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, 2019

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)*

555 Wireless Blvd.
Hauppauge, NY 11788
(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 ☐
Non-accelerated filer ☐
Emerging growth company ☐
Accelerated filer ☒
Smaller reporting 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 ☒

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.01 par value	CEMI	The NASDAQ Stock Market LLC

As of October 28, 2019, the registrant had 17,565,534 shares outstanding of its common stock, $.01 par value.

Quarterly Report on Form 10-Q
For The Quarterly Period Ended
September 30, 2019

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Chembio Diagnostics, Inc.

Unless the context requires otherwise, the words ‘‘we,’’ ‘‘our,’’ ‘‘our company,’’ ‘‘us,’’ ‘‘Chembio,’’ and similar terms refer to Chembio Diagnostics, Inc. and its consolidated subsidiaries.

STAT-PAK, STAT-VIEW, SURE CHECK and DPP are our registered trademarks, and CHEMBIO, MICRO READER and our logo design are our trademarks. For convenience, these trademarks appear in this Quarterly Report on Form 10-Q 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.

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," "design," "estimate," "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, 2019 (Unaudited)	December 31, 2018
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 21,867,892**	$ 12,524,551
Accounts receivable, net of allowance for doubtful accounts of $42,000 at September 30, 2019 and December 31, 2018	**5,377,985**	7,373,971
Inventories, net	**8,409,344**	7,851,222
Prepaid expenses and other current assets	**598,127**	702,010
TOTAL CURRENT ASSETS	**36,253,348**	28,451,754
FIXED ASSETS:		
Property, plant and equipment, net	**5,245,794**	2,873,920
Finance lease right-of-use assets	**222,036**	-
	5,467,830	2,873,920
OTHER ASSETS:		
Operating lease right-of-use assets	**6,697,896**	-
Intangible assets, net	**3,508,594**	3,884,831
Goodwill	**4,681,511**	4,983,127
Deposits and other assets	**308,159**	717,551
	15,196,160	9,585,509
TOTAL ASSETS	**$ 56,917,338**	$ 40,911,183
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 5,445,956**	$ 5,888,681
Deferred revenue	**237,500**	422,905
Current portion of long-term debt	**207,694**	207,694
Current portion of finance lease liabilities	**41,169**	-
Current portion of operating lease liabilities	**255,030**	-
TOTAL CURRENT LIABILITIES	**6,187,349**	6,519,280
OTHER LIABILITIES:		
Long-term operating lease liabilities	**6,706,918**	-
Long-term finance lease liabilities	**182,702**	-
Long-term debt, less current portion, and debt discount and issuance costs	**17,538,481**	171,821
Deferred tax liability	**505,618**	892,308
TOTAL LIABILITIES	**31,121,068**	7,583,409
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock - 10,000,000 shares authorized; none outstanding	**-**	-
Common stock - $.01 par value; 100,000,000 shares authorized; 17,565,534 and 17,166,459 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	**175,655**	171,664
Additional paid-in capital	**93,376,856**	90,953,788
Accumulated deficit	**(67,696,092)**	(57,909,874)
Accumulated other comprehensive (loss) income	**(60,149)**	112,196
TOTAL STOCKHOLDERS' EQUITY	**25,796,270**	33,327,774
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 56,917,338**	$ 40,911,183

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, 2019	September 30, 2018	**September 30, 2019**	September 30, 2018
REVENUES:				
Net product sales	**$ 8,510,629**	$ 8,304,370	**$ 23,381,906**	$ 22,108,727
License and royalty revenue	**238,330**	228,553	**703,352**	707,010
Research and development and grant revenue	**971,980**	1,292,202	**3,528,033**	3,995,115
TOTAL REVENUES	**9,720,939**	9,825,125	**27,613,291**	26,810,852
COSTS AND EXPENSES:				
Cost of product sales	**6,649,114**	7,223,081	**18,112,676**	17,824,557
Research and development expenses	**2,223,939**	1,897,751	**6,542,591**	5,736,265
Selling, general and administrative expenses	**4,455,588**	3,034,130	**12,565,601**	7,987,914
Acquisition costs	**-**	-	**395,612**	-
	13,328,641	12,154,962	**37,616,480**	31,548,736
LOSS FROM OPERATIONS	**(3,607,702)**	(2,329,837)	**(10,003,189)**	(4,737,884)
OTHER EXPENSE:				
Interest (expense) income, net	**(195,970)**	15,656	**(183,368)**	42,985
LOSS BEFORE INCOME TAXES	**(3,803,672)**	(2,314,181)	**(10,186,557)**	(4,694,899)
Income tax benefit:	**20,667**	-	**400,339**	-
NET LOSS	**$ (3,783,005)**	$ (2,314,181)	**$ (9,786,218)**	$ (4,694,899)
Basic loss per share	**$ (0.22)**	$ (0.16)	**$ (0.58)**	$ (0.34)
Diluted loss per share	**$ (0.22)**	$ (0.16)	**$ (0.58)**	$ (0.34)
Weighted average number of shares outstanding, basic	**16,923,695**	14,173,620	**16,912,583**	13,872,055
Weighted average number of shares outstanding, diluted	**16,923,695**	14,173,620	**16,912,583**	13,872,055

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		For the nine months ended	
	September 30, 2019	September 30, 2018	**September 30, 2019**	September 30, 2018
Net loss	**$ (3,783,005)**	$ (2,314,181)	**$ (9,786,218)**	$ (4,694,899)
Other comprehensive loss:				
Foreign currency translation adjustments	**(61,306)**	(104,657)	**(172,345)**	(26,187)
Comprehensive loss	**$ (3,844,311)**	$ (2,418,838)	**$ (9,958,563)**	$ (4,721,086)

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

	For the nine months ended September 30, 2019					
	Common Stock		Additional Paid-in-Capital	Accumulated Deficit	AOCI	Total
	Shares	Amount	Amount	Amount	Amount	Amount
Balance at December 31, 2018	**17,166,459**	**$ 171,664**	**$ 90,953,788**	**$ (57,909,874)**	**$ 112,196**	**$ 33,327,774**
Common Stock:						
Restricted stock compensation	-	-	281,248	-	-	281,248
Options:						
Stock option compensation	-	-	66,259	-	-	66,259
Foreign currency translation adjustments	-	-	-	-	202,186	202,186
Net loss	-	-	-	(2,816,533)	-	(2,816,533)
Balance at March 31, 2019	**17,166,459**	**$ 171,664**	**$ 91,301,295**	**$ (60,726,407)**	**$ 314,382**	**$ 31,060,934**
Common Stock:						
Restricted stock issued	375,000	3,750	(3,750)	-	-	-
Restricted stock compensation	-	-	307,774	-	-	307,774
Options:						
Exercised	24,075	241	(241)	-	-	-
Stock option compensation	-	-	69,097	-	-	69,097
Foreign currency translation adjustments	-	-	-	-	(313,225)	(313,225)
Net loss	-	-	-	(3,186,680)	-	(3,186,680)
Balance at June 30, 2019	**17,565,534**	**$ 175,655**	**$ 91,674,175**	**$ (63,913,087)**	**$ 1,157**	**$ 27,937,900**
Common Stock:						
Restricted stock compensation	-	-	440,396	-	-	440,396
Options:						
Stock option compensation	-	-	66,192	-	-	66,192
Warrant on term debt	-	-	1,196,093	-	-	1,196,093
Foreign currency translation adjustments	-	-	-	-	(61,306)	(61,306)
Net loss	-	-	-	(3,783,005)	-	(3,783,005)
Balance at September 30, 2019	**17,565,534**	**$ 175,655**	**$ 93,376,856**	**$ (67,696,092)**	**$ (60,149)**	**$ 25,796,270**

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

	For the nine months ended September 30, 2018					
	Common Stock		Additional Paid-in-Capital	Accumulated Deficit	AOCI	Total
	Shares	Amount	Amount	Amount	Amount	Amount
Balance at December 31, 2017	**12,318,570**	**$ 123,185**	**$ 62,821,288**	**$ (50,044,225)**	**$ 178,948**	**$ 13,079,196**
Common Stock:						
New stock from offering	1,783,760	17,838	10,916,514	-	-	10,934,352
Options:						
Exercised	60,372	604	71,309	-	-	71,913
Stock option compensation	-	-	97,250	-	-	97,250
Foreign currency translation adjustments	-	-	-	-	252,298	252,298
Net loss	-	-	-	(652,343)	-	(652,343)
Balance at March 31, 2018	**14,162,702**	**$ 141,627**	**$ 73,906,361**	**$ (50,696,568)**	**$ 431,246**	**$ 23,782,666**
Options:						
Exercised	10,918	109	(109)	-	-	-
Stock option compensation	-	-	127,035	-	-	127,035
Foreign currency translation adjustments	-	-	-	-	(173,828)	(173,828)
Net loss	-	-	-	(1,728,375)	-	(1,728,375)
Balance at June 30, 2018	**14,173,620**	**$ 141,736**	**$ 74,033,287**	**$ (52,424,943)**	**$ 257,418**	**$ 22,007,498**
Options:						
Exercised	-	-	-	-	-	-
Stock option compensation	-	-	74,759	-	-	74,759
Foreign currency translation adjustments	-	-	-	-	(104,657)	(104,657)
Net loss	-	-	-	(2,314,181)	-	(2,314,181)
Balance at September 30, 2018	**14,173,620**	**$ 141,736**	**$ 74,108,046**	**$ (54,739,124)**	**$ 152,761**	**$ 19,663,419**

