CHEMBIO DIAGNOSTICS, INC.
Form 10-Q
August 08, 2018

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

FORM 10 - Q

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

For the quarterly period ended June 30, 2018

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.
Yes No

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

As of August 2, 2018, the Registrant had 14,173,620 shares outstanding of its $.01 par value common stock.

Quarterly Report on FORM 10-Q
For The Quarterly Period Ended
June 30, 2018

Table of Contents

Chembio Diagnostics, Inc.

	Page
Part I. FINANCIAL INFORMATION:	
Item 1. Financial Statements:	
Condensed Consolidated Balance Sheets as of June 30, 2018 (unaudited) and December 31, 2017	3
Condensed Consolidated Statements of Operations (unaudited) for the three and six months ended June 30, 2018 and 2017	4
Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and six months ended June 30, 2018 and 2017	5
Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2018 and 2017	6
Notes to Condensed Consolidated Financial Statements (unaudited)	7
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	16
Item 3. Quantitative and Qualitative Disclosures About Market Risk	24
Item 4. Controls and Procedures	24
Part II. OTHER INFORMATION:	
Item 1. Legal Proceedings	25
Item 1A. Risk Factors	25
Item 6. Exhibits	26
SIGNATURES	28
EXHIBITS	

PART I
Item 1. FINANCIAL STATEMENTS

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

	June 30, 2018 (Unaudited)	December 31, 2017
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	$ 9,505,782	$ 3,790,302
Accounts receivable, net of allowance for doubtful accounts of $42,000 at June 30, 2018 and December 31, 2017	6,886,319	2,085,340
Inventories, net	6,349,640	4,423,618
Prepaid expenses and other current assets	788,740	554,383
TOTAL CURRENT ASSETS	23,530,481	10,853,643
FIXED ASSETS, net of accumulated depreciation	2,371,509	1,909,232
OTHER ASSETS:		
Intangible assets, net	1,515,112	1,597,377
Goodwill	1,673,144	1,666,610
Deposits and other assets	357,385	589,159
	3,545,641	3,853,146
TOTAL ASSETS	$ 29,447,631	$ 16,616,021
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$ 6,010,454	$ 3,046,303
Deferred revenue	660,750	50,000
TOTAL CURRENT LIABILITIES	6,671,204	3,096,303
OTHER LIABILITIES:		
Note payable	426,550	99,480
Deferred tax liability	342,379	341,042
TOTAL LIABILITIES	7,440,133	3,536,825
COMMITMENTS AND CONTINGENCIES (Note 6)		
STOCKHOLDERS' EQUITY:		
Preferred stock - 10,000,000 shares authorized; none outstanding	-	-
Common stock - $.01 par value; 100,000,000 shares authorized; 14,173,620 and 12,318,570 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	141,736	123,185
Additional paid-in capital	74,033,287	62,821,288
Accumulated deficit	(52,424,943)	(50,044,225)
Accumulated other comprehensive income	257,418	178,948
TOTAL STOCKHOLDERS' EQUITY	22,007,498	13,079,196

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$29,447,631	$ 16,616,021

See accompanying notes to condensed consolidated financial statements

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

	For the three months ended June 30,		For the six months ended June 30,	
	2018	June 30, 2017	2018	June 30, 2017
REVENUES:				
Net product sales	$6,857,861	$2,892,942	$13,256,088	$8,320,314
License and royalty revenue	276,526	227,635	478,457	327,689
R&D, milestone and grant revenue	1,585,939	994,237	2,702,913	1,791,977
TOTAL REVENUES	8,720,326	4,114,814	16,437,458	10,439,980
COSTS AND EXPENSES:				
Cost of product sales	5,935,428	2,203,843	10,053,207	5,423,057
Research and development expenses	1,991,412	1,982,426	3,838,514	4,228,998
Selling, general and administrative expenses	2,547,216	2,109,360	4,953,785	4,597,696
	10,474,056	6,295,629	18,845,506	14,249,751
LOSS FROM OPERATIONS	(1,753,730)	(2,180,815)	(2,408,048)	(3,809,771)
OTHER INCOME:				
Interest income, net	25,355	7,722	27,330	21,104
LOSS BEFORE INCOME TAXES	(1,728,375)	(2,173,093)	(2,380,718)	(3,788,667)
Income tax provision	-	-	-	-
NET LOSS	$(1,728,375)	$(2,173,093)	$(2,380,718)	$(3,788,667)
Basic loss per share	$(0.12)	$(0.18)	$(0.17)	$(0.31)
Diluted loss per share	$(0.12)	$(0.18)	$(0.17)	$(0.31)
Weighted average number of shares outstanding, basic	14,165,343	12,299,122	13,718,776	12,284,979
Weighted average number of shares outstanding, diluted	14,165,343	12,299,122	13,718,776	12,284,979

See accompanying notes to condensed consolidated financial statements

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

	For the three months ended June 30,		For the six months ended June 30,	
	2018	June 30, 2017	2018	June 30, 2017
Net loss	$(1,728,375)	$(2,173,093)	$(2,380,718)	$(3,788,667)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(173,828)	124,241	78,470	124,241
Comprehensive Loss	$(1,902,203)	$(2,048,852)	$(2,302,248)	$(3,664,426)

See accompanying notes to condensed consolidated financial statements

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

	June 30, 2018	June 30, 2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	$ 12,247,228	$ 8,920,921
Cash paid to suppliers and employees	(17,352,226)	(14,398,812)
Interest received, net	27,330	21,104
Net cash used in operating activities	(5,077,668)	(5,456,787)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of RVR Diagnostics Sdn Bhd	-	(850,000)
Acquisition of and deposits on fixed assets	(250,147)	(555,894)
Net cash used in investing activities	(250,147)	(1,405,894)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option exercises	71,914	-
Proceeds from sale of common stock, net	10,934,352	-
Net cash provided by financing activities	11,006,266	-
Effect of exchange rate changes on cash	37,029	-
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	5,715,480	(6,862,681)
Cash and cash equivalents - beginning of the period	3,790,302	10,554,464
Cash and cash equivalents - end of the period	$ 9,505,782	$ 3,691,783
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net Loss	$ (2,380,718)	$ (3,788,667)
Adjustments:		
Depreciation and amortization	446,625	773,566
Share based compensation	224,283	209,609
Changes in assets and liabilities:		
Accounts receivable	(4,800,979)	(1,287,898)
Inventories	(1,926,022)	(1,658,763)
Prepaid expenses and other current assets	(215,758)	(25,043)
Deposits and other assets	-	8,729
Accounts payable and accrued liabilities	2,964,151	542,841
Deferred revenue	610,750	(231,161)
Net cash used in operating activities	$ (5,077,668)	$ (5,456,787)
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	$ 257,455	$ 174,399
Seller-financed equipment purchases	327,070	-
Accrual of contingent earn-out	-	148,000
Issuance of common stock for net assets of business acquired	-	1,682,725

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2018
(UNAUDITED)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. and its subsidiaries (collectively, the "Company" or "Chembio") develop, manufacture, and commercialize point-of-care (POC) diagnostic tests that are used to detect or monitor diseases. The Company's product development efforts are focused on our patented DPP® technology, a novel point-of-care diagnostic platform that offers certain customer advantages as compared to traditional lateral flow technology. POC tests, by providing prompt and early diagnosis, can reduce patient stays, lower overall costs, improve therapeutic interventions and improve patient outcomes. POC tests can also prevent needless hospital admissions, simplify testing procedures, avoid delays from central lab batching, and eliminate the need for return visits.

Our product commercialization and product development efforts are focused in three areas: sexually transmitted disease, tropical & fever disease, and technology collaborations. In sexually transmitted disease, we are commercializing tests for HIV and Syphilis. In tropical and fever disease, we are commercializing a test for Zika virus, and developing tests for malaria, dengue virus, chikungunya virus, ebola, lassa, Marburg, leptospirosis, Rickettsia typhi, Burkholderia pseudomallei, and Orientia tsutsugamushi, individually or as part of fever panel tests. Through technology collaborations, we are developing tests for a specific form of cancer, concussion, bovine tuberculosis, and for an undisclosed biomarker, the latter in collaboration with global biopharmaceutical company AstraZeneca.

