CHEMBIO DIAGNOSTICS, INC.
Form 10-Q
November 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 September 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 every Interactive Data File required to be submitted 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 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.

Large accelerated filer	Accelerated filer
Non-accelerated filer	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 November 5, 2018, the Registrant had 17,187,184 shares outstanding of its $.01 par value common stock.

Quarterly Report on Form 10-Q
For The Quarterly Period Ended
September 30, 2018

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Chembio Diagnostics, Inc.

EXHIBITS

The words ''we,'' ''our,'' ''us,'' 'and ''Chembio'' refer to Chembio Diagnostics, Inc., unless otherwise we indicate.

STAT-PAK, STAT-VIEW, SURE CHECK and DPP are our registered trademarks, and our logo design is our trademark. For convenience, these trademarks appear in this Quarterly Report on Form 10-Q supplement without ® and ™ symbols, but that practice does not mean that we will not assert, to the fullest extent under applicable law, our rights to the trademarks.

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NOTE ABOUT FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “might,” “will,” “objective,” “intend,” “should,” “could,” “can,” “would,” “expect,” “believe,” “anticipate,” “project,” “target,” “predict,” “potential,” “plan” or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on our management’s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors, including those described or incorporated by reference in “Item 1A. Risk Factors” of Part II of this report, that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements.

Any forward-looking statement made by us in this report speaks only as of the date on which it is made. Except as required by law, we assume no obligation to update these statements publicly or to update the reasons actual results could differ materially from those anticipated in these statements, even if new information becomes available in the future.

You should read this report, and the documents that we reference in this report, including exhibits that are being filed as part of this report, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

PART I
Item 1. FINANCIAL STATEMENTS

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2018 (Unaudited)	December 31, 2017
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	$ 6,848,583	$ 3,790,302
Accounts receivable, net of allowance for doubtful accounts of $42,000 at September 30, 2018 and December 31, 2017, respectively	7,794,014	2,085,340
Inventories, net	5,978,426	4,423,618
Prepaid expenses and other current assets	1,579,750	554,383
TOTAL CURRENT ASSETS	22,200,773	10,853,643
FIXED ASSETS, net of accumulated depreciation	2,372,896	1,909,232
OTHER ASSETS:		
Intangible assets, net	1,431,921	1,597,377
Goodwill	1,628,864	1,666,610
Deposits and other assets	331,423	589,159
	3,392,208	3,853,146
TOTAL ASSETS	$ 27,965,877	$ 16,616,021
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$ 6,798,600	$ 3,046,303
Deferred revenue	760,750	50,000
Current portion of note payable	202,096	-
TOTAL CURRENT LIABILITIES	7,761,446	3,096,303
OTHER LIABILITIES:		
Notes payable	207,694	99,480
Deferred tax liability	333,318	341,042
TOTAL LIABILITIES	8,302,458	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 September 30, 2018 and December 31, 2017, respectively	141,736	123,185
Additional paid-in capital	74,108,046	62,821,288
Accumulated deficit	(54,739,124)	(50,044,225)
Accumulated other comprehensive income	152,761	178,948

TOTAL STOCKHOLDERS' EQUITY	19,663,419	13,079,196
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 27,965,877	$ 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		For the nine months ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
REVENUES:				
Net product sales	$7,856,038	$ 6,132,725	$21,112,126	$ 14,453,097
License and royalty revenue	228,553	150,000	707,010	477,631
R&D, milestone and grant revenue	1,292,202	1,304,649	3,995,115	3,096,626
TOTAL REVENUES	9,376,793	7,587,374	25,814,251	18,027,354
COSTS AND EXPENSES:				
Cost of product sales	6,774,749	4,064,791	16,827,956	9,487,848
Research and development expenses	1,897,751	1,805,738	5,736,265	6,034,735
Selling, general and administrative expenses	3,034,130	2,305,358	7,987,914	6,903,055
	11,706,630	8,175,887	30,552,135	22,425,638
LOSS FROM OPERATIONS	(2,329,837)	(588,513)	(4,737,884)	(4,398,284)
OTHER INCOME:				
Interest income, net	15,656	3,852	42,985	24,956
LOSS BEFORE INCOME TAXES	(2,314,181)	(584,661)	(4,694,899)	(4,373,328)
Income tax provision	-	-	-	-
NET LOSS	$(2,314,181)	$ (584,661)	$(4,694,899)	$ (4,373,328)
Basic loss per share	$(0.16)	$ (0.05)	$(0.34)	$ (0.36)
Diluted loss per share	$(0.16)	$ (0.05)	$(0.34)	$ (0.36)
Weighted average number of shares outstanding, basic	14,173,620	12,311,098	13,872,055	12,293,781
Weighted average number of shares outstanding, diluted	14,173,620	12,311,098	13,872,055	12,293,781