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, 2019	September 30, 2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	**$ 29,423,872**	$ 21,812,928
Cash paid to suppliers and employees	**(35,185,776)**	(29,386,421)
Cash paid for operating leases	**(474,150)**	-
Cash paid for finance leases	**(4,033)**	-
Interest and Taxes, net	**(158,120)**	42,985
Net cash used in operating activities	**(6,398,207)**	(7,530,508)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Patent application costs	**(346,663)**	-
Acquisition of and deposits on fixed assets	**(2,568,244)**	(401,897)
Working capital adjustment related to business combination	**145,760**	-
Net cash used in investing activities	**(2,769,147)**	(401,897)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option exercises	**-**	71,914
Proceeds from issuance of long-term debt, net	**18,850,000**	-
Payments on debt issuance costs	**(186,313)**	-
Payments on note payable	**(136,232)**	(15,800)
Proceeds from sale of common stock, net	-	10,934,352
Principal payments for finance leases	**(9,851)**	-
Net cash provided by financing activities	**18,517,604**	10,990,466
Effect of exchange rate changes on cash	**(6,909)**	220
INCREASE IN CASH AND CASH EQUIVALENTS	**9,343,341**	3,058,281
Cash and cash equivalents - beginning of the period	**12,524,551**	3,790,302
Cash and cash equivalents - end of the period	**$ 21,867,892**	$ 6,848,583
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net loss	**$ (9,786,218)**	$ (4,694,899)
Adjustments:		
Depreciation and amortization	**1,666,675**	663,250
Share based compensation	**1,230,966**	299,044
Benefit from deferred tax liability	**(402,639)**	-
Changes in assets and liabilities:		
Accounts receivable	**1,995,986**	(5,708,674)
Inventories	**(558,122)**	(1,554,808)
Prepaid expenses and other current assets	**103,883**	(997,468)
Deposits and other assets	**(20,608)**	-
Accounts payable and accrued liabilities	**(442,725)**	3,752,297
Deferred revenue	**(185,405)**	710,750
Net cash used in operating activities	**$ (6,398,207)**	$ (7,530,508)
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	**$** 430,000	$ 268,655
Seller-financed equipment purchases	-	326,110

See accompanying notes to condensed consolidated financial statements

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 and fever disease; and strategic collaborations with leading global healthcare companies, which leverage the DPP platform to provide Chembio with additional revenue streams. In infectious disease, the Company is commercializing tests for HIV, Syphilis, Zika virus, dengue virus, chikungunya virus, and ebola, and developing tests for malaria, lassa, Marburg, leptospirosis, *Rickettsia typhi*, *Burkholderia pseudomallei*, and *Orientia tsutsugamushi*. Certain of these are 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 for eosinophilic respiratory disease the last in collaboration with global pharmaceutical company AstraZeneca. Chembio is also developing a point-of-care test for an undisclosed biomarker for Takeda, also a global pharmaceutical company.

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 ("R&D") efforts.

NOTE 2 — ACQUISITION:

On November 6, 2018, pursuant to a share purchase agreement, the Company acquired all of the outstanding shares of opTricon GmbH (subsequently renamed Chembio Diagnostics GmbH), a privately held German developer and manufacturer of handheld analyzers for rapid diagnostic tests, for $5.5 million in cash. Since 2015, the two parties collaborated in developing theDPP Micro Reader, a handheld, battery-operated analyzer that uses an innovative image sensor to provide, when combined with the Company's DPP tests, a quantitative interpretation of diagnostic results. The Company believes the acquisition will enable it to promote DPP tests and DPP Micro Readers more actively across global markets. The results of the acquired company's operations have been reflected in the consolidated financial statements since November 6, 2018.

As a result of the consideration paid exceeding the fair value of the net assets acquired, goodwill in the amount of $3,337,000 was recorded in connection with this acquisition, none of which will be deductible for tax purposes. In addition, the Company recorded $2,260,000 in intangible assets associated with the addition of developed technology and customer base from the acquisition. During the nine months ended September 30, 2019, the Company reduced goodwill by $145,760 related to routine post-closing adjustments. The consolidated statements of operations for the three and nine months ended September 30, 2019 include $0 and $395,612 of transaction costs related to the acquisition.

The acquisition was accounted for using the purchase method of accounting. The following table summarizes the preliminary allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed on the closing date of November 6, 2018:

	Amount
Net current assets	$ 404,204
Property, plant and equipment	125,000
Goodwill	3,337,000
Deferred tax liability	(635,000)
Other intangible assets (estimated useful life):	
Developed technology (7 years)	1,900,000
Customer contracts / relationships (10 years)	360,000
Total consideration	$ 5,491,204

The Company calculated the fair value of the fixed assets based on the net book value of the acquired company, as net book value approximated fair value. The developed technology and customer contracts and relationships were based on discounted cash flows using management estimates.

As indicated, the allocation of the purchase price shown above is preliminary, pending completion of an analysis of the deferred tax liability. Therefore, an adjustment may be required.

NOTE 3 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

a) Basis of Presentation:

The preceding (a) condensed consolidated balance sheet as of December 31, 2018, which has been derived from audited financial statements, and (b) unaudited interim condensed consolidated financial statements as of September 30, 2019 and for the three and nine months ended September 30, 2019 and 2018 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, have been condensed or omitted pursuant to such rules and regulations. 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, 2019 and its condensed consolidated results of operations for the three and nine months ended September 30, 2019 and 2018 have been made. 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, 2018, which was filed with the SEC on March 18, 2019. The interim results of operations are not necessarily indicative of the operating results for the full fiscal year or any future periods.

The Company's future working capital needs will depend on many factors, including the rate of its business and revenue growth, the timing of its continuing automation of U.S. manufacturing, and the timing of its investment in R&D as well as sales and marketing. The Company believes that its existing cash and cash equivalents will be sufficient to meet the Company's anticipated cash needs for the foreseeable future consistent with its long-term operating plan. If, however, this source of liquidity becomes insufficient to fund the growth of the Company's business, the Company may need to reduce the level or slow the timing of its growth plans, which would likely curtail or delay the growth in the Company's business contemplated by its operating plan and could impair or defer its ability to achieve profitability and generate cash flow, or to seek to raise additional funds through debt or equity financings, strategic relationships, or other arrangements.

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, 2019 and, its condensed consolidated results of operations for the three and nine months ended September 30, 2019 and 2018 have been made. (Note 3q - Error Correction) 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") No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. 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 and grant revenues, no adjustment to retained earnings was required upon adoption.

The Company adopted the standards for 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 obligations.

Product Revenues

Revenues from product sales are recognized and commissions are accrued 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.

The Company's payment terms vary by the type and location of the Company's customer and products or services offered. Payment terms differ by jurisdiction and customer, but payment is generally required in a term ranging from 30 to 60 days from date of shipment or satisfaction of the performance obligation.

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 a licensee of products covered under patents that it owns. The Company does not have future performance obligations under this license arrangement. 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 and Grant Revenue

All R&D and grant 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 in accordance with ASU No. 2018-08, *Not-for-Profit Entities (Topic 958): Clarifying the Scope and Accounting Guidance for Contributions Received and Contributions Made*. Such contracts are further described under *Disaggregation of Revenue*, below. Grants are invoiced and revenue is recognized as 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 and planning, product development and design optimization, design verification, design validation and process validation, and pivotal studies.