Large and growing markets have been established for these kinds of tests, initially in high prevalence regions where they are critical for large scale prevention and treatment programs. Our product development is focused on areas where the availability of rapid, POC screening, diagnostic, or confirmatory results can improve health outcomes. More generally, we believe there is and will continue to be a growing demand for diagnostic products that can provide accurate, actionable diagnostic information in a rapid, cost-effective manner at the point of care.

Our 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, under our STAT PAK®, SURE CHECK®, STAT-VIEW® or DPP® registered trademarks, or under the private labels of our marketing partners.

The Company routinely enters into arrangements with governmental and non-governmental organizations for the funding of certain research and development efforts.

NOTE 2 — ACQUISITION:

On January 9, 2017, pursuant to a stock purchase agreement (the "Stock Purchase Agreement"), the Company acquired all of the outstanding common stock of RVR Diagnostics Sdn Bhd, ("RVR"), a privately-held Malaysia-based manufacturing company focused on assembly and sales of rapid medical POC assays, for $3,083,000. The Company acquired RVR, which subsequently changed its name to Chembio Diagnostics Malaysia Sdn Bhd ("CDM"), to have a better presence in Asia, access to lower cost, shorter approval time of in-country regulatory approvals, and a lower cost assembly operation.

Total consideration was: (i) a cash payment of $1,400,000, of which $550,000 was paid as a deposit in December 2016; (ii) 269,236 shares of Chembio's common stock, with a value at closing of $1,683,000, of which 7,277 shares were held back to satisfy certain potential claims under the Stock Purchase Agreement and became issuable to the sellers on the one-year anniversary of the closing; and, a contingent $148,000 milestone payment based on the

achievement of performance goals related to sales by CDM during the 12 months ended December 31, 2017. The performance goals were not achieved and the related $148,000 accrual was reversed during the fourth quarter of 2017 and recognized in selling, general, and administrative expenses associated with the change in fair value.

As a result of the consideration paid exceeding the fair value of the net assets acquired, goodwill in the amount of $1,651,361 was recorded in connection with this acquisition, none of which will be deductible for tax purposes. In addition, the Company recorded $1,800,000 in intangible assets associated with the addition of CDM's intellectual property, customer base and distribution channels, trade names, order backlog, industry reputation, and management talent and workforce.

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

	Amount
Property, plant and equipment	$235,141
Goodwill	1,651,361
Deferred tax liability	(307,636)
Contingent consideration	(148,000)
Other intangible assets (estimated useful life):	
Intellectual property (approximate 10 year weighted average)	800,000
Customer contracts / relationships (approximate 10 year weighted average)	700,000
Order backlog (3 months)	200,134
Trade names (approximate 11 year weighted average)	100,000
Total consideration	$3,231,000

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

NOTE 3 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

a) Basis of Presentation:

The preceding (a) condensed consolidated balance sheet as of December 31, 2017, which has been derived from audited financial statements, and (b) the unaudited interim condensed consolidated financial statements as of June 30, 2018 and for the three and six-month periods ended June 30, 2018 and 2017, 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, 2017, previously filed with the SEC on March 8, 2018.

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, 2018, its condensed consolidated results of operations for the three and six-month periods ended June 30, 2018 and 2017, respectively, and its condensed consolidated cash flows for the six-month periods ended June 30, 2018 and 2017, 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:

In May 2014, the Financial Accounting Standards Board (“FASB”) issued converged guidance on recognizing revenue in contracts with customers, ASU 2014-09, Revenue from Contracts with Customers. The intent of the new standard is to improve financial reporting and comparability of revenue globally. The core principle of the standard is for a company to recognize revenue in a manner that depicts the transfer of goods or services to customers in an amount that reflects the consideration which the company expects to receive in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of the time value of money in the transaction price, and in certain circumstances, allowing estimates of variable consideration to be recognized before contingencies are resolved. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of

revenue and cash flows arising from an entity's contracts with customers.

The new revenue standards became effective for the Company on January 1, 2018 and were adopted using the modified retrospective method. The adoption of the new revenue standards as of January 1, 2018 did not change our revenue recognition as our revenues continue to be recognized when the customer takes control of our product. As we did not identify any material accounting changes that impacted the amount of reported revenues with respect to our product revenue, license and royalty revenue, and R&D, milestone and grant revenues, no adjustment to retained earnings was required upon adoption.

We adopted the standards to contracts that were not completed at the date of initial application (January 1, 2018).

Under the new revenue standards, we recognize revenues when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenues following the five-step model prescribed under ASU No. 2014-09: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation.

Product Revenues

Revenues from product sales are recognized when the customer obtains control of our product, which occurs at a point in time, typically upon tendering to the customer. We expense incremental costs of obtaining a contract as and when incurred because the expected amortization period of the asset that we would have recognized is one year or less or the amount is immaterial.

Freight and distribution activities on products are performed after the customer obtains control of the goods. The Company has made an accounting policy election to account for shipping and handling activities that occur either when or after goods are tendered to the customer as a fulfillment activity, and therefore recognizes freight and distribution expenses in Cost of Product Sales.

Reserves for Discounts and Allowances

Revenues from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with our customers. Our process for estimating reserves established for these variable consideration components does not differ materially from our historical practices.

Product revenue reserves, which are classified as a reduction in product revenues, are generally related to discounts. Estimates of variable consideration and the determination of whether to include estimated amounts in the transaction price are based on all information (historical, current and forecasted) that is reasonably available to the company, taking into consideration the type of customer, the type of transaction and the specific facts and circumstances of each arrangement. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

Royalty Revenues

We receive royalty revenues on sales by our licensees of products covered under patents that we own. We do not have future performance obligations under these license arrangements. We record these revenues based on estimates of the sales that occurred during the relevant period as a component of license and royalty revenues. The relevant period estimates of sales are based on interim data provided by licensees and analysis of historical royalties that have been paid to us, adjusted for any changes in facts and circumstances, as appropriate. Differences between actual and estimated royalty revenues are adjusted for in the period in which they become known, typically the following quarter. Historically, adjustments have not been material when compared to actual amounts paid by licensees.

R&D, milestone and grant revenue

All such contracts are evaluated under the five-step model described above. For certain contracts that represent grants where the funder does not meet the definition of a customer, the Company recognizes revenue when earned. Such

contracts are further described under Disaggregation of Revenue, below. Grants are invoiced and revenue is recognized after expenses are incurred as that is the depiction of the timing of the transfer of services. Performance obligations generally follow the major phases of product development processes: design feasibility & planning, product development & design optimization, design verification, design validation & process validation, and pivotal studies.

The Company follows the recognition of revenue under the milestone method for certain collaborative research projects defining milestones at the inception of the agreement.

Disaggregation of Revenue

In August 2016, the Company was awarded a grant of $5.9 million from BARDA, which is part of the U.S. Department of Health and Human Resources to develop a rapid Zika virus assay. The Company earned $0.8 million and $1.2 million during the three and six-months ended June 30, 2018, respectively as R&D, milestone and grant revenue in the Consolidated Statements of Operations.

In September 2016, the Company was awarded a $0.7 million contract from the USDA to develop a Bovid TB assay. The Company earned $0.1 million and $0.1 million during the three and six-months ended June 30, 2018, respectively as R&D, milestone and grant revenue in the Consolidated Statements of Operations.

The following table disaggregates Total Revenues for the three and six-months ended June 30, 2018:

	For the three months ended			For the six months ended		
	Exchange Transactions	Non-Exchange Transactions	Total	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	$6,857,861	$ -	$6,857,861	$13,256,088	$ -	$13,256,088
License and royalty revenue	276,526	-	276,526	478,457	-	478,457
R&D, milestone and grant revenue	755,570	830,369	1,585,939	1,367,375	1,335,538	2,702,913
	$7,888,957	$ 830,369	$8,720,326	$15,101,920	$ 1,335,538	$16,437,458

Contract Liabilities

Deferred revenue relates to payments received in advance of performance under the contract. Deferred revenue is recognized as revenue as (or when) we perform under the contract. At December 31, 2017, we reported $50,000 in deferred revenue of which $50,000 was earned and recognized as R&D, milestone and grant revenue during the six-months ended June 30, 2018, respectively.

c) Inventories

Inventories consist of the following at:

	June 30, 2018	December 31, 2017
Raw materials	$ 3,019,464	$1,767,684
Work in process	566,286	286,413
Finished goods	2,763,890	2,369,521
	$ 6,349,640	$4,423,618

Inventories are stated at the lower of cost and net realizable value. There were reserves against inventory of approximately $130,000 and $195,000 as of June 30, 2018 and December 31, 2017, respectively.

d) Loss Per Share:

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted loss per share for the three and six-month periods ended June 30, 2018 and 2017 reflects the potential dilution from the exercise or conversion of other securities into common stock, if dilutive.