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 September		For the nine months ended September	
	30, 2018	September 30, 2017	30, 2018	September 30, 2017
Net loss	$ (2,314,181)	$ (584,661)	$ (4,694,899)	$ (4,373,328)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(104,657)	4,375	(26,187)	128,616
Comprehensive loss	$ (2,418,838)	$ (580,286)	$ (4,721,086)	$ (4,244,712)

See accompanying notes to condensed consolidated financial statements

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

	September 30, 2018	September 30, 2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	$ 20,816,327	$ 15,249,646
Cash paid to suppliers and employees	(28,389,820)	(22,451,537)
Interest received, net	42,985	24,956
Net cash used in operating activities	(7,530,508)	(7,176,935)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of RVR Diagnostics Sdn Bhd	-	(850,000)
Acquisition of and deposits on fixed assets	(401,897)	(789,827)
Net cash used in investing activities	(401,897)	(1,639,827)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option and warrant exercises	71,914	34,800
(Payments on) proceeds from note payable	(15,800)	99,480
Proceeds from sale of common stock, net	10,934,352	-
Net cash provided by financing activities	10,990,466	134,280
Effect of exchange rate changes on cash	220	-
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	3,058,281	(8,682,482)
Cash and cash equivalents - beginning of the period	3,790,302	10,554,464
Cash and cash equivalents - end of the period	$ 6,848,583	$ 1,871,982
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net loss	$ (4,694,899)	$ (4,373,328)
Adjustments:		
Depreciation and amortization	663,250	1,011,349
Share based compensation	299,044	296,674
Changes in assets and liabilities:		
Accounts receivable	(5,708,674)	(2,385,191)
Inventories	(1,554,808)	(1,899,976)
Prepaid expenses and other current assets	(997,468)	(114,887)
Deposits and other assets	-	23,262
Accounts payable and accrued liabilities	3,752,297	657,679
Deferred revenue	710,750	(392,517)
Net cash used in operating activities	$ (7,530,508)	$ (7,176,935)
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	$ 268,655	$ 210,472
Seller-financed equipment purchases	326,110	-
Accrual of contingent earn-out	-	148,000

Issuance of common stock for net assets of business acquired	-	1,682,725

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 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 its patented DPP technology, a novel POC 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.

The Company's product commercialization and product development efforts are focused in two areas: infectious disease, which includes both sexually transmitted and tropical & fever disease; and strategic collaborations with leading global healthcare companies in order to leverage the DPP platform. In infectious disease, the Company is commercializing tests for HIV, Syphilis, Zika virus, dengue virus, and chikungunya virus, and developing tests for hepatitis C, malaria, ebola, lassa, Marburg, leptospirosis, Rickettsia typhi, Burkholderia pseudomallei, and Orientia tsutsugamushi. Certain of these are also being developed as part of fever panel tests. Through strategic collaborations, the Company is developing tests for a specific form of cancer, concussions, bovine tuberculosis, and, in collaboration with global biopharmaceutical company AstraZeneca, an undisclosed biomarker.

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. The Company's product development is focused on areas where the availability of rapid, POC screening, diagnostic, or confirmatory results can improve health outcomes. More generally, the Company believes 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.

The Company's products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments, both domestically and internationally, under its STAT-PAK, SURE CHECK, STAT-VIEW and DPP registered trademarks, or under the private labels of its 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 "RVR 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 RVR 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, which was shipped in the first quarter of 2017 and valued at an amount equal to 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 September 30, 2018 and for the three- and nine-month periods ended September 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 the Company believes 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 September 30, 2018, its condensed consolidated results of operations for the three- and nine-month periods ended September 30, 2018 and 2017, and its condensed consolidated cash flows for the nine-month periods ended September 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, Accounting Standards Update (“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 the Company's revenue recognition as its revenues continue to be recognized when the customer takes control of its product. As the Company did not identify any material accounting changes that impacted the amount of reported revenues with respect to its product revenue, license and royalty revenue, and R&D, milestone and grant revenues, no adjustment to retained earnings was required upon adoption.

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

Under the new revenue standards, the Company recognizes revenues when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. The Company recognizes 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) the Company satisfies the performance obligation.

Product Revenues

Revenues from product sales are recognized when the customer obtains control of the Company's product, which occurs at a point in time, typically upon tendering to the customer. The Company expenses incremental costs of obtaining a contract as and when incurred because the expected amortization period of the asset that it 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 the Company's customers. The Company's process for estimating reserves established for these variable consideration components does not differ materially from its 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 the Company's estimates. If actual results vary, the Company adjusts these estimates, which could have an effect on earnings in the period of adjustment.

Royalty Revenues

The Company receives royalty revenues on sales by its licensees of products covered under patents that it owns. The Company does not have future performance obligations under these license arrangements. The Company records 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 the Company, 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 $0.3 million and $1.5 million during the three and nine months ended September 30, 2018, respectively as R&D, milestone and grant revenue in the Condensed Consolidated Statements of Operations.