Disaggregation of Revenue

The following tables disaggregate total revenues:

	For the three months ended September 30, 2019			For the three months ended September 30, 2018		
	Exchange Transactions	**Non-Exchange Transactions**	**Total**	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	**$ 8,510,629**	**$ -**	**$ 8,510,629**	$ 8,304,370	$ -	$ 8,304,370
License and royalty revenue	**238,330**	**-**	**238,330**	228,553	-	228,553
R&D and grant revenue	**880,458**	**91,522**	**971,980**	960,332	331,870	1,292,202
	$ 9,629,417	**$ 91,522**	**$ 9,720,939**	$ 9,493,255	$ 331,870	$ 9,825,125

	Total	Total
Africa	**$ 1,250,063**	$ 3,193,098
Asia	**505,379**	216,527
Europe & Middle East	**1,629,965**	1,666,066
Latin America	**4,296,903**	3,404,623
United States	**2,038,629**	1,344,811
	$ 9,720,939	$ 9,825,125

	For the nine months ended September 30, 2019			For the nine months ended September 30, 2018		
	Exchange Transactions	**Non-Exchange Transactions**	**Total**	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	**$ 23,381,906**	**$ -**	**$ 23,381,906**	$ 22,108,727	$ -	$ 22,108,727
License and royalty revenue	**703,352**	**-**	**703,352**	707,010	-	707,010
R&D and grant revenue	**2,272,454**	**1,255,579**	**3,528,033**	2,328,058	1,667,057	3,995,115
	$ 26,357,712	**$ 1,255,579**	**$ 27,613,291**	$ 25,143,795	$ 1,667,057	$ 26,810,852

	Total	Total
Africa	**$ 6,009,103**	$ 7,156,822
Asia	**746,025**	1,212,839
Europe & Middle East	**4,880,744**	3,831,580
Latin America	**9,981,874**	9,743,764
United States	**5,995,545**	4,865,847
	$ 27,613,291	$ 26,810,852

Exchange transactions are recognized in accordance with ASU No. 2014-09, and non-exchange transactions are recognized in accordance with ASU No. 2018-08.

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, 2018, the Company reported $422,905 in deferred revenue, all of which was earned and recognized as R&D and grant revenue during the nine months ended September 30, 2019. At September 30, 2019, the Company reported $237,500 in deferred revenue that is expected to be recognized during the last quarter of 2019.

c) Inventories

Inventories consist of the following at:

	September 30, 2019	December 31, 2018
Raw materials	**$ 2,653,368**	$ 2,803,677
Work in process	**1,313,045**	263,043
Finished goods	**4,442,931**	4,784,502
	$ 8,409,344	$ 7,851,222

Inventories, consisting of material, labor and manufacturing overhead, are stated at the lower of cost and net realizable value. Cost is determined on the first-in, first-out method. The Company's policy is to periodically evaluate the market value of the inventory and the stage of product life cycle, and record a write-down for any inventory considered slow moving or obsolete. There were reserves against inventory of approximately $67,000 and $78,000 as of September 30, 2019 and December 31, 2018, 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 excluding unvested restricted stock. Diluted loss per share for the three and nine months ended September 30, 2019 and 2018 reflects the potential dilution from the exercise or conversion of other securities into common stock, if dilutive.

There were 650,093 and 693,116 weighted-average number of options outstanding as of September 30, 2019 and 2018, respectively, that were not included in the calculation of diluted per common share equivalents for the three months ended September 30, 2019 and 2018, respectively, because the effect would have been anti-dilutive. There were 672,472 and 709,042 weighted-average number of options outstanding as of September 30, 2019 and 2018, respectively, that were not included in the calculation of diluted per common share equivalent for the nine months ended September 30, 2019 and 2018, respectively, because the effect would have been anti-dilutive. There were 550,000 shares of warrants issued in September 2019. The weighted average of these shares were excluded from the calculation of diluted EPS as 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 (the "2008 Plan"), 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 2008 Plan by 125,000 to 750,000. Under the terms of the 2008 Plan, which expired during 2018, the Board of Directors (the "Board") or its Compensation Committee had the discretion to select the persons to whom awards were to be granted. Awards could be stock options, restricted stock and/or restricted stock units ("Equity Award Units"). The Equity Award Units became vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through September 30, 2019, there were 508,889 options exercised, and at September 30, 2019, 99,132 options were outstanding and no Equity Award Units were available to be issued under the 2008 Plan.

Effective June 19, 2014, the Company's stockholders voted to approve the 2014 Stock Incentive Plan (the "2014 Plan"), with 800,000 shares of common stock available to be issued. Under the terms of the 2014 Plan, the Board or its Compensation Committee has the discretion to select the persons to whom Equity Award Units were to be granted. Awards can be in the form of Equity Award Units. The Equity Award Units vest at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through September 30, 2019, there were 132,282 options exercised, and at September 30, 2019, 344,093 options were outstanding. Upon approval of the 2019 Plan (defined below), no additional Equity Award Units could be issued under the 2014 Plan. During 2018, 266,839 shares of restricted stock and 20,725 restricted stock units were awarded under the 2014 Plan.

Effective June 18, 2019, the Company's stockholders voted to approve the 2019 Omnibus Incentive Plan (the "2019 Plan"), with 2,400,000 shares of common stock available to be issued. Under the terms of the 2019 Plan, the Board or its Compensation Committee 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 Board or its Compensation Committee. As of September 30, 2019, 375,000 shares of restricted stock had been awarded under the 2019 Plan, and 2,025,000 Equity Award Units were available to be issued.

f) Stock-Based Compensation:

The fair value of restricted stock and restricted stock unit awards are their fair value on the date of grant. Stock-based compensation expense for stock options is calculated using the Black-Scholes valuation model based on awards ultimately expected to vest, together with the fair value of restricted stock and restricted stock unit awards, are reduced for actual forfeitures and expensed on a straight-line basis over the requisite service period of the grant.

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

Stock-based compensation expense recognized in the condensed consolidated statements of operations was classified as follows:

	For the three months ended		**For the nine months ended**	
	September 30, 2019	September 30, 2018	**September 30, 2019**	September 30, 2018
Cost of product sales	**$ 2,691**	$ 5,800	**$ 8,479**	$ 19,800
Research and development expenses	**56,251**	3,600	**172,346**	19,000
Selling, general and administrative expenses	**447,646**	65,359	**1,050,141**	260,244
	$ 506,588	$ 74,759	**$ 1,230,966**	$ 299,044

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

	For the three months ended		For the nine months ended	
	September 30, 2019	September 30, 2018	**September 30, 2019**	September 30, 2018
Expected term (in years)	N/A	4.5	N/A	4.9
Expected volatility	N/A%	39.69%	N/A%	39.91%
Expected dividend yield	N/A%	0%	N/A%	0%
Risk-free interest rate	N/A%	2.70%	N/A%	2.70%

The following table provides stock option activity for the nine months ended September 30, 2019:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contract Term	Aggregate Intrinsic Value
Outstanding at December 31, 2018	**711,968**	**$ 5.62**	**3.33 years**	**$ 687,364**
Granted	-	-		-
Exercised	46,875	3.48		172,242
Forfeited/expired/cancelled	15,000	5.68		30,286
Outstanding at September 30, 2019	**650,093**	**$ 5.77**	**2.79 years**	**$ 730,142**
Exercisable at September 30, 2019	**447,759**	**$ 4.98**	**2.16 years**	**$ 713,762**

The following table summarizes information about stock options outstanding at September 30, 2019:

	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	257,468	1.41	3.44	689,143	257,468	3.44	689,143
4.6 to 6.39999	137,875	2.70	5.87	40,999	87,125	5.89	24,619
6.4 to 8.19999	207,875	4.31	7.31	-	84,416	7.32	-
8.2 to 12	46,875	3.85	11.45	-	18,750	11.45	-
Total	650,093	2.79	$ 5.77	$ 730,142	447,759	$ 4.98	$ 713,762

As of September 30, 2019, there was $496,296 of net unrecognized compensation cost related to stock options that had not vested, which is expected to be recognized over a weighted average period of approximately 1.82 years. The total fair value of shares vested during the nine months ended September 30, 2019 and 2018 was $295,412 and $379,384, respectively.

The following table summarizes information about restricted stock and restricted stock units outstanding as of September 30, 2019:

	Number of Shares & Units	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2018	287,564	$ 9.65
Granted	375,000	5.80
Earned/released	-	-
Forfeited/expired/cancelled	-	-
Outstanding at September 30, 2019	**662,564**	**$ 7.47**

As of September 30, 2019, there was $3,639,325 of net unrecognized compensation cost related to restricted stock and restricted stock units that had not vested, which is expected to be recognized over a weighted average period of approximately 2.42 years.

g) 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, 2019	September 30, 2018	**September 30, 2019**	September 30, 2018
Africa	**$ 1,250,063**	$ 3,193,098	**$ 6,009,103**	$ 7,156,822
Asia	**505,379**	216,527	**746,025**	1,212,839
Europe & Middle East	**1,027,147**	728,073	**2,946,813**	1,773,872
Latin America	**4,296,904**	3,404,683	**9,981,874**	9,743,764
United States	**1,431,136**	761,989	**3,698,091**	2,221,430
	$ 8,510,629	$ 8,304,370	**$ 23,381,906**	$ 22,108,727

Long-lived assets by geographic area were as follows at:

	September 30, 2019	December 31, 2018
Asia	**419,719**	466,185
Europe & Middle East	**157,257**	123,752
United States	**4,668,818**	2,283,983
	$ 5,245,794	$ 2,873,920

h) Fair Value of Financial Instruments:

Fair value measurements of all financial assets and liabilities that are being measured and reported on a fair value basis are required to be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and,

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The carrying values for cash and cash equivalents, accounts receivable, accounts payable and accrued expenses and other current liabilities approximate fair value due to the immediate or short-term maturity of these financial instruments. Included in cash and cash equivalents were $20.5 million and $4.7 million as of September 30, 2019 and December 31, 2018, respectively, of money market funds that are Level 1 fair value measurements under the hierarchy.