There were 683,829 and 674,795 weighted-average number of options outstanding as of June 30, 2018 and 2017, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended June 30, 2018 and 2017 respectively, because the effect would have been anti-dilutive. There were 707,880 and 677,592 weighted-average number of options outstanding as of June 30, 2018 and 2017, respectively, that were not included in the calculation of diluted per common share equivalent for the six months ended June 30, 2018 and 2017 respectively, because the effect would have been anti-dilutive.

e) Stock Incentive Plan:

Effective June 3, 2008, the Company’s stockholders voted to approve the 2008 Stock Incentive Plan (“SIP”), 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. Awards can be stock options, restricted stock and/or restricted stock units ("Equity Award Units"). The awards vest at such times and under such conditions as determined by the Compensation Committee. As of June 30, 2018, there were 510,631 options exercised, 94,132 options outstanding and 145,237 Equity Award Units still available to be issued under the SIP.

Effective June 19, 2014, the Company's stockholders voted to approve the 2014 Stock Incentive Plan ("SIP14"), with 800,000 shares of Common Stock available to be issued. Under the terms of the SIP14, the Compensation Committee of the Company's Board has the discretion to select the persons to whom awards are to be granted. Awards can be in the form of Equity Award Units. The awards vest at such times and under such conditions as determined by the Compensation Committee. As of June 30, 2018, there were 60,066 options exercised, 364,093 options outstanding and 375,841 Equity Award Units still available to be issued under the SIP14.

Stock-based compensation expense recognized in the Condensed Consolidated Statements of Operations was classified as the following approximate amounts:

	For the three months ended		For the six months ended	
	June 30, 2018	June 30, 2017	June 30, 2018	June 30, 2017
Cost of product sales	$ 5,800	$12,800	$ 14,000	$21,400
Research and development expenses	3,600	12,100	15,500	65,200
Selling, general and administrative expenses	117,700	48,800	194,800	123,000
	$ 127,100	$73,700	$ 224,300	$209,600

Stock option compensation expense in each of the periods presented represents the estimated fair value of options outstanding, amortized on a straight-line basis over the requisite vesting period of the entire award.

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 historical volatility of our stock and other contributing factors. The expected term is based on the Company's historical experience with similar type options.

The weighted-average assumptions made in calculating the fair values of options are as follows:

	For the three months ended June 30,			For the six months ended June 30,		
	2018		June 30, 2017	2018		June 30, 2017	
Expected term (in years)	5.4		n/a	5.4		5.0	
Expected volatility	40.12	%	n/a	40.12	%	44.18	%
Expected dividend yield	0	%	n/a	0	%	0	%
Risk-free interest rate	2.70	%	n/a	2.70	%	1.58	%

The following table provides stock option activity for the six months ended June 30, 2018:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2017	810,670	$ 5.18	3.69 years	$2,477,853
Granted	46,875	8.15		-
Exercised	144,947	4.83		$523,327
Forfeited/expired/cancelled	47,505	8.82		-
Outstanding at June 30, 2018	665,093	$ 5.21	3.74 years	$3,919,140
Exercisable at June 30, 2018	324,363	$ 4.07	2.66 years	$2,279,731

The following table summarizes information about stock options outstanding at June 30, 2018:

	Stock Options Outstanding				Stock Options Exercisable		
Range of Exercise Prices	Shares	Average Remaining Contract Life (Year)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
1 to 2.79999	-	-	$ -	$-	-	$ -	$-
2.8 to 4.59999	304,343	2.41	3.45	2,328,522	254,343	3.46	1,944,337
4.6 to 6.39999	152,875	3.94	5.85	802,387	48,645	5.75	260,338
6.4 to 8.19999	207,875	5.56	7.31	788,231	21,375	7.59	75,056
8.2 to 10	-	-	-	-	-	-	-
Total	665,093	3.74	$ 5.21	$3,919,140	324,363	$ 4.07	$2,279,731

As of June 30, 2018, there was $678,237 of net unrecognized compensation cost related to stock options that are not vested, which is expected to be recognized over a weighted average period of approximately 2.55 years. The total fair value of shares vested during the six-month periods ended June 30, 2018 and 2017 was $319,549 and $302,712, respectively.

f) Geographic Information and Economic Dependency

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

For the six months ended

	For the three months ended			
	June 30, 2018	June 30, 2017	June 30, 2018	June 30, 2017
Africa	$2,226,540	$493,852	$3,865,070	$862,679
Asia	22,348	92,596	989,922	1,513,018
Europe & Middle East	635,579	599,435	1,027,649	1,040,160
Latin America	3,266,290	672,765	5,956,183	1,760,104
United States	707,104	1,034,294	1,417,264	3,144,353
	$6,857,861	$2,892,942	$13,256,088	$8,320,314

g) Fair Value of Financial Instruments:

The carrying value for cash and cash equivalents, accounts receivable, and accounts payable, approximate fair value due to the immediate or short-term maturity of these financial instruments. The fair value of the Company's note payable approximates the recorded value as the rate is based upon the current rates offered to the Company for similar financial instruments.

h) Accounts Payable and Accrued Liabilities:

Accounts payable and accrued liabilities consist of:

	June 30, 2018	December 31, 2017
Accounts payable – suppliers	$ 3,558,450	$ 1,494,759
Accrued commissions	291,127	126,827
Accrued royalties / license fees	511,292	429,297
Accrued payroll	352,257	187,305
Accrued vacation	356,686	309,767
Accrued bonuses	428,665	282,500
Accrued expenses – other	511,977	215,848
TOTAL	$ 6,010,454	$ 3,046,303

i) Goodwill and Intangible Assets:

Goodwill represents the excess of the purchase price we paid over the fair value of the net tangible and identifiable intangible assets acquired in our acquisition of CDM in January 2017. Goodwill is not amortized but rather is tested annually as of the first day of the fiscal fourth quarter for impairment or more frequently if we believe that indicators of impairment exist. We make a qualitative evaluation about the likelihood of goodwill impairment, which is based on a number of applicable factors. If we conclude that it is more likely than not that the carrying value of the applicable reporting unit is greater than its fair value, then we would recognize an impairment charge for the amount by which the carrying value exceeds the reporting unit's fair value, provided the impairment charge does not exceed the total amount of goodwill allocated to the reporting unit.

There was no impairment recorded for the six months ended June 30, 2018. Following is a table that reflects changes in Goodwill:

Beginning balance December 31, 2017	$1,666,610
Change in foreign currency exchange rate	6,534
Balance at June 30, 2018	$1,673,144

In addition, the Company recorded certain intangible assets as part of the CDM acquisition as follows:

	June 30, 2018			December 31, 2017		
	Cost	Accumulated Amortization	Net Book Value	Cost	Accumulated Amortization	Net Book Value
Intellectual property	$ 890,349	$ 133,553	$ 756,796	$886,872	$ 88,687	$798,185
Customer contracts/relationships	779,056	116,858	662,198	776,013	77,601	698,412
Order backlog	222,736	222,736	-	221,867	221,867	-
Trade names	111,294	15,176	96,118	110,859	10,079	100,780
	$ 2,003,435	$ 488,323	$ 1,515,112	$1,995,611	$ 398,234	$1,597,377

Amortization expense for the three months ended June 30, 2018 and 2017 was approximately $45,000 and $52,000, respectively. Amortization expense for the six months ended June 30, 2018 and 2017 was approximately $90,000 and $292,000, respectively.

j) Taxes:

The Tax Cuts and Jobs Act (the "Act") was enacted on December 22, 2017. The Act reduces the U.S. federal corporate income tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries previously deferred from tax, generally eliminates U.S federal income taxes on dividends from foreign subsidiaries, and creates a new provision designed to tax global intangible low-taxed income ("GILTI"). Also on December 22, 2017, the U.S. Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 ("SAB 118") which provides for a measurement period of up to one year from the enactment for companies to complete their accounting for the Act. The Company is applying the guidance in SAB 118 in its accounting for the enactment-date effects of the Act.