In September 2016, the Company was awarded a $0.7 million contract from the U.S. Department of Agriculture to develop a Bovid TB assay. The Company earned $20,000 and $0.2 million during the three and nine months ended September 30, 2018, respectively, as R&D, milestone and grant revenue in the Condensed Consolidated Statements of Operations.

The following table disaggregates Total Revenues for the three and nine months ended September 30, 2018:

	For the three months ended			For the nine months ended		
	Exchange Transactions	Non-Exchange Transactions	Total	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	$7,856,038	$ -	$7,856,038	$21,112,126	$ -	$21,112,126
License and royalty revenue	228,553	-	228,553	707,010	-	707,010
R&D, milestone and grant revenue	960,332	331,870	1,292,202	2,328,058	1,667,057	3,995,115
	$9,044,923	$ 331,870	$9,376,793	$24,147,194	$ 1,667,057	$25,814,251

Contract Liabilities

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

c) Inventories

Inventories consist of the following at:

	September 30, 2018	December 31, 2017
Raw materials	$ 2,750,356	$ 1,767,684
Work in process	780,114	286,413
Finished goods	2,447,956	2,369,521
	$ 5,978,426	$ 4,423,618

Inventories are stated at the lower of cost and net realizable value. There were reserves against inventory of approximately $67,000 and $195,000 as of September 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 nine-month periods ended September 30, 2018 and 2017 reflects the potential dilution from the exercise or conversion of other securities into common stock, if dilutive.

There were 693,116 and 699,663 weighted-average number of options outstanding as of September 30, 2018 and 2017, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended September 30, 2018 and 2017 respectively, because the effect would have been anti-dilutive. There were 709,042 and 668,510 weighted-average number of options outstanding as of September 30, 2018 and 2017, respectively, that were not included in the calculation of diluted per common share equivalent for the nine months ended September 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, which expired in 2018, the Compensation Committee of the

Company's Board had the discretion to select the persons to whom awards are to be granted. Awards could be stock options, restricted stock and/or restricted stock units ('Equity Award Units"). The awards became vested at such times and under such conditions as determined by the Compensation Committee. As of September 30, 2018, there were 508,889 options exercised, 99,132 options outstanding and no options 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 of Directors 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 September 30, 2018, 85,407 shares of common stock had been issued pursuant to the exercise of options granted under the SIP14, options to purchase 405,968 shares of common stock were outstanding and 332,224 shares of common stock were available to be issued pursuant to Equity Award Units granted 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 September		For the nine months ended September	
	30, 2018	September 30, 2017	30, 2018	September 30, 2017
Cost of product sales	$ 5,800	$ 12,800	$ 19,800	$ 34,200
Research and development expenses	3,600	12,100	19,000	77,300
Selling, general and administrative expenses	65,400	62,200	260,200	185,200
	$ 74,800	$ 87,100	$ 299,000	$ 296,700

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 periods of the entire awards.

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 the Company's common 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 September 30,				For the nine months ended September 30,			
	2018		September 30, 2017		2018		September 30, 2017	
Expected term (in years)	4.5		4.5		4.9		4.8	
Expected volatility	39.69	%	41.22	%	39.91	%	43.01	%
Expected dividend yield	0	%	0	%	0	%	0	%
Risk-free interest rate	2.70	%	1.48	%	2.70	%	1.54	%

The following table provides stock option activity for the nine months ended September 30, 2018:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contract Term	Aggregate Intrinsic Value
Outstanding at December 31, 2017	810,670	$ 5.18	3.69 years	$2,477,853
Granted	93,750	9.80		-
Exercised	144,947	4.83		523,527
Forfeited/expired/cancelled	47,505	8.82		-
Outstanding at September 30, 2018	711,968	$ 5.62	3.58 years	$3,520,084
Exercisable at September 30, 2018	343,113	$ 4.33	2.51 years	$2,126,832

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

	Stock Options Outstanding				Stock Options Exercisable		
Range of Exercise Prices	Number of Shares	Average Remaining Contract Term (Year)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
1 to 2.79999	-	-	$ -	$-	-	$ -	$-
2.8 to 4.59999	304,343	2.15	3.45	2,145,916	254,343	3.46	1,791,731
4.6 to 6.39999	152,875	3.69	5.85	710,662	58,020	5.80	272,870
6.4 to 8.19999	207,875	5.31	7.31	663,506	21,375	7.59	62,231
8.2 to 12	46,875	4.85	11.45	-	9,375	11.45	-
Total	711,968	3.58	$ 5.62	$3,520,084	343,113	$ 4.33	$2,162,832

As of September 30, 2018, there was $790,321 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 2.64 years. The total fair value of shares vested during the nine-month periods ended September 30, 2018 and 2017 was $379,384 and $323,113, 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 were as follows:

	For the three months ended	For the nine months ended

	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Africa	$ 3,064,034	$ 965,606	$ 6,929,104	$ 1,797,285
Asia	211,261	93,101	1,201,182	1,637,065
Europe & Middle East	716,030	401,730	1,743,680	1,441,890
Latin America	3,115,811	3,556,815	9,071,994	6,701,923
United States	748,902	1,115,473	2,166,166	2,874,934
	$ 7,856,038	$ 6,132,725	$ 21,112,126	$ 14,453,097

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:

	September 30, 2018	December 31, 2017
Accounts payable – suppliers	$ 4,199,275	$ 1,494,759
Accrued commissions	451,741	126,827
Accrued royalties / license fees	667,207	429,297
Accrued payroll	285,233	187,305
Accrued vacation	404,933	309,767
Accrued bonuses	494,340	282,500
Accrued expenses – other	295,871	215,848
TOTAL	$ 6,798,600	$ 3,046,303

i) Goodwill and Intangible Assets:

Goodwill represents the excess of the purchase price the Company paid over the fair value of the net tangible and identifiable intangible assets acquired in its 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 the Company believes that indicators of impairment exist. The Company makes a qualitative evaluation about the likelihood of goodwill impairment, which is based on a number of applicable factors. If the Company concludes that it is more likely than not that the carrying value of the applicable reporting unit is greater than its fair value, then the Company recognizes 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 nine months ended September 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	(37,746)
Balance at September 30, 2018	$1,628,864

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

	September 30, 2018			December 31, 2017		
	Cost	Accumulated Amortization	Net Book Value	Cost	Accumulated Amortization	Net Book Value
Intellectual property	$866,786	$ 151,687	$715,099	$886,872	$ 88,687	$798,185
Customer contracts/relationships	758,438	132,727	625,711	776,013	77,601	698,412
Order backlog	216,842	216,842	-	221,867	221,867	-
Trade names	108,348	17,237	91,111	110,859	10,079	100,780
	$1,950,414	$ 518,493	$1,431,921	$1,995,611	$ 398,234	$1,597,377

Order backlog was amortized during the period of the related sales during 2017, and intellectual property, customer contracts/relationships, and trade names are amortized over 10, 10, and 11 years, respectively. Amortization expense for the three months ended September 30, 2018 and 2017 was approximately $43,854 and $47,199, respectively. Amortization expense for the nine months ended September 30, 2018 and 2017 was approximately $134,208 and $339,000, respectively.

j) Taxes:

The Company did not record an income tax provision for the three and nine month period ended September 30, 2018, resulting in an effective tax rate of zero. The zero rate reflects the Company's judgement that based on the weight of positive and negative evidence a valuation allowance on all domestic deferred tax assets is needed and the tax holiday in effect with respect to foreign operations.

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 tax deferred and creates new taxes on certain foreign-sourced earnings.

The Company has applied the guidance in ASU 2018-05, Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118, when accounting for the enactment-related effects of the Act. The Company has accounted for the tax effects of the Act under the guidance of SAB 118 on a provisional basis. During the nine months ended September 30, 2018, the Company did not recognize any adjustments to the provisional amounts recorded as of December 31, 2017. The Company will continue to assess the Act's impact for the rest of 2018, including its interpretation by regulatory authorities and the courts, and will adjust its disclosures and financial presentation as necessary.

k) Recent Accounting Pronouncements Affecting the Company:

In May 2014, 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 for the Company as of January 1, 2018.

In addition to expanding disclosures in these interim financial statements, the Company completed its evaluation of the new standard and assessed the impact of adoption on its consolidated financial statements. The Company reviewed significant open contracts with customers for each revenue stream, and based on its 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, the Company 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 the 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, FASB issued 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 ASU 2016-02, which amends the ASC and creates Topic 842, Leases. Topic 842 will require lessees to recognize lease assets and lease liabilities for those leases classified as operating leases under previous US GAAP on the balance sheet. This guidance is effective for annual periods beginning after December 15, 2018 and early adoption is permitted. The Company is in the initial stages of evaluating the effect of the standard on its 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 the Company's current cash flow classifications, and it was adopted effective January 1, 2018, without any material impact

on the Company's 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 the Company's 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") with 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 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 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 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.

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.

During the third quarter of 2017, options to purchase 46,000 shares of the Company's common stock were exercised on a cashless basis into 19,448 shares of common stock at an exercise price of $4.24 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 nine months ended	

	September 30, 2018		September 30, 2017		September 30, 2018		September 30, 2017		Accounts Receivable as of	
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	September 30, 2018	Dec. 31, 2017
Customer 1	$3,039,722	39 %	$3,530,364	58 %	$8,666,867	41 %	$6,426,158	45 %	$3,267,075	$ -
Customer 2	1,852,186	24 %	*	*	3,312,816	16 %	*	*	1,852,186	*
Customer 3	*	*	602,087	10 %	*	*	*	*	*	*

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 nine months ended				Accounts Payable as of	
	September 30, 2018		September 30, 2017		September 30, 2018		September 30, 2017		September 30, 2018	Dec. 31, 2017
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	$*	*	$*	*	$*	*	$ 698,838	13 %	$ *	$ *
Vendor 2	508,646	22 %	383,827	14 %	1,372,521	17 %	711,865	13 %	*	*
Vender 3	*	*	420,410	16 %	*	*	605,931	11 %	*	*

In the table above, an asterisk (*) indicates that purchases from the vendor did not exceed 10% for the period indicated.