The fair value of the Company's total debt of $20.2 million (carrying value of $17.7 million) and $0.2 million as of September 30, 2019 and December 31, 2018, respectively, is a Level 2 fair value measurement under the hierarchy and the company's debt face value approximates the recorded value as the rate is based upon the current rates available to the Company for similar financial instruments.

i) Accounts Payable and Accrued Liabilities:

Accounts payable and accrued liabilities consisted of:

	September 30, 2019	December 31, 2018
Accounts payable – suppliers	**$ 2,975,913**	$ 3,622,765
Accrued commissions and royalties	**819,405**	867,344
Accrued payroll	**320,266**	48,867
Accrued vacation	**659,358**	264,789
Accrued bonuses	**497,190**	494,318
Accrued expenses – other	**173,824**	590,598
TOTAL	**$ 5,445,956**	$ 5,888,681

j) Goodwill Long-Lived Assets 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 the Company's acquisition of Chembio Diagnostics GmbH in November 2018 and Chembio Diagnostics Malaysia Sdn Bhd 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.

The following table reflects changes in goodwill:

Beginning balance at December 31, 2018	$ 4,983,127
Chembio Diagnostics GmbH measurement period adjustment	(145,760)
Change in foreign currency exchange rate	(155,856)
Balance at September 30, 2019	$ 4,681,511

Intangible assets consisted of the following at:

		September 30, 2019			December 31, 2018		
	Weighted Average Remaining Useful Life	**Cost**	**Accumulated Amortization**	**Net Book Value**	Cost	Accumulated Amortization	Net Book Value
Intellectual property	6	$ 1,203,121	$ 258,045	$ 945,076	$ 1,089,688	$ 173,633	$ 916,055
Developed technology	6	1,816,190	194,592	1,621,598	1,910,315	-	1,910,315
Customer contracts/relationships	8	1,093,521	231,894	861,627	1,121,600	151,929	969,671
Trade names	8	107,057	26,764	80,293	108,521	19,731	88,790
		$ 4,219,889	$ 711,295	$ 3,508,594	$ 4,230,124	$ 345,293	$ 3,884,831

Intellectual property, developed technology, customer contracts/relationships, and trade names are amortized over 10, 7, 10, and 11 years, respectively. Amortization expense for the nine months ended September 30, 2019 and 2018 was approximately $378,691 and $134,208, respectively. Amortization expense, subject to changes in currency exchange rates, is expected to be $499,871 per year from 2019 through 2023, and total $1,381,699 for all of the years thereafter.

Long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the related carrying amounts may not be recoverable. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment. If there are indications of impairment, the Company uses future undiscounted cash flows of the related asset or asset grouping over the remaining life in measuring whether the assets are recoverable. In the event such cash flows are not expected to be sufficient to recover the recorded asset values, the assets are written down to their estimated fair value.

No impairment of goodwill, long-lived tangible, and intangible assets was recorded for the nine months ended September 30, 2019 and 2018.

k) Taxes:

At the end of each interim reporting period, the Company estimates its effective tax rate expected to be applied for the full year. This estimate is used to determine the income tax provision or benefit on a year-to-date basis, and may change in subsequent interim periods. Accordingly, the Company's effective tax benefit for the three and nine-month periods ended September 30, 2019 was 0.5% and 3.9%, compared to the effective tax rate of 0.0% for the three and nine-month periods ended September 30, 2018. The Company's effective tax rates for both periods were affected primarily by a full valuation allowance on domestic net deferred tax assets and the benefit from foreign net operating losses.

l) R&D:

R&D costs are expensed as incurred. Advance payments for goods and services that will be used in future R&D activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

m) Allowance for Doubtful Accounts:

The Company records allowances for doubtful accounts for the estimated probable losses on uncollectible accounts receivable. The allowance is based upon the credit worthiness of the Company's customers, the Company's historical experience, the age of the receivable and current market and economic conditions. Receivables are written off against these allowances in the period they are determined to be uncollectible.

n) Foreign Currency Translation:

The functional currency of a foreign subsidiary is the local currency. Assets and liabilities of foreign subsidiaries that use a currency other than U.S. dollars as their functional currency are translated to U.S. dollars at end of period currency exchange rates. The consolidated statements of operations of foreign subsidiaries are translated to U.S. dollars at average period currency exchange rates. The effect of translation for foreign subsidiaries is generally reported in Other Comprehensive Loss / Income. Foreign transaction gains and losses are immaterial.

o) Acquisition Costs:

Acquisition costs include period expenses, primarily professional services, related to acquisition activities.

p) Recent Accounting Pronouncements Affecting the Company:

In February 2016 the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. ASU No. 2016-02 requires the entity to recognize the assets and liabilities for the rights and obligations created by leased assets. Leases are to be classified as either finance or operating, with classification affecting expense recognition in the income statement. In July 2018 the FASB issued ASU No. 2018-10, *Codification Improvements to Topic 842, Leases*, and ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which provide supplemental adoption guidance and clarification to ASU No. 2016-02, which must be adopted concurrently with the adoption of ASU No. 2016-02 (ASU Nos. 2016-02, 2018-10 and 2018-11 are collectively referred to as "Topic 842"). Topic 842 was effective for the Company in the first quarter of 2019 and is to be applied using either a modified retrospective approach or an optional transition method, which allows an entity to apply the new standard at the adoption date with a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption.

As further discussed at Note 5(e) - Leases, the Company adopted Topic 842 on January 1, 2019 under the optional transition method and elected the short-term lease exception and available practical expedients. Under the transition method, the Company did not adjust its comparative period financial information or make the new required lease disclosures for periods before the effective date.

In July 2017, the FASB issued ASU 2017-11, Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. Part I of this ASU addresses the complexity of accounting for certain financial instruments with down round features. Per the ASU, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. The ASU is effective for public entities for fiscal years beginning after December 15, 2018 and the Company adopted it effective January 1, 2019. This ASU is applicable to the stock warrants issued as part of the Credit Agreement, as further discussed in Note 7 – Warrant.

q) Error Correction

As discussed in Note 3b – Revenue Recognition, the Company established an accounting policy to recognize freight and distribution expenses within cost of product sales. In connection with the closing of the Company's books and the preparation and review of the financial statements for the quarter ended September 30, 2019, management noted that this accounting policy had not been correctly implemented and, as a result, the cost of freight and distribution expenses was netted within net product sales.

The following table presents the impact of adjustments to correctly reflect the adopted accounting policy. These adjustments (i) increase net product sales, total revenues, cost of product sales, total costs and expenses, cash received from customers and grants and cash paid to suppliers and employees by an equal amount within each period and (ii) have no impact on product margins, operating results, earnings per share, net assets, net cash used in operating activities, or equity in any period.