As of June 30, 2018, the Company has not completed its accounting for the tax effects of the Act, but has made reasonable estimates of the effects on the re-measurement of its deferred tax assets and liabilities, as well as its transition tax liability. During the three and six-month periods ended June 30, 2018, the Company made no adjustments to the provisional amounts recorded at December 31, 2017. Additionally, the Company has not yet collected and analyzed all necessary tax and earnings data of its foreign operations; therefore, the Company has also not yet completed its accounting for the income tax effects of the transition tax. The Company will continue to make and refine its calculations as additional analysis is completed.

The Act also subjects a U.S. shareholder to tax on GILTI earned by certain foreign subsidiaries. Under U.S. GAAP, the Company is permitted to make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. Given the complexity of the GILTI provisions, the Company is still evaluating the effects of the GILTI provisions and has not yet made its accounting policy election.

k) Recent Accounting Pronouncements Affecting the Company:

In May 2014, the Financial Accounting Standards Board ("FASB") issued converged guidance on recognizing revenue in contracts with customers, ASU 2014-09, Revenue from Contracts with Customers. The intent of the new standard is to improve financial reporting and comparability of revenue globally. The core principle of the standard is for a company to recognize revenue in a manner that depicts the transfer of goods or services to customers in an amount that reflects the consideration which the company expects to receive in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of the time value of money in the transaction price, and in certain circumstances, allowing estimates of variable consideration to be recognized before contingencies are resolved. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. The standard was effective January 1, 2018.

In addition to expanding disclosures in these interim financial statements, we completed our evaluation of the new standard and assessed the impact of adoption on our consolidated financial statements. We reviewed significant open contracts with customers for each revenue stream, and based on our evaluation, revenue recognition under the new standard did not have a material impact on the Company's consolidated financial statements. The Company also assessed its control framework as a result of adopting the new standard and noted minimal, insignificant changes to its systems and other controls processes.

The new standard permits two adoption methods under ASU 2014-09. The guidance may be adopted through either retrospective application to all periods presented in the consolidated financial statements (full retrospective) or through a cumulative effect adjustment to retained earnings at the effective date (modified retrospective). The Company adopted the new standard effective January 1, 2018 using the modified retrospective transition method. Under that method, we applied the rules to all contracts existing as of January 1, 2018. The cumulative effect was immaterial, and therefore no adjustment to the opening balance of retained earnings was required.

The disclosures in our notes to the consolidated financial statements related to revenue recognition are expanded under the new standard, specifically around the quantitative and qualitative information about performance obligations, changes in contract assets and liabilities, and disaggregation of revenue.

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 ASU was adopted January 1, 2018.

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

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, which provides guidance related to cash flows presentation and is effective for annual reporting periods beginning after December 15, 2017. The guidance in ASU 2016-15 is generally consistent with our current cash flow classifications, and it was adopted effective January 1, 2018, without any material impact on our

consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting, to provide clarity to which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. This update was adopted effective January 1, 2018, without any material effect on our consolidated financial statements.

NOTE 4 — RIGHTS AGREEMENT:

In March 2016, the Company entered into a Rights Agreement dated as of March 8, 2016 (the “Rights Agreement”) between the Company and Action Stock Transfer Corp., as Rights Agent. Pursuant to the Rights Agreement, the Company declared a dividend of one preferred share purchase right (a “Right”) for each outstanding share of common stock, $0.01 par value (the “Common Stock”), of the Company. The Board of Directors set the payment date for the distribution of the Rights as March 8, 2016, and the Rights were distributed to the Company’s shareholders of record on that date. The description and terms of the Rights are set forth in the Rights Agreement.

Rights Initially Not Exercisable. The Rights are not exercisable until a Distribution Date, which is defined below. Until a Right is exercised, the holder thereof, in his capacity as a holder of Rights, will have no rights as a shareholder of the Company, including, without limitation, the right to vote or to receive dividends.

Separation and Distribution of Rights. The Rights will be evidenced by the certificates for shares of Common Stock registered in the names of the holders thereof, and not by separate rights certificates until the earlier to occur of (i) the close of business on the tenth business day following a public announcement that an Acquiring Person (as defined in the Rights Agreement) acquired a Combined Ownership (as defined in the Rights Agreement) of 20% or more of the outstanding shares of the Common Stock (the "Shares Acquisition Date") or (ii) the later of (A) the close of business on the tenth business day (or such later date as may be determined by action of the Board of Directors prior to such time as any person or group of affiliated or associated persons becomes an Acquiring Person) after the date that a tender or exchange offer or intention to commence a tender or exchange offer by any person is first published, announced, sent or given within the meaning of Rule 14d-4(A) under the Securities Exchange Act of 1934, as amended, the consummation of which would result in any person having Combined Ownership of 20% or more of the outstanding shares of the Common Stock, or (B) if such a tender or exchange offer has been published, announced, sent or given before the date of the Rights Agreement, then the close of business on the tenth business day after the date the Rights Agreement was entered into (or such later date as may be determined by action of the Board of Directors prior to such time as any person becomes an Acquiring Person); (the earlier of such dates referred to in (i) and (ii), which date may include any such date that is after the date of the Rights Agreement but prior to the issuance of the Rights, being called the "Distribution Date").

NOTE 5 — STOCKHOLDERS' EQUITY:

During the first quarter of 2018, options to purchase 119,947 shares of the Company's common stock were exercised on a cashless basis into 60,372 shares of common stock at an exercise price of $4.71 by the option holder surrendering options and shares of common stock already owned as payment of the exercise price.

During the second quarter of 2018, options to purchase 25,000 shares of the Company's common stock were exercised on a cashless basis into 10,918 shares of common stock at an exercise price of $5.07 by the option holder surrendering options and shares of common stock already owned as payment of the exercise price.

On February 13, 2018, the Company closed on an underwritten registered public offering of 1,783,760 shares of its common stock at a public offering price of $6.75 per share for gross proceeds of approximately $12.0 million. The net proceeds, after underwriting discounts and commissions, were $10.9 million. The net proceeds are intended for business expansion and working capital, including product development; operational expansion or improvements, such as new automated equipment and a facilities update; clinical trials and other related activities; and, sales and marketing.

During the first quarter of 2017, options to purchase 10,969 shares of the Company's common stock were exercised on a cashless basis into 3,039 shares of common stock at an exercise price of $4.00 by the option holder surrendering options and shares of common stock already owned.

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, 2018		June 30, 2017		June 30, 2018		June 30, 2017		June 30, 2018	Dec. 31, 2017
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales		
Customer 1	$3,217,387	47 %	$956,207	33 %	$5,627,145	42 %	$2,895,794	35 %	$ 3,051,052	$ *
Customer 2	1,460,630	21 %	*	*	1,460,630	11 %	*	*	1,460,630	*
Customer 3	*	*	*	*	*	*	1,326,171	16 %	*	*
Customer 4	*	*	399,482	14 %	*	*	754,408	9 %	*	*

In the table above, an asterisk (*) indicates that product sales to the customer did not exceed 10% for the period indicated.

Sales include product sales only, while accounts receivable reflects the total due from the customer, including freight.

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

	For the three months ended				For the six months ended				Accounts Payable as of	
	June 30, 2018		June 30, 2017		June 30, 2018		June 30, 2017		June 30, 2018	Dec. 31, 2017
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	$548,605	18 %	$*	*	$*	*	$*	*	$ **	$ *
Vendor 2	*	*	*	*	*	*	698,838	26 %	*	*
Vendor 3	394,518	13 %	204,781	11 %	863,875	14 %	*	*	223,507	*
Vender 4	326,282	11 %	*	*	*	*	*	*	*	*

In the table above, an asterisk (*) indicates that purchases from the vendor did not exceed 10% for the period indicated. Two asterisks (**) indicates that the balance due to the vendor was classified as a Note payable.