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 U.S. Food and Drug Administration,U.S. 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 September 30, 2018:

2018	$192,500
2019	485,493
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% of salary (or up to 2% of salary) that an employee contributes to the plan. Matching contribution expenses totaled $71,858 and $68,821 for the nine months ended September 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.

NOTE 8 — SUBSEQUENT EVENTS:

a) Public Offering

On November 5, 2018, the Company closed an underwritten registered public offering of 2,726,000 shares of its common stock, including the underwriter's exercise of its overallotment of 355,565 shares, at a public offering price of $6.75 per share for gross proceeds of approximately $18.4 million. The net proceeds, after underwriting discounts and commissions and estimated expenses, were approximately $16.6 million. The Company intends to use the net proceeds (a) to support its business growth strategy, including broadening its U.S. manufacturing automation and expanding and improving its facilities, and (b) for other general corporate purposes, which may include acquiring additional complementary businesses, technologies and products.

b) Acquisition

On November 6, 2018, the Company completed an acquisition of opTricon GmbH ("opTricon"), pursuant to a share purchase agreement, dated as of October 17, 2018 (the "opTricon Purchase Agreement") pursuant to which the Company acquired all of the outstanding shares of opTricon for a purchase price of $5.5 million in cash. The opTricon Purchase Agreement contains customary representations and warranties from the Company and opTricon. Of the purchase price paid at closing, $100,000 was deposited in escrow for a potential purchase price adjustment based on the working capital of opTricon and $750,000 was deposited in escrow to satisfy certain claims that the Company may make against the sellers in accordance with the terms of the opTricon Purchase Agreement.

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

You should read the following discussion of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes and other financial information included elsewhere in this report and our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, or our Annual Report. The following discussion contains forward-looking statements that reflect our plans, estimates, and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this report, particularly in the section titled "Item 1A. Risk Factors" in Part I of our Annual Report. 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.

Our management's discussion and analysis of financial condition and results of operations is intended to help you understand the business operations and financial condition of the Company as of September 30, 2018, and for the three and nine months ended September 30, 2018. This discussion should be read in conjunction with Item 1. Financial Statements. Our management's discussion and analysis of financial condition and results of operations 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. Our 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 Diagnostics, Inc. is a Nevada corporation formed in 1985.

Business Strategy
We are a leading provider of point-of-care diagnostic products for the detection and diagnosis of infectious diseases. We have been expanding our product portfolio based upon our proprietary DPP technology platform, which uses a small drop of blood from the fingertip to provide high-quality, cost-effective diagnostic results in approximately 15 minutes. We seek to build additional revenue streams by entering into strategic collaborations with leading global healthcare companies in order to leverage the DPP platform.

Compared with traditional lateral flow technology, the DPP technology platform provides enhanced sensitivity and specificity, advanced multiplexing capabilities, and, when used with the DPP Micro Reader, quantitative results. Our DPP HIV test provides sensitivity of 99.8% and specificity of 100%, and has been approved by the U.S. Food and Drug Administration, or FDA, and approved as a waived test under the Clinical Laboratory Improvement Amendments of 1988.

We are pursuing four corporate priorities, aimed at executing on our key building blocks to drive growth and operating efficiency:

- expand our core point-of-care infectious disease business;
- leverage our patented DPP technology and scientific expertise through collaborations;
- broaden our sales channels worldwide; and
- automate our U.S. manufacturing operations to increase capacity and margin.

Recent accomplishments and highlights:

- Closed the acquisition of opTricon GmbH, a privately-held developer and manufacturer of hand-held analyzers for rapid diagnostic tests.
- Filed CE Mark for a point-of-care DPP® test to detect an undisclosed biomarker through the AstraZeneca funded collaboration and development program.
- Received a $10.5 million purchase commitment from Bio-Manginhos for the production of DPP HIV and DPP Leishmania assays in Brazil and their subsequent supply to Brazil's Ministry of Health.
- Completed an underwritten public offering that provided an estimated $16.6 million of net proceeds to the Company.

Our product commercialization and product development efforts are focused in two areas: infectious disease, which includes both sexually transmitted and tropical & fever disease; and strategic collaborations with leading global healthcare companies, which leverage the DPP platform to provide us with additional revenue streams. In infectious disease, we are commercializing tests for HIV, Syphilis, Zika virus, dengue virus, and chikungunya virus, and developing tests for hepatitis C, malaria, ebola, lassa, Marburg, leptospirosis, Rickettsia typhi, Burkholderia pseudomallei, and Orientia tsutsugamushi. Certain of these are also being developed as part of fever panel tests. Through strategic collaborations, we are developing tests for a specific form of cancer, concussions, bovine tuberculosis, and, in collaboration with global biopharmaceutical company AstraZeneca, an undisclosed biomarker.