	Net Product Sales			Total Revenues			Cost of Product Sales			Total Costs and Expenses			Cash received from customers and grants			Cash paid to suppliers and employees		
	As Filed	Adjustment	Revised	As Filed	Adjustment	Revised	As Filed	Adjustment	Revised	As Filed	Adjustment	Revised	As Filed	Adjustment	Revised	As Filed	Adjustment	Revised
2019:																		
3 months ended March 31	$ 6,382,986	$ 241,299	$ 6,624,285	$ 8,300,966	$ 241,299	$ 8,542,265	$ 4,770,337	$ 241,299	$ 5,011,636	$ 11,396,652	$ 241,299	$ 11,637,951	$ 7,869,167	$ 241,299	$ 8,110,466	$ (12,349,126)	$ (241,299)	$ (12,590,425)
3 months ended June 30	8,488,291	296,750	8,785,041	9,591,386	296,750	9,888,136	6,693,225	296,750	6,989,975	12,891,187	296,750	13,187,937	N/A	N/A	N/A	N/A	N/A	N/A
6 months ended June 30	14,871,277	538,049	15,409,326	17,892,352	538,049	18,430,401	11,463,562	538,049	12,001,611	24,287,839	538,049	24,825,888	17,627,823	538,049	18,165,872	(24,421,683)	(538,049)	(24,959,732)
2018:																		
3 months ended March 31	6,398,227	307,813	6,706,040	7,717,132	307,813	8,024,945	4,117,779	307,813	4,425,592	8,371,450	307,813	8,679,263	6,039,385	307,813	6,347,198	(8,358,631)	(307,813)	(8,666,444)
3 months ended June 30	6,857,861	240,456	7,098,317	8,720,326	240,456	8,960,782	5,935,428	240,456	6,175,884	10,474,056	240,456	10,714,512	N/A	N/A	N/A	N/A	N/A	N/A
6 months ended June 30	13,256,088	548,269	13,804,357	16,437,458	548,269	16,985,727	10,053,207	548,269	10,601,476	18,845,506	548,269	19,393,775	12,247,228	548,269	12,795,497	(17,352,226)	(548,269)	(17,900,495)
3 months ended Sept. 30	7,856,038	448,332	8,304,370	9,376,793	448,332	9,825,125	6,774,749	448,332	7,223,081	11,706,630	448,332	12,154,962	N/A	N/A	N/A	N/A	N/A	N/A
9 months ended Sept. 30	21,112,126	996,601	22,108,727	25,814,251	996,601	26,810,852	16,827,956	996,601	17,824,557	30,552,135	996,601	31,548,736	20,816,327	996,601	21,812,928	(28,389,820)	(996,601)	(29,386,421)
Year ended Dec. 31	26,741,020	1,172,189	27,913,209	33,409,251	1,172,189	34,581,440	21,427,243	1,172,189	22,599,432	41,391,919	1,172,189	42,564,108	28,632,084	1,172,189	29,804,273	(40,452,110)	(1,172,189)	(41,624,299)
2017:																		
Year ended Dec. 31	19,322,302	1,193,524	20,515,826	24,015,427	1,193,524	25,208,951	12,921,157	1,193,524	14,114,681	30,497,977	1,193,524	31,691,501	24,971,299	1,193,524	26,164,823	(30,028,299)	(1,193,524)	(31,221,823)

NOTE 4 — STOCKHOLDERS' EQUITY:

During the first nine months of 2019, options to purchase 46,875 shares of the Company's common stock were exercised on a cashless basis into 24,075 shares of common stock. During the first nine months of 2018, options to purchase 114,947 shares of the Company's common stock were exercised on a cashless basis into 71,290 shares of common stock.

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

NOTE 5 — COMMITMENTS, CONTINGENCIES, AND CONCENTRATIONS:

a) Concentrations:

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				Accounts Receivable as of	
	September 30, 2019		September 30, 2018		September 30, 2019		September 30, 2018			
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	September 30, 2019	Dec. 31, 2018
Customer 1	$ 3,966,142	46.6%	$ 3,256,390	39%	$ 10,012,644	42.8%	$ 9,241,445	42%	$ 2,209,986	$ 3,499,340
Customer 2	-	-%	1,852,186	22%	4,378,773	18.7%	3,312,816	15%	189,283	1,033,824

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, 2019		September 30, 2018		September 30, 2019		September 30, 2018			
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	September 30, 2019	Dec. 31, 2018
Vendor 1	*	*%	508,646	22%	*	*%	1,372,521	17%	*	*

In the table above, an asterisk (*) indicates that purchases from the vendor did not exceed 10% for the period indicated or that accounts payable by the vendor did not exceed 10% of total accounts payable at the date 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 applicable requirements can lead to sanctions, including withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, civil money penalties, injunctions, and criminal prosecution.

c) Employment Contracts:

The Company has multi-year contracts with two key employees that call for salaries presently aggregating $820,000 per year. The contracts expire in March 2020 and December 2021. The following table is a schedule of future minimum salary commitments as of September 30, 2019:

2019	$ 205,000
2020	478,800
2021	365,000

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 approximately $74,600 and $71,900 for the nine months ended September 30, 2019 and 2018, respectively.

e) Leases:

Chembio's leases have historically been limited to its facilities in New York, Germany, and Malaysia. As of September 30, 2019, the Company was a party to seven leases. One of the leases is subject to a sublease for the remainder of its term, as further described below.

The Company's leases generally include optional renewal periods. Upon entering into a new lease, the Company evaluates the leasehold improvements and regulatory requirements related to its operations in that location. To the extent that the initial lease term of the related lease is less than the useful life of the leasehold improvements and potential regulatory costs associated with moving the facility, the Company concludes that it is reasonably certain that a renewal option will be exercised, and thus that renewal period is included in the lease term and the related payments are reflected in the right-of-use ("ROU") asset and lease liability.

The Company's leases generally include fixed rental payments with defined annual increases. While certain of the Company's leases are gross leases, the majority of the Company's leases are net leases in which the Company makes separate payments to the lessor based on the lessor's property and casualty insurance costs, the property taxes assessed on the property, and a portion of the common area maintenance where applicable. The Company has elected the practical expedient not to separate lease and nonlease components for all of the Company's facility leases. The Company has also elected the practical expedient for short-term lease exception for all of its facility leases.

The components of lease expense for the three and nine months ended September 30, 2019 were as follows:

	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Operating lease expense	**$ 425,757**	**$ 1,108,016**
Finance lease cost		
Amortization of right-of-use assets	**$ 11,686**	**$ 11,686**
Interest on lease liabilities	**4,033**	**4,033**
Total finance lease expense	**$ 15,719**	**$ 15,719**

Supplemental cash flow information related to leases was as follows.

	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	**$ 158,050**	**$ 474,150**
Operating cash flows for finance leases	**4,033**	**4,033**
Financing cash flows for finance leases	**9,851**	**9,851**
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	**$ -**	**$ 6,697,896**
Finance leases	**-**	**222,036**

Supplemental balance sheet information related to leases was as follows:

	September 30, 2019
Operating Leases	
Operating lease right-of-use assets	$ 6,697,896
Current portion of operating lease liability	255,030
Operating lease liabilities	6,706,918
Total operating lease liabilities	$ 6,961,948
Finance Leases	
Finance lease right of use asset	$ 233,722
Accumulated depreciation	(11,686)
Finance lease right of use asset, net	$ 222,036
Current portion of finance lease liability	41,169
Finance lease liability	182,702
Total finance lease liabilities	$ 223,871
Weighted Average Remaining Lease Term	
Operating leases	9.9 years
Finance leases	4.8 years
Weighted Average Discount Rate	
Operating leases	8.51%
Finance leases	7.00%

During the nine months ended September 30, 2019, the Company executed an operating sublease related to its former Holbrook, New York facility. The sublease runs conterminously with the base lease in Holbrook, for which the Company remains primarily responsible. In addition, the Company entered into a finance lease agreement relating to the office furniture in June 2019. The Company recognized the corresponding lease asset and liability effective June 30, 2019 and recorded related depreciation starting on July 1, 2019. Monthly payments towards this lease commenced in July 2019.

At the time of the assessment, the Company did not have an established incremental borrowing rate and the interest rates implicit in each of the leases were not readily determinable, therefore the Company used an interest rate based on the market place for the public debt. In September 2019, the Company has entered into a credit agreement for a $20 million term loan as described on Note 6 - Long Term Debt.

Maturities of lease liabilities as of September 30, 2019 were as follows.

	Operating Leases	Finance Leases
2019	$ 158,050	$ 13,884
2020	813,443	55,536
2021	998,071	55,536
2022	1,026,044	55,536
2023	1,011,085	55,536
Thereafter	6,792,762	27,767
Total lease payments	$ 10,799,455	$ 263,795
Less: imputed interest	3,837,507	39,924
Total	$ 6,961,948	$ 223,871

As previously disclosed in the Company's 2018 Annual Report on Form 10-K, and under the previous lease accounting standard, future minimum lease payments for operating leases having initial or remaining non-cancellable lease terms in excess of one year would have been as follows for the years ending December 31:

2019	$ 384,308
2020	88,576
2021	-
	$ 472,884

f) Litigation:

From time to time, the Company is involved in certain legal actions arising in the ordinary course of business. The outcomes of such actions, either individually or in the aggregate, are not expected to have a material adverse effect on the Company's future financial position or results of operations.

NOTE 6 — LONG-TERM DEBT:

In September 2017, the Company entered into an agreement with an equipment vendor to purchase automated assembly equipment for approximately $660,000. The terms call for payments of 30% down, 60% at time of factory acceptance testing and 10% after delivery. The vendor agreed to lend the Company 15%, 40%, and 10% of each originally scheduled payment, respectively. The Company paid interest at an annual rate of 12% until delivery. Beginning in September 2018, 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.