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

b) Governmental Regulation:

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

c) Employment Contracts:

The Company has multi-year contracts with two key employees that call for salaries presently aggregating $770,000 per year. The contracts expire in March 2019 and March 2020. The following table is a schedule of future minimum salary commitments as of June 30, 2018:

2018	$385,000
2019	485,500
2020	85,000

d) Pension Plan:

The Company has a 401(k) plan established for its employees whereby it matches 40% of the first 5% (or 2% of salary) that an employee contributes to the plan. Matching contribution expenses totaled $46,000 and $45,900 for

the six months ended June 30, 2018 and 2017, respectively.

NOTE 7 — NOTE PAYABLE:

In September 2017, the Company entered into an agreement with an equipment vendor to purchase automated assembly equipment for approximately $660,000. The Company paid interest at an annual rate of 12% prior to delivery. Thirty days after delivery, the Company began making monthly payments of principal and interest of approximately $20,150, at an annual rate of 12% over a twenty-four-month period.

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

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, including exhibits that are being filed as part of this report, as well as other statements made by Chembio Diagnostics, Inc. ("Chembio", the "Company", "we", "us", and "our"), contain "forward-looking statements" that include information relating to future events, future financial performance, strategies, expectations, competitive environment and regulation. Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in tense, identify forward-looking statements.

These forward-looking statements include such things as: investment objectives and the Company's ability to make investments in a timely manner on acceptable terms; references to future success of the Company's products; the Company's business strategy; estimated future capital expenditures; sales of the Company's products; competitive strengths and goals; and, other similar matters.

These forward-looking statements reflect the Company's current beliefs and expectations with respect to future events and are based on assumptions and are subject to risks and uncertainties and other factors outside the Company's control that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those referenced in this Report under Item 1A entitled "Risk Factors", matters described elsewhere in this Report, and the following: ability to market and sell products, whether through our internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the FDA or other regulatory entities; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of our products; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention and other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; ability to maintain sustained profitability; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; changes in laws or regulations; global and regional economic conditions, including conditions affecting the credit markets, such as those resulting from the United Kingdom referendum held on June 23, 2016 in which United Kingdom voters approved an exit from the European Union; and general political, business and market conditions.

Although the Company believes the expectations reflected in such forward-looking statements are based upon reasonable assumptions, these are only assumptions, and forward-looking statements should not be read as a guarantee of future performance or results and will probably not be accurate indications of when such performance or results will be achieved. Investors are cautioned that forward-looking statements may not be reliable and speak only as of the date they are made and that, except as required by law, the Company undertakes no obligation to update these forward-looking statements to reflect any future events or circumstances. All subsequent written or oral forward-looking statements attributable to the Company or to individuals acting on its behalf are expressly qualified in their entirety by this section.

Investors should also be aware that while we do, from time to time, communicate with securities analysts, it is against our policy to disclose any material non-public information or other confidential commercial information to securities analysts unless and until we have made it publicly available. Accordingly, stockholders should not assume that we agree with any statement or report issued by any analyst irrespective of the content of the statement or report. Furthermore, we have a policy against issuing or confirming financial forecasts or projections issued by others. Thus, to the extent that reports issued by securities analysts contain any projections, forecasts or opinions, such reports are not the responsibility of the Company.

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, 2017, with the exception of revenue recognition.

This management's discussion and analysis of financial condition and results of operations ("MD&A") is intended to help you understand the business operations and financial condition of the Company as of June 30, 2018, and for the three and six months ended June 30, 2018. This discussion should be read in conjunction with Item 8. Financial Statements and Supplementary Data. Our MD&A is presented in six sections:

Executive Overview
Consolidated Results of Operations
Liquidity and Capital Resources
Recent Developments
Significant Accounting Policies and Critical Accounting Estimates
Recently Issued Accounting Pronouncements

Executive Overview

Our Business

Through our wholly-owned subsidiaries, Chembio Diagnostic Systems Inc. and Chembio Diagnostics Malaysia Sdn Bhd, we develop, manufacture, and commercialize point-of-care diagnostic tests that are used to detect or monitor diseases. The Company's product development efforts are focused on our patented DPP® technology, a novel point-of-care diagnostic platform that offers certain customer advantages as compared to traditional lateral flow technology. Chembio was formed in 1985.

Business Strategy

Recent accomplishments and highlights:

Advanced to Phase 2 in the AstraZeneca-funded collaboration to develop a DPP® Assay that identifies an "undisclosed" biomarker.
Entered collaboration with the Foundation for Innovative New Diagnostics (FIND) to expedite the feasibility testing of a rapid diagnostic test for hepatitis C virus.
Installed the first automated manufacturing line in the New York facility which will reduce cost and increase capacity.
Submitted a dossier to the World Health Organization (WHO) for the prequalification of the Malaysia facility which upon approval will allow manufacturing transfer of certain products

Our product commercialization and product development efforts are focused in three areas: sexually transmitted disease, tropical & fever disease, and technology collaborations. In sexually transmitted disease, we are commercializing tests for HIV and Syphilis. In tropical and fever disease, we are commercializing tests for Zika virus, dengue virus, and chikungunya virus, and developing tests for malaria, ebola, lassa, Marburg, leptospirosis, Rickettsia typhi, Burkholderia pseudomallei, and Orientia tsutsugamushi, individually or as part of a fever panel test. Through technology collaborations, we are developing tests for a specific form of cancer, concussion, bovine tuberculosis, and for an undisclosed biomarker, the latter in collaboration with global biopharmaceutical company AstraZeneca.

Large and growing markets have been established for these kinds of tests, initially in high prevalence regions where they are indispensable for large-scale prevention and treatment programs. Our product development is focused on areas where the availability of rapid POC screening, diagnostic, or confirmatory results can improve health outcomes. More generally, we believe there is and will continue to be a growing demand for diagnostic products that can provide accurate, actionable diagnostic information in a rapid, cost-effective manner at the point of care.

Our products are sold globally, directly and through distributors, to hospitals and clinics, physician offices, clinical laboratories, public health organizations, government agencies, and consumers.

Consolidated Results of Operations

Three Months Ended June 30, 2018 versus Three Months Ended June 30, 2017

The results of operations for the three months ended June 30, 2018 and 2017 were as follows:

	June 30, 2018		June 30, 2017	
TOTAL REVENUE	$8,720,326	100%	$4,114,814	100%
OPERATING COSTS AND EXPENSES:				
Cost of product sales	5,935,428	68 %	2,203,843	54 %
Research and development expenses	1,991,412	23 %	1,982,426	48 %
Selling, general and administrative expenses	2,547,216	29 %	2,109,360	51 %
	10,474,056		6,295,629	
LOSS FROM OPERATIONS	(1,753,730)		(2,180,815)	
OTHER INCOME, NET	25,355		7,722	
LOSS BEFORE INCOME TAXES	(1,728,375)	(20)%	(2,173,093)	(53)%
Income tax provision	-		-	
NET LOSS	$(1,728,375)		$(2,173,093)	

Percentages in the table reflect the percent of total revenues.

Total Net Revenues

Total net revenues during the three months ended June 30, 2018 were $8.7 million, an increase of $4.6 million, or 112% compared to the three months ended June 30, 2017. The increase in total net revenues was comprised of the following:

$4.0 million, or 137% increase in net product sales compared to the three months ended June 30, 2017, reflecting strong gains in Latin America and Africa, the latter including both ongoing growth and the Company’s initial shipment to Ethiopia, and
$0.6 million, or 52% increase in R&D milestone and grant, and license and royalty revenues compared to the three months ended June 30, 2017, reflecting the benefit of increased technology and scientific collaborations associated with our DPP® technology platform.

Gross Product Margin

Cost of product sales is primarily comprised of material, labor, manufacturing overhead, depreciation and amortization, and other operating expenses. Gross product margin is net product sales less cost of product sales, and gross margin percentage is gross margin as a percentage of net product sales.