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

The results of operations for the three months ended September 30, 2018 and 2017 were as follows (dollars in thousands):

	September 30, 2018		September 30, 2017	
TOTAL REVENUES	$9,377	100%	$7,587	100%
OPERATING COSTS AND EXPENSES:				
Cost of product sales	6,775	72 %	4,065	54 %
Research and development expenses	1,898	20 %	1,806	24 %
Selling, general and administrative expenses	3,034	32 %	2,305	30 %
	11,707		8,176	
LOSS FROM OPERATIONS	(2,330)		(589)	
INTEREST INCOME, NET	16		4	
LOSS BEFORE INCOME TAXES	(2,314)	(24)%	(585)	(8)%
Income tax provision	-		-	
NET LOSS	$(2,314)		$(585)	

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during the three months ended September 30, 2018 were $9.4 million, an increase of $1.8 million, or 23.6% compared to the three months ended September 30, 2017. The increase in total revenues was comprised of the following:

$1.7 million, or a 28.1% increase in net product sales compared to the three months ended September 30, 2017, reflecting gains in Africa ($2.1 million, or 217.3%), including both ongoing growth and continued shipments to Ethiopia, and Europe & Middle East ($0.3 million, or 78.2%), and
$0.1 million, or a 4.5% increase in R&D, milestone and grant, and license and royalty revenues compared to the three months ended September 30, 2017, reflecting ongoing technology and scientific collaborations.

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 three months ended September 30, 2018 decreased by $1.0 million, or 47.7% compared to the three months ended September 30, 2017. The following schedule calculates gross product margin and gross product margin percentage (dollars in thousands):

For the three months ended		Favorable/(unfavorable)	
	September 30, 2017	$ Change	% Change

	September 30, 2018						
Net product sales	$ 7,856		$ 6,133		$ 1,723	28.1	%
Less: Cost of product sales	6,775		4,065		(2,710)	(66.7)	%
Gross product margin	$ 1,081		$ 2,068		$ (987)	(47.7)	%
Gross margin percentage	13.76	%	33.72	%			

The $1.0 million decrease in gross product margin was comprised of the following:

$0.6 million from favorable net product sales volume as described above, and
offset by $1.6 million decrease from lower product margins, related to the sales growth in markets with lower average selling prices, coupled with costs incurred through the scaling of labor and production reflecting the current manual assembly process to deliver the 28.1% increase in net product sales volume.

The decrease in gross product margin percentage 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 (dollars in thousands):

	For the three months ended		Favorable/(unfavorable)	
	September 30, 2018	September 30, 2017	$ Change	% Change
Clinical & regulatory affairs	$244	$ 485	$ 241	50.0 %
Other research & development	1,654	1,321	(333)	(25.2)%
Total Research and Development	$1,898	$ 1,806	$ (92)	(5.1)%

The decrease in clinical & regulatory affairs costs for the three months ended September 30, 2018 compared to the three months ended September 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, or SG&A, includes administrative expenses, sales and marketing costs (including commissions), and other corporate items.

The $0.7 million, or 31.6% increase in SG&A for the three months ended September 30, 2018 compared to the three months ended September 30, 2017, was primarily associated with merger and acquisition expenses and increased head count and related costs.

Interest Expense, net

Interest expense, net is interest income earned on the Company's deposits, net of interest expense on the note payable. This increased on a net basis by approximately $12,000 for the three months ended September 30, 2018 compared to the three months ended September 30, 2017.

Nine Months Ended September 30, 2018 versus Nine Months Ended September 30, 2017

The results of operations for the nine months ended September 30, 2018 and 2017 were as follows (dollars in thousands):

	September 30, 2018		September 30, 2017	
TOTAL REVENUES	$25,814	100%	$18,027	100%
COSTS AND EXPENSES:				
Cost of product sales	16,828	65 %	9,488	53 %
Research and development expenses	5,736	22 %	6,035	33 %
Selling, general and administrative expenses	7,988	31 %	6,903	38 %
	30,552		22,426	
LOSS FROM OPERATIONS	(4,738)		(4,399)	
INTEREST INCOME, NET	43		25	

LOSS BEFORE INCOME TAXES	(4,695)	(18)%	(4,374)	(24)%
Income tax provision	-		-	
NET LOSS	$(4,695)		$(4,374)	

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during the nine months ended September 30, 2018 were $25.8 million, an increase of $7.8 million, or 43.2% compared to the nine months ended September 30, 2017. The increase in total revenues was comprised of the following:

$6.7 million, or a 46.1% increase in net product sales compared to the nine months ended September 30, 2017, reflecting strong gains in Africa ($5.1 million, or 279.0%), including both ongoing growth and the Company’s continued shipments to Ethiopia, Latin America ($2.4 million, or 35.3%) and Europe & Middle East ($0.3 million, or 20.7%), and
$1.1 million, or a 31.6% increase in R&D, milestone and grant revenues and license and royalty revenues compared to the nine months ended September 30, 2017, reflecting growing governmental, non-governmental, and commercial collaborations.