On September 3, 2019, the Company entered into a Credit Agreement and Guaranty (the "Credit Agreement") with Perceptive Credit Holdings II, LP (the "Lender"). The Credit Agreement provides for a $20,000,000 senior secured term loan credit facility, which was drawn in full on September 4, 2019. Under the terms of the Credit Agreement, the Company may use the proceeds (i) for general working capital purposes and other permitted corporate purposes, (ii) to refinance certain of the Company's existing indebtedness and (iii) to pay fees, costs and expenses incurred in connection with the Credit Agreement, including the Lender's closing cost amount of $550,000, which was netted from the proceeds, and a financing fee of $600,000 (3.0% of gross proceeds) payable to Craig-Hallum Capital Group LLC, the Company's financial advisor for the financing.

Principal outstanding under the Credit Agreement bears interest at a rate per annum equal to the sum of (a) the greater of the one-month London Interbank Offered Rate and 2.5% plus (b) 8.75%. At any time at which an event of default has occurred and is continuing, the interest rate will increase by 4.0%. Accrued interest is payable on a monthly basis.

No principal repayments are due under the Credit Agreement prior to September 30, 2022, unless the Company elects to prepay principal or principal is accelerated pursuant to an event of default identified in the Credit Agreement. Principal installments in the amount of $300,000 are payable on the last day of each of the eleven months from September 2022 through July 2023, and all remaining principal is payable at maturity on September 3, 2023. The Company may prepay outstanding principal from time to time, subject to payment of a premium on the prepaid principal amount equal to 10% through September 3, 2020, 8% from September 4, 2020 through September 3, 2021, and 4% from September 4, 2021 through September 3, 2022. No premium will be due with respect to any prepayment made on or after September 4, 2022.

As of September 30, 2019, the loan balance, net of unamortized discounts and debt issuance costs, was $17.5 million and the company was in compliance with its loan covenants. Our obligations under the Credit Agreement are secured by a first priority, perfected lien on substantially all of our property and assets, including our equity interests in our subsidiaries.

NOTE 7 — WARRANT:

In connection with entering into the Credit Agreement, on September 3, 2019, the Company issued to the Lender a seven-year warrant (the "Warrant") to purchase up to 550,000 shares of the Company's common stock at a per-share exercise price of $5.22. The Warrant is exercisable for cash or on a net, or "cashless," basis, and the exercise price of the Warrant is subject to price-based, weighted-average antidilution adjustments for one year after issuance.

The Warrant was evaluated by the Company and classified to stockholder's equity. Its fair value was estimated using a Black-Scholes option-pricing model using the assumptions below.

Stock price on issuance date	$	5.40	
Strike Price	$	5.22	
Risk-free interest rate		1.45	%
Volatility		43.65	%
Expected life		7 years	

The fair value of the Warrant was determined to be approximately $1.4 million at $2.49 per share.

As of September 30, 2019 the balance recorded in the Company's Stockholders' Equity for the Warrants, net of allocated issuance costs, was $1.2M.

As of September 30, 2019, no warrants were exercised and no warrants have expired.

NOTE 8 — SUBSEQUENT EVENTS:

The Company and its newly formed subsidiary Chembio Diagnostics Brazil LLC entered into a definitive agreement to purchase all of the outstanding equity securities of Orangelife Comercio e Industria Ltda ("Orangelife"), a Brazilian manufacturer and distributor of point-of-care diagnostic tests for infectious diseases. Chembio will deliver $150,000 in cash and 153,707 common shares at closing to the former Orangelife equity holders , and will deliver up to an additional 497,288 common shares based on the achievement of certain milestones between 2020 and 2022. Subject to customary closing conditions, the transaction is expected to close during the fourth quarter of 2019.

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, 2018, 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, or 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 our business operations and financial condition as of September 30, 2019, and for the three and nine months ended September 30, 2019. This discussion should be read in conjunction with Item 1. Financial Statements.

The following discussion 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., Chembio Diagnostics Malaysia Sdn. Bhd. and Chembio Diagnostics GmbH, we develop, manufacture and commercialize point-of-care diagnostic tests that are used to detect or diagnose diseases. All products that are currently being developed are based on our patented DPP technology, a novel point-of-care diagnostic platform that offers certain customer advantages as compared to traditional lateral flow technology.

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 three corporate priorities:

- Expand our commercialization;
- Advance our research and development pipeline; and
- Prepare for additional growth.

Our accomplishments during the third quarter of 2019 included:

- Closed a $20 million dollar term loan with Perceptive Advisors, one of the world's leading healthcare-focused investment firms;
- Signed a definitive agreement to acquire Orangelife Comercio e Industria Ltda ("Orangelife"), a brazilian manufacturer and distributor of point-of-care diagnostic tests for infectious diseases;
- Received World Health Organization (WHO) Prequalification approval of our Malaysia manufacturing facility;
- Received WHO Prequalification approval for our SURE CHECK HIV Self-Test, which allows us to expand our commercialization of this novel test; and,
- Entered into a collaboration with Takeda Pharmaceutical, a global pharmaceutical company, to develop a quantitative point-of-care test to detect an undisclosed biomarker.

Our product commercialization and product development efforts are focused in two areas: infectious disease, which includes both sexually transmitted and tropical and 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, chikungunya virus, and ebola, and developing tests for malaria, 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 for eosinophilic respiratory disease, the last in collaboration with global biopharmaceutical company AstraZeneca. As noted above, we are also developing a point-of-care test for an undisclosed biomarker for Takeda, also a global pharmaceutical company.

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 point-of-care 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, 2019 versus Three Months Ended September 30, 2018

The results of operations for the three months ended September 30, 2019 and 2018 were as follows (dollars in thousands):

	September 30, 2019		September 30, 2018	
TOTAL REVENUES	**$ 9,721**	**100%**	$ 9,825	100%
OPERATING COSTS AND EXPENSES:				
Cost of product sales	**6,649**	**68%**	7,223	74%
Research and development expenses	**2,224**	**23%**	1,898	19%
Selling, general and administrative expenses	**4,456**	**46%**	3,034	31%
	13,329		12,155	
LOSS FROM OPERATIONS	**(3,608)**		(2,330)	
OTHER (EXPENSE) INCOME, NET	**(196)**		16	
LOSS BEFORE INCOME TAXES	**(3,804)**	**(39)%**	(2,314)	(24)%
Income tax benefit	**21**		-	
NET LOSS	**$ (3,783)**		$ (2,314)	

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during the quarter ended September 30, 2019 were $9.7 million, a decrease of $0.1 million, or 1%, compared to the quarter ended September 30, 2018. The decrease in total net revenues was composed of the following:

- $2.1 million increase in product sales driven by gains in nearly every region, led by Latin America the U.S., Europe and Asia. Latin America benefited from Dengue and Chikungunya assay sales, and the U.S. benefitted from a large public health customer and initial increased demand related to competitor shipment delays.
- Offset by $1.9 million decrease in product sales in Africa related to tender timing and a $0.3 million decrease in R&D revenues related to the timing and cadence of program performance obligations.

Gross Product Margin

Cost of product sales is primarily composed 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 product margin percentage is gross product margin as a percentage of net product sales. Gross product margin increased by $0.8 million, or 72% compared to 2018. The following schedule calculates gross product margin (dollars in thousands):

	For the three months ended		Favorable/(unfavorable)	
	September 30, 2019	September 30, 2018	**$ Change**	**% Change**
Net product sales	**$ 8,511**	$ 8,304	$ 207	2%
Less: Cost of product sales	**6,649**	7,223	574	8%
Gross product margin	**$ 1,862**	$ 1,081	$ 781	72%
Gross product margin percentage	**21.88%**	13.02%		

The $0.8 million increase in gross product margin was composed of the following:

- $0.2 million favorable product sales volume as described above, and
- $0.6 million favorable reduction in labor costs and increase in average selling prices.

As noted above, we have two additional automated manufacturing lines on order. We expect the automation to both reduce our reliance on manual labor and contribute to improving margins.

Research and Development

This category includes costs incurred for clinical and regulatory affairs and other research and development, as follows (dollars in thousands):

	For the three months ended		Favorable/(unfavorable)	
	September 30, 2019	September 30, 2018	**$ Change**	**% Change**
Clinical and regulatory affairs	**$** 333	$ 244	$ (89)	$ 6%
Other research and development	1,891	1,654	(237)	14%
Total research and development	**$** 2,224	$ 1,898	$ (326)	17%

The increase in R&D costs for the three months ended September 30, 2019 compared to the three months ended September 30, 2018 was primarily associated with product development activities, as well as the acquisition of Chembio Diagnostics Germany GmbH.

Selling, General and Administrative Expense

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

The $1.4 million, or 47%, increase in selling, general and administrative expense for the three months ended September 30, 2019 compared to the three months ended September 30, 2018, was primarily associated with the acquisition of Chembio Diagnostics Germany, higher non-cash equity compensation costs, and rent and other costs related to leasing our new facility in Hauppauge, NY.