Gross product margin during the three months ended June 30, 2018 increased by $0.2 million, or 34% compared to the three months ended June 30, 2017. The following schedule calculates gross margin from product sales:

	For the three months ended		Favorable/	
	June 30, 2018	June 30, 2017	(unfavorable)	% Change
Net product sales	$6,857,861	$2,892,942	$3,964,919	137 %

Less: Cost of product sales	(5,935,428)		(2,203,843)		(3,731,585)	(169	)%
Gross Product Margin	$922,433		$689,099		$233,334	34	%
Gross Product Margin %	13.5	%	23.8	%			

The $0.2 million increase in gross product margin was comprised of the following:

$0.9 million from favorable net product sales volume as described above, and
offset by $0.7 million decrease from lower product margins, related to the sales growth in markets with lower average selling prices, coupled with inefficiencies incurred through the scaling of labor and production to deliver the 137% increase in net product sales volume.

The decrease in Gross Product Margin % is related to the same factors described above with respect to lower Gross Product Margin.

Research and Development

This category includes costs incurred for clinical & regulatory affairs and other research & development, as follows:

	For the three months ended June 30, 2018	June 30, 2017	Favorable/ (unfavorable)	% Change
Clinical & regulatory affairs	$199,844	$478,138	$ 278,294	58 %
Other research & development	1,791,568	1,504,288	(287,280)	(19)%
Total Research and Development	$1,991,412	$1,982,426	$ (8,986)	(1)%

The decrease in clinical & regulatory affairs costs for the three months ended June 30, 2018 compared to the three months ended June 30, 2017 is primarily associated with decreased spending on the Company's U.S. clinical trial evaluating its DPP® HIV-Syphilis System. The increase in other research & development costs is primarily associated with a higher R&D headcount and an increase in spending on materials & supplies, each corresponding with the growth in R&D milestone and grant revenue-related projects.

Selling, General and Administrative Expense

Selling, general and administrative expense ("SG&A") includes administrative expenses, sales and marketing costs including commissions, and other corporate items.

The $0.4 million, or 21% increase in SG&A for the three months ended June 30, 2018 compared to the three months ended June 30, 2017 is primarily associated with higher sales commissions and compensation expense related to the 137% increase in net product sales volume.

Other Income (Expense)

Other income (expense) is principally interest income earned on the Company's deposits, net of interest expense on the note payable. This increased on a net basis by approximately $17,600 for the three months ended June 30, 2018 compared to the three months ended June 30, 2017.

Six Months Ended June 30, 2018 versus Six Months Ended June 30, 2017

The results of operations for the six months ended June 30, 2018 and 2017 were as follows:

	June 30, 2018		June 30, 2017	
TOTAL REVENUES	$16,437,458	100%	$10,439,980	100%
COSTS AND EXPENSES:				
Cost of product sales	10,053,207	61 %	5,423,057	52 %
Research and development expenses	3,838,514	23 %	4,228,998	41 %
Selling, general and administrative expenses	4,953,785	30 %	4,597,696	44 %
	18,845,506		14,249,751	
LOSS FROM OPERATIONS	(2,408,048)		(3,809,771)	
OTHER INCOME, NET	27,330		21,104	
LOSS BEFORE INCOME TAXES	(2,380,718)	(14)%	(3,788,667)	(36)%

Income tax provision	-	-
NET LOSS	$(2,380,718)	$(3,788,667)

Percentages in the table reflect the percent of total revenues.

Total Net Revenues

Total net revenues during the six months ended June 30, 2018 were $16.4 million, an increase of $6.0 million, or 57% compared to the six months ended June 30, 2017. The increase in total net revenues was comprised of the following:

$4.9 million, or 59% increase in net product sales compared to the six months ended June 30, 2018, reflecting increased sales to Latin America and Africa, and
$1.1 million, or 50% increase in Royalty and R&D milestone and grant revenues compared to the six months ended June 30, 2017, reflecting growing governmental, non-governmental, and commercial partnerships associated with our DPP® technology platform.

Gross Product Margin

Cost of product sales is primarily comprised of material, labor, manufacturing overhead, depreciation and amortization, and other operating expenses. Gross product margin is net product sales less cost of product sales, and gross margin percentage is gross product margin as a percentage of net product sales.

Gross product margin during the six months ended June 30, 2018 increased by $0.3 million, or 11.0% compared to the six months ended June 30, 2017 . The following schedule calculates gross product margin:

	For the six months ended June 30, 2018	June 30, 2017	Favorable/ (unfavorable)	% Change
Net product sales	$13,256,088	$8,320,314	$4,935,774	59 %
Less: Cost of product sales	(10,053,207)	(5,423,057)	(4,630,150)	(85)%
Gross Product Margin	$3,202,881	$2,897,257	$305,624	11 %
Gross Product Margin %	24.2 %	34.8 %		

The $0.3 million increase in gross product margin was comprised of the following:

$1.7 million from favorable product sales volume as described above, and
offset by $1.4 million decrease from lower product margins, related to the sales growth in markets with lower average selling prices, coupled with inefficiencies incurred through the scaling of labor and production to deliver the 59% increase in net product sales volume.

The decrease in Gross Product Margin % is related to the same factors described above with respect to lower Gross Product Margin.

Research and Development

This category includes costs incurred for clinical & regulatory affairs and other research & development, as follows:

	For the six months ended June 30, 2018	June 30, 2017	Favorable/ (unfavorable)	% Change
Clinical & regulatory affairs	$684,079	$1,103,505	$ 419,426	38 %
Other research & development	3,154,435	3,125,493	(28,942)	(1)%
Total Research and Development	$3,838,514	$4,228,998	$ 390,484	9 %

Expenses for Clinical & Regulatory Affairs decreased by $0.4 million for the six months ended June 30, 2018, as compared to the six months ended June 30, 2017, primarily related to a decrease in clinical trial expenses for the DPP® HIV-Syphilis System.

The $29,000 increase in other research & development costs is primarily associated with a higher R&D headcount and an increase in spending on materials & supplies, each corresponding with the growth in R&D milestone and grant revenue-related projects.

Selling, General and Administrative Expense

Selling, general and administrative expense (“SG&A”) includes administrative expenses, sales and marketing costs including commissions, and other corporate items.

The $0.4 million increase in SG&A for the six months ended June 30, 2018, as compared to the six months ended June 30, 2017, was associated with higher sales commissions, compensation expenses and travel expenses, offset by lower corporate expenses.

Other Income

Other income is principally interest income earned on the Company's deposits, net of interest expense on the note payable, which increased by approximately $6,000 for the six months ended June 30, 2018, as compared to the six months ended June 30, 2017, reflecting interest on funds raised in the 2018 public offering.

Liquidity and Capital Resources

Overview

Our liquidity requirements are primarily to fund our business operations, including capital expenditures and working capital requirements, as well as to fund opportunistic investments that align with our focused business strategy. Our primary sources of liquidity are cash flows from operations, our existing cash balance, and as necessary, additional capital. We will continually explore ways to enhance our capital structure.

As of June 30, 2018, we had cash and cash equivalents of $9.5 million.

Public Offering

As described in Note 5 – Stockholders' Equity to the unaudited, condensed consolidated financial statements included herein, on February 13, 2018, the Company consummated an underwritten registered public offering of 1,783,760 shares of its common stock at a public offering price of $6.75 per share for gross proceeds of approximately $12.0 million. The net proceeds, after underwriting discounts and commissions, and estimated expenses, were approximately $10.9 million.

Acquisition

On January 9, 2017, Chembio acquired 100% of the equity interests of RVR Diagnostics Sdn Bhd, a Malaysia manufacturer and distributor of rapid medical assays, for $1.4 million in cash and for common shares with a value at closing of approximately $1.7 million. As further described in Note 2 – Acquisition to the audited consolidated financial statements contained herein, the acquisition was accounted for as a business combination, with the operating results of RVR Diagnostics included within the Company's operating results from the date of acquisition. The Company financed the cash portion of the acquisition with funds raised in its 2016 public equity offering. After the acquisition, the Company changed the name RVR Diagnostics Sdn Bhd to Chembio Diagnostics Malaysia Sdn Bhd.

