executive Officer)

Date: May 12, 2016 By: /s/ Richard J. Larkin  
Richard J. Larkin  
Chief Financial Officer  
(Principal Financial and Accounting Officer)