Other Income (Expense), net

Other expenses/income, net consists principally of interest expense, net of interest income earned on our deposits, which increased in the third quarter of 2019 as compared to the third quarter of 2018 due to interest accruing on long-term debt incurred on September 3, 2019, of which $20 million (carrying value of $17.5 million) was outstanding at September 30, 2019. For a description of this long-term debt, please see "—Liquidity and Capital Resources—Sources of Funds—Credit Agreement" below.

Income Tax Provision

During the third quarter of 2019, we recognized a tax benefit of $21,000 related to losses generated by our foreign subsidiaries. As of September 30, 2019 and 2018, our U.S. deferred tax assets included a full valuation allowance.

Nine Months Ended September 30, 2019 versus Nine Months Ended September 30, 2018

The results of operations for the nine months ended September 30, 2019 and 2018 were as follows (dollars in thousands):

	September 30, 2019		September 30, 2018	
TOTAL REVENUES	**$ 27,613**	**100%**	$ 26,811	100%
OPERATING COSTS AND EXPENSES:				
Cost of product sales	**18,113**	**66%**	17,825	66%
Research and development expenses	**6,543**	**24%**	5,736	21%
Acquisition cost	**395**	**1%**	-	
Selling, general and administrative expenses	**12,565**	**45%**	7,988	30%
	37,616		31,549	
LOSS FROM OPERATIONS	**(10,003)**		(4,738)	
OTHER (EXPENSE) INCOME, NET	**(183)**		43	
LOSS BEFORE INCOME TAXES	**(10,186)**	**(37)%**	(4,695)	(18)%
Income tax benefit	**400**		-	
NET LOSS	**$ (9,786)**		$ (4,695)	

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during the nine months ended September 30, 2019 were $27.6 million, an increase of $0.8 million, or 3% compared to the nine months ended September 30, 2018. The increase in total net revenues was composed of the following:

- $1.3 million net increase in product sales, reflecting gains in the U.S., Europe and Latin America, offset in part by lower sales in Africa and Asia. U.S. sales benefited from our winning back a large public health program and Latin America benefited from initial sales of febrile tests. Europe includes contribution from our acquisition of Chembio Diagnostics GmbH in November 2018. Asia and Africa declines were affected by the timing of national tenders.
- $0.5 million, or 10%, decrease in R&D and grant and license and royalty revenues, related to the timing and cadence of program performance obligations.

Gross Product Margin

Cost of product sales is primarily composed of material, labor, manufacturing overhead, depreciation and amortization, and other operating expenses.

Gross product margin increased by $0.9 million, or 23%, compared to the first nine months of 2018. The following schedule calculates gross product margin (dollars in thousands):

	For the nine months ended		Favorable/(unfavorable)	
	September 30, 2019	September 30, 2018	$ Change	% Change
Net product sales	**$ 23,382**	**$ 22,109**	$ 1,273	6%
Less: Cost of product sales	**18,113**	**17,825**	(288)	2%
Gross product margin	**$ 5,269**	**$ 4,284**	$ 985	23%
Gross product margin percentage	**22.53%**	**19.38%**		

The $0.9 million increase in gross product margin was composed of the following:

- $0.4 million favorable product sales volume as described above, together with
- $0.5 million from favorable product margins related to the impact of geographic mix on average selling price, initial benefits from our first automated assembly line, and reduced contract labor costs.

As noted above, we have commenced automated manufacturing on our first line and have two other lines on order. We expect the automation to both reduce our reliance on manual labor and contribute to improving gross product margin.

Research and Development

This category includes costs incurred for clinical and regulatory affairs and other research and development, as follows (dollars in thousands):

	For the nine months ended		Favorable/(unfavorable)	
	September 30, 2019	September 30, 2018	**$ Change**	**% Change**
Clinical and regulatory affairs	**$ 1,096**	$ 927	$ (169)	18%
Other research and development	**5,447**	4,809	(638)	13%
Total Research and Development	**$ 6,543**	$ 5,736	$ (807)	14%

The increase in clinical and regulatory affairs costs for the nine months ended September 30, 2019 compared to the nine months ended September 30, 2018 was primarily associated with obtaining new regulatory approvals. The increase in other research and development costs related to product development, as well as the acquisition of Chembio Diagnostics Germany GmbH.

Selling, General and Administrative Expense

The $4.6 million, or 57%, increase in selling, general and administrative expense for the nine months ended September 30, 2019 compared to the nine months ended September 30, 2018, was primarily associated with the acquisition of Chembio Diagnostics Germany, higher non-cash equity compensation costs, and rent and other costs related to leasing our new facility in Hauppauge, NY.

Other (Expense) Income, net

Other expense/income, net consists principally of interest expense, net of interest income earned on our deposits, which increased in the first nine months of 2019 as compared to the first nine months of 2018 due to the interest accruing on long-term debt incurred on September 3, 2019, of which $20 million (carrying value of $17.5 million) was outstanding at September 30, 2019. For a description of this long-term debt, please see "—Liquidity and Capital Resources—Sources of Funds—Credit Agreement" below.

Income Tax Provision

During the first nine months of 2019, we recognized a tax benefit of $0.4 million related to losses generated by our foreign subsidiaries. As of September 30, 2019 and 2018, our U.S. deferred tax assets included a full valuation allowance.

Liquidity and Capital Resources

During the nine months ended September 30, 2019, we funded our business operations, including capital expenditures and working capital requirements, principally from cash and cash equivalents. Our operations used cash flow of $6.4 million. As of September 30, 2019, we had outstanding debt (excluding leases) in the amount of $20.2 million (carrying amount of $17.7 million), consisting of loans of $20.0 million under a credit agreement entered into on September 3, 2019 (see "—Sources of Funds—Credit Agreement" below) and $0.2 million under a seller-financed note payable incurred in connection with our purchase of automated manufacturing equipment.

We continually evaluate our liquidity requirements, capital needs and availability of capital resources based on our operating needs and our planned growth initiatives. We believe our existing cash and cash equivalents will be sufficient to meet our anticipated cash needs for at least the next twelve months.

Our future working capital needs will depend on many factors, including the rate of our business and revenue growth, the timing of our continuing automation of U.S. manufacturing, and the timing of investment in our research and development as well as sales and marketing. If, however, those sources of liquidity become insufficient to fund the growth of our business, we may need to reduce the level or slow the timing of its growth plans, which would likely curtail or delay the growth in our business contemplated by our operating plan and could impair or defer our ability to achieve profitability and generate cash flow, or to seek to raise additional funds through debt or equity financings, strategic relationships, or other arrangements, to the extent funding would be available to us on acceptable terms or at all. If we were to raise additional funds through the issuance of equity or convertible securities, the issuance could result in substantial dilution to existing stockholders, and the holders of these new securities or debt may have rights, preferences and privileges senior to those of the holders of common stock.

Sources of Funds

Credit Agreement. On September 3, 2019, we, as borrower, and certain of our subsidiaries, as guarantors, entered into a Credit Agreement and Guaranty, or the Credit Agreement, with Perceptive Credit Holdings II, LP, or the Lender.

- *Principal Amount*. The Credit Agreement provides for a $20,000,000 senior secured term loan credit facility, which was drawn in full on September 4, 2019. Under the terms of the Credit Agreement, we may use the proceeds (i) for general working capital purposes and other permitted corporate purposes, (ii) to refinance certain of our existing indebtedness and (iii) to pay fees, costs and expenses incurred in connection with the Credit Agreement, including the Lender's closing cost amount of $550,000, which was netted from the proceeds, and a financing fee of $600,000 (3.0% of gross proceeds) payable to Craig-Hallum Capital Group LLC, our financial advisor for the financing.

- *Interest Rate*. Principal outstanding under the Credit Agreement bears interest at a rate per annum equal to the sum of (a) the greater of the one-month London Interbank Offered Rate and 2.5% plus (b) 8.75%. At any time at which an event of default (as described under "—*Default Provisions*" below) has occurred and is continuing, the interest rate will increase by 4.0%. Accrued interest is payable on a monthly basis.

- *Scheduled Repayment*. No principal repayments are due prior to September 30, 2022, unless we elect to prepay principal as described under "—*Optional Prepayment*" below or principal is accelerated pursuant to an event of default as described under "—*Default Provisions*" below. Principal installments in the amount of $300,000 are payable on the last day of each of the eleven months from September 2022 through July 2023, and all remaining principal is payable at maturity on September 3, 2023.

- *Optional Prepayment.* We may prepay outstanding principal from time to time, subject to payment of a premium on the prepaid principal amount equal to 10% through September 3, 2020, 8% from September 4, 2020 through September 3, 2021, and 4% from September 4, 2021 through September 3, 2022. No premium will be due with respect to any prepayment made on or after September 4, 2022.

- *Guaranties*. Our subsidiaries Chembio Diagnostic Systems Inc. and Chembio Diagnostics Malaysia Sdn Bhd. have guaranteed, and the Lender from time to time may require our other subsidiaries to guarantee, our obligations under the Credit Agreement.