Government, Non-Governmental Organization, and Non-Profit Programs

Chembio commonly seeks research and development programs that may be awarded by government, non-governmental organization ("NGO"), and non-profit entities including private foundations. Chembio currently has or has recently undertaken development programs that are competitively awarded from agencies of the U.S. Federal Government including the U.S. Department of Health and Human Services and U.S. Department of Agriculture, as well as from FIND, the Bill & Melinda Gates Foundation, and The Paul G. Allen Family Foundation.

Cash Flows

As of June 30, 2018, the Company had cash and equivalents of $9.5 million and no outstanding debt except for a $0.4 million seller-financed note payable associated with automated manufacturing equipment.

	For the six months ended		Favorable/		
	June 30, 2018	June 30, 2017	(unfavorable)	% Change	
Net cash used in operating activities	$(5,077,668)	$(5,456,787)	$379,119	7	%
Net cash used in investing activities	(250,147)	(1,405,894)	1,155,747	82	%
Net cash provided by financing activities	11,006,266	-	11,006,266	100	%
Effect of exchange rate changes on cash	37,029	-	37,029	100	%
Increase (Decrease) in Cash and Cash Equivalents	$5,715,480	$(6,862,681)	$12,578,161	183	%

The Company's cash flows for the six months ended June 30, 2018 increased by $12.6 million as compared to the six months ended June 30, 2017, primarily due to capital raised, offset by the use of cash to fund increases in accounts receivable and inventory, net of the benefit of supplier payment terms and cash collections for deferred revenue.

Cash used in operating activities during the six months ended June 30, 2018 was $5.1 million, primarily due to the $4.8 million increase in accounts receivable associated with the increase in total revenues, and the $2.4 million net loss during the six months ended June 30, 2018. In addition, inventories increased by $1.9 million to support higher sales volumes during the six months ended June 30, 2018 and build product for the Ethiopia HIV tender that began shipping during the second quarter of 2018. The $1.9 million increase in inventory was more than offset by a $3.0 million increase in accounts payable and accrued liabilities.

Cash used in investing activities of $0.3 million during the six months ended June 30, 2018 related to the purchase of manufacturing equipment and other fixed assets.

Cash provided by financing activities during the six months ended June 30, 2018, primarily relate to proceeds from an underwritten registered public offering. Please see the “Public Offering” section, above, for further information.

Off-Balance Sheet Arrangements

The Company does not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K under the Securities Exchange Act of 1934, as amended.

Recent Developments

In July, 2018, the Company announced a collaboration with the Foundation for Innovative New Diagnostics (FIND) to expedite the feasibility testing of a rapid diagnostic test for hepatitis C virus (HCV). Chembio is one of three companies selected by FIND for HCV feasibility studies, and Chembio will use its patented DPP® technology platform for the testing of a rapid HCV core antigen assay.

Significant Accounting Policies and Critical Accounting Estimates

Our significant accounting policies are described in Note 3 – Significant Accounting Policies to the audited consolidated financial statements included herein. Certain of our accounting policies require the application of significant judgment by management in selecting the appropriate assumptions for calculating financial estimates. By their nature, these judgments are subject to an inherent degree of uncertainty. These judgments are based on our historical experience, terms of existing contracts, our evaluation of trends in the industry, information provided by our customers and information available from other outside sources, as appropriate. We consider an accounting estimate to be critical if:

It requires us to make assumptions about matters that were uncertain at the time we were making the estimate, and
Changes in the estimate or different estimates that we could have selected would have had a material impact on our financial condition or results of operations.

The following listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by accounting principles generally accepted in the United States of America, with no need for management's judgment in their application. There are also areas in which management's judgment in selecting any viable alternative would not produce a materially different result. There have been no significant changes in our critical accounting estimates during the six months ended June 30, 2018, except for those changes pertaining to our adoption of ASC 606, Revenue Recognition.

Revenue Recognition

We recognize revenues when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenues following the five-step model prescribed under ASU No. 2014-09: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation. Revenues from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with our customers.

All contracts related to R&D, milestone and grants revenues are evaluated under the five-step model described above. For certain contracts, we recognize revenue from R&D, milestone and grant revenues when earned. Grants are invoiced after expenses are incurred, as that is the depiction of the timing of the transfer of services. Performance obligations generally follow the major phases of product development processes: design feasibility & planning, product development & design optimization, design verification, design validation & process validation, and pivotal studies. Further details regarding revenue recognition are document at Note 3(b) – Summary of Significant Accounting Policies: Revenue Recognition to the Unaudited Condensed Consolidated Financial Statements.

Stock-Based Compensation

We recognize the fair value of equity-based awards as compensation expense in our statement of operations. The fair value of our stock option awards was estimated using a Black-Scholes option valuation model. This valuation model's computations incorporate highly subjective assumptions, such as the expected stock price volatility and the estimated

life of each award. The fair value of the options, after considering the effect of expected forfeitures, is then amortized, generally on a straight-line basis, over the related vesting period of the option.

Research & Development Costs

Research and development activities consist primarily of new product development, continuing engineering for existing products, and regulatory and clinical trial costs. Costs related to research and development efforts on existing or potential products are expensed as incurred.

Inventories

Inventories are stated at the lower of cost and net realizable value, using the first-in, first-out method (FIFO) to determine cost. Our policy is to periodically evaluate the market value of the inventory and the stage of product life cycle, and record a reserve for any inventory considered slow moving or obsolete. For example, each additional 1% of obsolete inventory would reduce such inventory by approximately $63,000.

Accounts Receivable

Our policy is to review our accounts receivable on a periodic basis, no less frequently than monthly. On a quarterly basis an analysis is made of the adequacy of our allowance for doubtful accounts and adjustments are made accordingly. The current allowance is approximately 1% of accounts receivable. For example, each additional 1% of accounts receivable that becomes uncollectible would reduce such balance of accounts receivable by approximately $69,000.

Acquisitions

In accordance with accounting guidance for the provisions in FASB ASC 805, Business Combinations, we allocate the purchase price of an acquired business to its identifiable assets and liabilities based on estimated fair values. The excess of the purchase price over the amount allocated to the assets and liabilities, if any, is recorded as goodwill. In addition, an acquisition may include a contingent consideration component, such as our acquisition agreements for RVR Diagnostics. The fair value of the contingent consideration is estimated as of the date of the acquisition and is recorded as part of the purchase price. This estimate is updated in future periods and any changes in the estimate, which are not considered an adjustment to the purchase price, are recorded in our consolidated statements of operations.

We use all available information to estimate fair values. We typically engage outside appraisal firms to assist in the fair value determination of identifiable intangible assets and any other significant assets or liabilities. We adjust the preliminary purchase price allocation, as necessary, up to one year after the acquisition closing date as we obtain more information regarding asset valuations and liabilities assumed.

Our purchase price allocation methodology contains uncertainties because it requires management to make assumptions and to apply judgment to estimate the fair value of acquired assets and liabilities. Management estimates the fair value of assets and liabilities based upon quoted market prices, the carrying value of the acquired assets and widely accepted valuation techniques, including discounted cash flows and market multiple analyses. Unanticipated events or circumstances may occur which could affect the accuracy of our fair value estimates, including assumptions regarding industry economic factors and business strategies.

Other estimates used in determining fair value include, but are not limited to, future cash flows or income related to intangibles, market rate assumptions, actuarial assumptions for benefit plans and appropriate discount rates. Our estimates of fair value are based upon assumptions believed to be reasonable, but that are inherently uncertain, and therefore, may not be realized. Accordingly, there can be no assurance that the estimates, assumptions, and values reflected in the valuations will be realized, and actual results could vary materially.

Goodwill and Intangible Assets

We periodically review goodwill for impairment indicators. We review goodwill for impairment annually on the first day of the fourth quarter or more frequently if events or changes in circumstances indicate that goodwill might be impaired. The Company performs the goodwill impairment review at the reporting unit level. We make a qualitative evaluation about the likelihood of goodwill impairment, which is based on a number of applicable factors. If we conclude that it is more likely than not that the carrying value of the applicable reporting unit is greater than its fair value, then we would recognize an impairment charge for the amount by which the carrying value exceeds the reporting unit’s fair value, provided the impairment charge does not exceed the total amount of goodwill allocated to the reporting unit.