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 nine months ended September 30, 2018 decreased by $0.7 million, or 13.7% compared to the nine months ended September 30, 2017 . The following schedule calculates gross product margin and gross product margin percentage (dollars in thousands):

			Favorable/(unfavorable)	
	For the nine months ended September			
	30, 2018	September 30, 2017	$ Change	% Change
Net product sales	$ 21,112	$ 14,453	$ 6,659	46.1 %
Less: Cost of product sales	16,828	9,488	(7,340)	(77.4)%
Gross product margin	$ 4,284	$ 4,965	$ (681)	(13.7)%
Gross product margin percentage	20.29 %	34.35 %		

The $0.7 million decrease in gross product margin was comprised of the following:

$2.3 million from favorable product sales volume as described above, and
offset by $3.0 million decrease from lower product margins, related to the sales growth in markets with lower average selling prices, coupled with costs incurred through the scaling of labor and production reflecting the current manual assembly process to deliver the 46.1% increase in net product sales volume.

The decrease in gross product margin percentage 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 (dollars in thousands):

			Favorable/(unfavorable)	
	For the nine months ended September			
	30, 2018	September 30, 2017	$ Change	% Change
Clinical & regulatory affairs	$ 927	$ 1,589	$ 662	41.6 %
Other research & development	4,809	4,446	(363)	(8.2)%
Total Research and Development	$ 5,736	$ 6,035	$ 299	5.0 %

Expenses for Clinical & regulatory affairs decreased by $0.7 million for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, primarily related to a decrease in clinical trial expenses for the DPP HIV-Syphilis System.

The $0.4 million increase in other research & development costs was primarily associated with a higher R&D headcount and an increase in spending on materials & supplies, each corresponding with the $1.0 million growth in R&D milestone and grant revenue-related projects.

Selling, General and Administrative Expense

SG&A includes administrative expenses, sales and marketing costs including commissions, and other corporate items.

The $1.1 million increase in SG&A for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, was associated with merger & acquisition expenses, and increased sales commissions, head count and related costs.

Interest Expense, net

Interest expense, net is interest income earned on the Company's deposits, net of interest expense on the note payable, which increased by approximately $18,000 for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, reflecting interest on funds raised in the February 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 continue to explore ways to enhance our capital structure.

As of September 30, 2018, we had cash and cash equivalents of $6.8 million.

Public Offerings

As described in Note 5 – Stockholders' Equity to the unaudited condensed consolidated financial statements included herein, on February 13, 2018, we consummated an underwritten registered public offering of 1,783,760 shares of 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.

As described in Note 8 – Subsequent Events to the unaudited condensed consolidated financial statements included herein, on November 5, 2018, we consummated an underwritten registered public offering of 2,726,000 shares of common stock at a public offering price of $6.75 per share for gross proceeds of approximately $18.4 million. The net proceeds, after underwriting discounts and commissions and estimated expenses, were approximately $16.6 million.

Acquisitions

On January 9, 2017, we 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 shares of common stock with a value at closing of approximately $1.7 million. As further described in Note 2 – Acquisition to the unaudited condensed consolidated financial statements contained herein, the acquisition was accounted for as a business combination, with the operating results of RVR Diagnostics included within our operating results from the date of acquisition. We financed the cash portion of the acquisition with funds raised in our 2016 public equity offering. After the acquisition, we changed the name RVR Diagnostics Sdn Bhd to Chembio Diagnostics Malaysia Sdn Bhd.

As described in Note 8 – Subsequent Events to the unaudited condensed consolidated financial statements included herein, on November 6, 2018, we acquired 100% of the equity interests in opTricon GmbH, a Berlin, Germany-based privately-held developer and manufacturer of hand-held analyzers for rapid diagnostic tests, for approximately $5.5 million, subject to certain post-closing working capital and other adjustments.