- *Security*. Our obligations under the Credit Agreement are secured by a first priority, perfected lien on substantially all of our property and assets, including our equity interests in our subsidiaries. Our subsidiary Chembio Diagnostic Systems Inc. has secured its guarantee of our Credit Agreement obligations with a lien on substantially all of its assets, and the Lender from time to time may require Chembio Diagnostics Malaysia Sdn Bhd. and any of our other subsidiaries that has guaranteed our Credit Agreement obligations to do the same.

- *Representations and Warranties; Financial and Other Covenants*. In the Credit Agreement we made customary representations and warranties as well as customary affirmative and negative covenants, including covenants limiting additional indebtedness, liens, guaranties, mergers and acquisitions, substantial asset sales, investments and loans, sale and leasebacks, transactions with affiliates, and fundamental changes. The Credit Agreement also contains financial covenants requiring that (i) we maintain aggregate unrestricted cash of not less than $3,000,000 at all times and (ii) we achieve specified minimum rolling four-quarter ("last twelve month") total revenue amounts as of September 30, 2019 and the last day of each calendar quarter thereafter. The minimum total revenue amounts, which range from $32.0 million to $50.1 million, were developed for purposes of the Credit Agreement and do not reflect the internal estimates and plans used by our management and board of directors to understand and evaluate our operating performance, to establish budgets, and to establish operational goals for managing our business. We therefore do not believe that the covenant requirements provide useful information to investors or others in enhancing an understanding of our future prospects.

- *Default Provisions*. The Credit Agreement provides for customary events of default, including events of default based on non-payment of amounts due under the Credit Agreement, defaults on other debt, misrepresentations, covenant breaches, changes of control, insolvency, bankruptcy and the occurrence of a material adverse effect on the Company. Upon an event of default resulting from a voluntary or involuntary proceeding for bankruptcy, insolvency or receivership, the amounts outstanding under the Credit Agreement will become immediately due and payable and the Lender's commitments will be automatically terminated. Upon the occurrence and continuation of any other event of default, the Lender may accelerate payment of all obligations and terminate the Lender's commitments under the Credit Agreement. Upon an acceleration of payment following an event of default occurring prior to September 4, 2021, the amounts due and payable by us will include a prepayment premium on accelerated principal in the amount described under "—*Optional Prepayment*" above.

In connection with entering into the Credit Agreement, on September 3, 2019, we issued to the Lender a seven-year warrant, or the Warrant, to purchase up to 550,000 shares of our common stock at a per-share exercise price of $5.22. The Warrant is exercisable for cash or on a net, or "cashless," basis, and the exercise price of the Warrant is subject to price-based, weighted-average antidilution adjustments for one year after issuance.

The foregoing descriptions of the Credit Agreement and the Warrant do not purport to be complete and are subject to, and qualified in their entirety by, the full text of the Credit Agreement and the Warrant, which are included as Exhibits 10.1 and 4.1 to this report and are incorporated herein by reference.

Research and Development Awards. We frequently seek research and development programs that may be awarded by government, non-governmental organizations, and non-profit entities, including private foundations. During the nine months ended September 30, 2019, we recognized grant revenue totaling $1.3 million from government, non-governmental organizations, and non-profit entities.

Working Capital. The following table sets forth selected working capital information:

	September 30, 2019
	(in thousands)
Cash and cash equivalents	$ 21,868
Accounts receivable, net of allowance for doubtful amounts	5,378
Inventories, net	8,409
Prepaid expenses and other current assets	598
Total current assets	36,253
Less: Total current liabilities	(6,187)
Working capital	$ 30,066

Current liabilities include $0.3 million current portion of operating and finance lease liabilities in accordance with Accounting Standards Codification Topic 842, *Leases,* which was adopted effective January 1, 2019.

Our cash and cash equivalents at September 30, 2019 were unrestricted and held for working capital purposes. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends. We have not entered into, and do not expect to enter into, investments for trading or speculative purposes. Our accounts receivable balance fluctuates from period to period, which affects our cash flow from operating activities. Fluctuations vary depending on cash collections, client mix, and the timing of shipment of our products and the invoicing of our research and development activities.

Uses of Funds

Cash Flow Used in Operating Activities. Our operations used $6.4 million of cash during the nine months ended September 30, 2019, reflecting a net loss adjusted for non-cash items of $7.3 million, a $2.0 million decrease in accounts receivable, a $0.6 increase in inventory, a $0.5 million decrease in prepaid expenses, other current assets and deposits related to prepaid rent and security deposits for our new Hauppauge corporate headquarters facility, and a $0.4 million decrease in accounts payable and accrued liabilities.

Capital Expenditures. During the nine months September 30, 2019, we continued to invest in manufacturing equipment, leasehold improvements and other fixed assets. Our capital expenditures totaled $2.6 million in the nine months ended September 30, 2019.

Off-Balance Sheet Arrangements

As of September 30, 2019, we did 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.

Critical Accounting Estimates

There were no significant changes in our critical accounting estimates during the three months ended September 30, 2019 to augment the critical accounting estimates disclosed under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report, other than those described in the notes to the condensed consolidated financial statements included elsewhere in this report.

Recently Issued Accounting Pronouncements

A discussion of recent accounting pronouncements is included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and is updated in Note 3 to the condensed consolidated financial statements included elsewhere in this report.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Item 10(f)(1) of Regulation S-K under the Securities Act of 1933 and as such are not required to provide information under this Item.

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, 2019 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, 2019, 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

There have been no material changes to the risk factors discussed in Part I, Item 1A, "Risk Factors," in our Annual Report on Form 10-K for the year ended December 31, 2018. In addition to the other information set forth in this report, you should carefully consider those risk factors, which could materially affect our business, financial condition and future operating results. Those risk factors are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may have a material adverse effect on our business, financial condition and operating results.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

In September 2019 we issued to the Lender, in connection with the Credit Agreement, the Warrant, which is a seven-year warrant to purchase up to 550,000 shares of our common stock at a per-share exercise price of $5.22 as described in "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Sources of Funds—Credit Agreement" of Part I. This transaction did not involve any underwriter, any underwriting discount or commission, or any public offering. We believe the offer, sale and issuance of the Warrant were exempt from registration under the Securities Act of 1933 by virtue of Section 4(a)(2) thereof (or Regulation D promulgated thereunder) because the issuance of the Warrant to the Lender did not involve a public offering. The Lender represented its intention to acquire the Warrant and the underlying shares of common stock for investment only and not with a view to or for sale in connection with any distribution thereof, and an appropriate legend was placed on the Warrant. The Lender had adequate access, through the negotiation of the Credit Agreement and the Warrant, to information about us. The sale of the Warrant was made without any general solicitation or advertising.

ITEM 6. EXHIBITS

Number	Description
4.1	Warrant to Purchase Common Stock dated as of September 3, 2019, issued by Chembio Diagnostics, Inc. to Perceptive Credit Holdings II, LP
10.1*	Credit Agreement and Guaranty dated as of September 3, 2019, among Chembio Diagnostics, Inc., as the Borrower, the Guarantors from time to time party thereto, and Perceptive Credit Holdings II, LP and its successors and assigns party thereto, as Administrative Agent and Lender
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

* Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. We hereby undertake to furnish copies of the omitted exhibits and schedules upon request by the Securities Exchange Commission, provided that we may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934 for the exhibits and schedules so furnished.

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 7, 2019

By: /s/ John J. Sperzel III
John J. Sperzel III
Chief Executive Officer and President

Date: November 7, 2019

By: /s / Neil A. Goldman
Neil A. Goldman
Chief Financial Officer and
Executive Vice President

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John J. Sperzel, certify that:

1. I have reviewed this quarterly report Form 10-Q of Chembio Diagnostics, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(e) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls.

Date: November 7, 2019

/s/ John J. Sperzel III
John J. Sperzel III
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Neil A. Goldman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Chembio Diagnostics, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls.

Date: November 7, 2019

/s/ Neil A. Goldman
Neil A. Goldman
Chief Financial Officer and Executive Vice President
(Principal Financial Officer)

Exhibit 32

CERTIFICATION PURSUANT TO 18 U.S.C. 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Chembio Diagnostics, Inc. for the quarterly period ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge on the date hereof:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Chembio Diagnostics, Inc. for the period presented therein.

Date: November 7, 2019

/s/ John J. Sperzel III
John J. Sperzel III
Chief Executive Officer and President
(Principal Executive Officer)

Date: November 7, 2019

/s/ Neil A. Goldman
Neil A. Goldman
Chief Financial Officer and Executive Vice President
(Principal Financial Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Sec. 1350 and is not being filed as part of the Report or as a separate disclosure document.