We review indefinite-lived intangible assets for impairment annually or more frequently if events or changes in circumstances indicate the assets might be impaired. Similar to the goodwill assessment described above, the Company first performs a qualitative assessment of whether it is more likely than not that an indefinite-lived intangible asset is impaired. If necessary, the Company then performs a quantitative impairment test by comparing the estimated fair of the asset, based upon its forecasted cash flows, to its carrying value. Other intangible assets with definite lives are amortized over their useful lives and are subject to impairment testing only if events or circumstances indicate that the asset might be impaired, as described above.

Income Taxes

Income taxes are accounted for under ASC 740 authoritative guidance ("Guidance"), which requires the asset and liability method of accounting for deferred income taxes. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities. Deferred tax assets or liabilities at the end of each period are determined using the tax rate expected to be in effect when taxes are actually paid or recovered.

The Guidance also requires that a valuation allowance be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence needs to be considered, including a company's current and past performance, the market environment in which the company operates, length of carryback and carryforward periods and existing contracts that will result in future profits. The Company believes that it is more likely than not that it will not be able to utilize its net operating loss carryforwards and maintains a full valuation allowance. The Company maintains a full valuation allowance on research and development tax credits.

The Guidance also prescribes a comprehensive model for recognizing, measuring, presenting and disclosing in the consolidated financial statements tax positions taken or expected to be taken on a tax return, including a decision whether to file or not to file in a particular jurisdiction.

Recently Issued Accounting Pronouncements

The information concerning recently issued accounting pronouncements contained in Note 3 – Summary of Significant Accounting Policies, to the unaudited, condensed consolidated financial statements included in Part 1, Item 1 of this report is incorporated herein by reference.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk.

The Company does not hold any amounts of derivative financial instruments or derivative commodity instruments and, accordingly, has no material derivative risk to report under this Item. As of June 30, 2018, the Company did not have any foreign currency exchange contracts nor purchase currency options to hedge local currency cash flows.

We are exposed to market risks from changes in currency exchange rates and certain commodity prices. All sales from our U.S. subsidiary, regardless of the customer location, are denominated in U.S. dollars. Sales denominated in foreign currencies are associated with a portion of the sales from our subsidiary, Chembio Diagnostics Malaysia, and comprised approximately 5% of our total revenues for the six months ended June 30, 2018.

ITEM 4. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures. Under the supervision and with the participation of our senior management, consisting of our principal executive officer and our principal financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as of the end of the period covered by this report. Based on this evaluation, our management, including our principal executive officer and principal financial officer, concluded that as of June 30, 2018 our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our Exchange Act reports is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

(b) Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 under the Exchange Act that occurred during the three months ended June 30, 2018, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. We know of no material, existing or pending legal proceedings against us, nor are we involved as a plaintiff in any material proceeding or pending litigation. There are no proceedings in which any of our directors, officers or affiliates, or any registered or beneficial shareholder, is an adverse party or has a material interest that is adverse to our interest.

ITEM 1A. RISK FACTORS

The following are updated risk factors to be included in Item 1A., entitled “Risk Factors,” in our Annual Report on Form 10-K for the year ended December 31, 2017:

Doing Business with and in Foreign Countries Increases Our Risks and Exposes Our Business to Geopolitical, International and Other Challenges.

Doing business in and with foreign countries could adversely affect the performance of our business and/or cause us to incur substantially increased costs. Factors that could adversely affect our business and costs include: (i) the U.S. government, other governments, or international organizations imposing additional sanctions that could restrict us from doing business directly or indirectly in or with certain countries or parties; (ii) uncertainty in the application of foreign laws, the interpretation of contracts with foreign parties, and import/export licensing requirements; (iii) cultural and political differences that favor local competitors or make it difficult to effectively market, sell and gain acceptance of our products; (iv) exchange rates, currency fluctuations, extended payment terms and dependence on international distributors or representatives; (v) trade protection measures, tariffs and other barriers (vi) our inability to obtain or maintain regulatory approvals or registrations for our products; (vii) economic conditions, political instability, the absence of available funding sources, terrorism, civil unrest, war and natural disasters in foreign countries; (viii) reduced protection for, or enforcement of, our patents and other intellectual property rights in foreign countries; (ix) our inability to identify international distributors and negotiate acceptable terms for distribution agreements; and (x) restrictions on our ability to repatriate investments and earnings from foreign operations.

Economic, cultural and political conditions and foreign regulatory requirements may slow or prevent the manufacture of our products in countries other than the United States or the supply of our products manufactured in the United States to customers in other countries. Interruption of the supply of our products could reduce revenues or cause us to incur significant additional expenses in finding an alternative source of supply. Foreign currency fluctuations and economic conditions in foreign countries could also increase the costs of manufacturing our products in foreign countries.

Changes in U.S. Trade Policy, Including the Imposition of Tariffs and the Resulting Consequences, may have a Material Adverse Impact on our Business and Results of Operations.

The U.S. government has indicated its intent to adopt a new approach to trade policy and in some cases to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements. It has also initiated or is considering the imposition of tariffs on certain foreign products. Changes in U.S. trade policy have resulted in, and could continue to result in, one or more of U.S. trading partners adopting responsive trade policy making it more difficult or costly for us to export our products to those countries. These measures could also result in increased costs for goods imported into the United States. This in turn could require us to increase prices to our customers which may reduce demand, or, if we are unable to increase prices, result in lowering our margin on products sold.

There is also a concern that the imposition of additional tariffs by the United States could result in the adoption of tariffs by other countries. The resulting trade war could have a significant adverse effect on world trade and the world economy. To the extent that trade tariffs and other restrictions imposed by the United States increase the price of, or limit the amount of, raw materials imported into the United States, the costs of our raw materials may be adversely affected and the demand from our customers for products and services may be diminished, which could adversely affect our revenues and profitability.

We cannot predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business. The adoption and expansion of trade restrictions, the occurrence of a trade war, or other governmental action related to tariffs or trade agreements or policies has the potential to adversely impact demand for our products, our costs, our customers, our suppliers, and the U.S. economy, which in turn could adversely impact our business, financial condition and results of operations.

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 under Rights Agreement (to be filed by amendment)
10.1*	Employment Agreement dated effective as of March 13, 2017 with John J. Sperzel III (15)
10.2*	Employment Agreement dated effective March 5, 2016 with Javan Esfandiari (8)
10.3*	Employment Agreement dated effective December 18, 2017 with Neil Goldman (17)
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)
10.9	Amended And Restated Stock Purchase Agreement, dated as of December 7, 2016, by and among Chembio Diagnostics, Inc., RVR Diagnostics Sdn Bhd, Avijit Roy and Magentiren Vajuram (14)
10.10	Underwriting Agreement, dated February 9, 2018, by and between the Registrant and Craig-Hallum Capital Group LLC (17)
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

Footnotes to Exhibits Index

1 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on July 29, 2010.

2 Incorporated by reference to the Registrant's registration statement on Form SB-2 (File No. 333-85787) filed with the Commission on August 23, 1999 and the Registrant's Forms 8-K filed on May 14, 2004, December 20, 2007 and April 18, 2008.

3 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on August 3, 2012.

4 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on May 8, 2014.

5 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on April 29, 2014.

6 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on August 7, 2014.

7 Incorporated by reference to the Registrant's registration statement on Form 8-A filed with the Commission on April 7, 2016.

8 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on March 14, 2016.

9 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 27, 2017.

10 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.

11 Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Commission on March 5, 2015.

12 Incorporated by reference to the Registrant's Annual Report on Form 10-KSB filed with the Commission on March 30, 2006.

13 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on April 7, 2016.

14 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on January 10, 2017.

15 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on May 9, 2017.

16 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on February 13, 2018.

17 Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Commission on March 8, 2018.

(*) 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: August 8, 2018 By: /s/ John J. Sperzel III
John J. Sperzel III
Chief Executive Officer
(Principal Executive Officer)

Date: August 8, 2018 By: /s / Neil A. Goldman
Neil A. Goldman
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)