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

We seek research and development programs awarded by government, non-governmental organization, and non-profit entities, including private foundations. We have, or have 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 September 30, 2018, we had cash and equivalents of $6.8 million and our only outstanding indebtedness was a $0.4 million seller-financed note payable associated with automated manufacturing equipment. Following is a

summary of the changes in cash and cash equivalents (dollars in thousands):

	For the nine months ended		Favorable/(unfavorable)	
	September 30, 2018	September 30, 2017	$ Change	% Change
Net cash used in operating activities	$ (7,530)	$ (7,177)	$ (353)	(5.0)%
Net cash used in investing activities	(402)	(1,640)	1,238	75.5 %
Net cash provided by financing activities	10,990	134	10,856	8201.5 %
Effect of exchange rate changes on cash	-	-	-	NA %
Increase (Decrease) in Cash and Cash Equivalents	$ 3,058	$ (8,683)	$ 11,741	135.2 %

Our cash flows for the nine months ended September 30, 2018 increased by $11.7 million as compared to the nine months ended September 30, 2017, primarily due to capital raised, offset in part 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 nine months ended September 30, 2018 was $7.5 million, primarily due to the $5.7 million increase in accounts receivable associated with the increase in total revenues, and the $4.7 million net loss (excluding non-cash items) during the nine months ended September 30, 2018. In addition, inventories increased by $1.6 million to support higher sales volumes during the nine months ended September 30, 2018 and build product for the Ethiopia HIV tender that began shipping during the second quarter of 2018. The $1.6 million increase in inventory was more than offset by a $3.8 million increase in accounts payable and accrued liabilities.

Cash used in investing activities of $0.4 million during the nine months ended September 30, 2018 related to the purchase of manufacturing equipment and other fixed assets.

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

Off-Balance Sheet Arrangements

We do 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 October 2018, we announced it had received a $10.5 million purchase commitment from Bio-Manginhos for the production of DPP HIV and DPP Leishmania assays in Brazil and their subsequent supply to Brazil's Ministry of Health.

In November 2018, we announced that we had received FDA EUA for DPP Ebola Antigen System for use with fingerstick and venous whole blood.

Significant Accounting Policies and Critical Accounting Estimates

Our significant accounting policies are described in Note 3 – Summary of Significant Accounting Policies to the Unaudited Condensed 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 nine months ended September 30, 2018, except for those changes pertaining to our adoption of Accounting Standards Codification Topic 606, Revenue From Contracts With Customers.

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 Accounting Standards Update No. 2014-09: (i) identify contract 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 described in 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 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 $60,000.

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 $78,000.

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. 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, or the 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. We believe that it is more likely than not that we will not be able to utilize our net operating loss carryforwards and maintains a full valuation allowance. We maintain 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.

We do not hold any amounts of derivative financial instruments or derivative commodity instruments and, accordingly, have no material derivative risk to report under this Item. As of September 30, 2018, we did not have any foreign currency exchange contracts or 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 4% of our total revenues for the nine months ended September 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, or the Exchange Act, as of the end of the period covered by this report. Based on this evaluation, our management, including our principal executive officer and principal financial officer, concluded that as of September 30, 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 principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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

Except as set forth below, there have been no material changes to the risk factors discussed in in Part I, Item 1A, entitled “Risk Factors,” in our Annual Report on Form 10-K for the year ended December 31, 2017.:

We may not generate the expected benefits of our acquisition of opTricon GmbH, and the acquisition could disrupt our ongoing business, distract our management and increase our expenses.

We entered into a share purchase agreement with opTricon GmbH, or opTricon, with the expectation that the acquisition of all of the outstanding shares of opTricon, or the Acquisition, will result in various benefits, including securing global commercial rights and reducing cost of goods. Achieving the anticipated benefits of the Acquisition is subject to a number of uncertainties, including whether our business and the business of opTricon can be integrated in an efficient and effective manner. We cannot assure you that we will be able to accurately forecast the performance or ultimate impact of the Acquisition.

It is possible that the integration process could take longer than anticipated and could result in the loss of valuable employees, additional and unforeseen expenses, the disruption of our ongoing business, processes and systems, or inconsistencies in standards, controls, procedures, practices, policies and compensation arrangements, any of which could adversely affect our ability to achieve the anticipated benefits of the Acquisition. There may be increased risk due to integrating financial reporting and internal control systems. The integration process is subject to a number of uncertainties, and no assurance can be given that the anticipated benefits, expense savings and synergies will be realized or, if realized, the timing of their realization. Failure to achieve these anticipated benefits could result in increased costs or decreases in the amount of expected revenues and could adversely affect our future business, financial condition, operating results and prospects.

We have incurred and will continue to incur non-recurring expenses in connection with the Acquisition, including legal, accounting and other expenses. Additional unanticipated costs may be incurred following consummation of the Acquisition in the course of the integration of the business of opTricon into our business. We cannot be certain that the realization of efficiencies related to the integration of the two businesses will offset the transaction and integration costs in the near term or any losses from undiscovered liabilities not covered by an indemnification from the sellers of opTricon.

ITEM 6. EXHIBITS

Number	Description
3.1*	Amended and Restated Bylaws of Chembio Diagnostics Inc.
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

* Previously filed

SIGNATURES

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

Chembio Diagnostics, Inc.

Date: November 8, 2018 By: /s/ John J. Sperzel III
John J. Sperzel III
Chief Executive Officer and President
(Principal Executive Officer)

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