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 March 31, 2020

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)*

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

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 ☒

As of April 29, 2020, the registrant had 17,548,910 shares outstanding of its common stock, $.01 par value.

Quarterly Report on Form 10-Q
For The Quarterly Period Ended
March 31, 2020

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Chembio Diagnostics, Inc.

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

DPP, STAT-PAK, STAT-VIEW and SURE CHECK are our registered trademarks, and CHEMBIO, MICRO READER and our logo design are our trademarks. For convenience, these trademarks appear in this report 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.

FORWARD-LOOKING STATEMENTS AND STATISTICAL ESTIMATES

This report contains statements reflecting our views about our future performance that constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are generally identified through the inclusion of words such as “anticipate,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “objective,” “outlook,” “plan,” “potential,” “project,” “seek,” “should,” “strategy,” “target,” “will,” “would” or variations of such words or similar expressions. All statements addressing our future operating performance, and statements addressing events and developments that we expect or anticipate will occur in the future, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are based upon currently available information, operating plans, and projections about future events and trends.

This report contains estimates, projections and other data concerning our industry, our business and the markets for our products. Where expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by the World Health Organization, or WHO. We also include data that we have compiled, obtained, identified or otherwise derived from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. Other than WHO, we do not expressly refer to the sources from which this data is derived.

Forward-looking statements and statistical estimates inherently involve risks and uncertainties that could cause actual results to differ materially from those predicted or expressed in this report. These risks and uncertainties include those described in Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the Securities and Exchange Commission on March 13, 2020 and in Part II, Item 1A, “Risk Factors,” of this report. You should interpret many of the risks identified in these reports as being heightened as a result of the ongoing and numerous adverse impacts of the COVID-19 pandemic. Investors are cautioned not to place undue reliance on any forward-looking statements or statistical estimates, which speak only as of the date they are made. We undertake no obligation to update any forward-looking statement or statistical estimate, whether as a result of new information, future events or otherwise.

PART I

Item 1. FINANCIAL STATEMENTS

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	(Unaudited) March 31, 2020	December 31, 2019
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 11,238,017**	$ 18,271,352
Accounts receivable, net of allowance for doubtful accounts of $62,000 at both March 31, 2020 and December 31, 2019	**4,877,842**	3,661,325
Inventories, net	**10,930,159**	9,598,030
Prepaid expenses and other current assets	**798,228**	693,013
TOTAL CURRENT ASSETS	**27,844,246**	32,223,720
FIXED ASSETS:		
Property, plant and equipment, net	**6,659,279**	5,933,569
Finance lease right-of-use asset, net	**226,305**	210,350
OTHER ASSETS:		
Operating lease right-of-use assets, net	**6,785,668**	7,030,744
Intangible assets, net	**3,655,858**	3,914,352
Goodwill	**5,493,045**	5,872,690
Deposits and other assets	**528,261**	543,539
TOTAL ASSETS	**$ 51,192,662**	$ 55,728,964
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 6,536,134**	$ 5,526,243
Deferred revenue	**543,345**	125,000
Finance lease liabilities	**47,192**	41,894
Operating lease liabilities	**766,896**	568,294
Note payable	**112,928**	180,249
TOTAL CURRENT LIABILITIES	**8,006,495**	6,441,680
OTHER LIABILITIES:		
Long-term operating lease liabilities	**6,770,005**	6,969,603
Long-term finance lease liabilities	**184,095**	171,953
Long-term debt, less current portion, and debt discount and issuance costs	**17,771,268**	17,644,149
Deferred tax liability	**327,542**	466,326
TOTAL LIABILITIES	**33,059,405**	31,693,711
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock - 10,000,000 shares authorized; none outstanding	**-**	-
Common stock - $0.01 par value; 100,000,000 shares authorized; 17,327,235 shares and 17,733,617 shares issued at March 31, 2020 and December 31, 2019, respectively	**173,272**	177,335
Additional paid-in capital	**95,543,043**	95,433,077
Accumulated deficit	**(76,584,552)**	(71,585,003)
Treasury Stock, 31,486 shares at cost	**(145,056)**	-
Accumulated other comprehensive (loss) income	**(853,450)**	9,844
TOTAL STOCKHOLDERS' EQUITY	**18,133,257**	24,035,253
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 51,192,662**	$ 55,728,964

See accompanying notes to condensed consolidated financial statements

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

	For the three months ended March 31,	
	2020	2019
REVENUES:		
Net product revenue	**$ 5,716,593**	$ 6,624,285
R&D and grant revenue	**907,687**	1,701,789
License and royalty revenue	**235,304**	216,191
TOTAL REVENUES	**6,859,584**	8,542,265
COSTS AND EXPENSES:		
Cost of product revenue	**4,374,442**	5,011,636
Research and development expenses	**1,958,853**	2,217,632
Selling, general and administrative expenses	**4,156,641**	4,013,071
Severance and related costs	**723,118**	-
Acquisition costs	**63,497**	395,612
	11,276,551	11,637,951
LOSS FROM OPERATIONS	**(4,416,967)**	(3,095,686)
OTHER EXPENSE:		
Interest (expense) income, net	**(662,141)**	6,684
LOSS BEFORE INCOME TAXES	**(5,079,108)**	(3,089,002)
Income tax (benefit)	**(79,559)**	(272,469)
NET LOSS	**$ (4,999,549)**	$ (2,816,533)
Basic loss per share	**$ (0.29)**	$ (0.16)
Diluted loss per share	**$ (0.29)**	$ (0.16)
Weighted-average number of shares outstanding, basic	**17,197,301**	17,166,459
Weighted-average number of shares outstanding, diluted	**17,197,301**	17,166,459

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 March 31,	
	2020	2019
Net loss	**$ (4,999,549)**	$ (2,816,533)
Other comprehensive loss:		
Foreign currency translation adjustments, net of tax	**(863,294)**	202,186
Comprehensive loss	**$ (5,862,843)**	$ (2,614,347)

See accompanying notes to condensed consolidated financial statements

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

	For the three months ended March 31, 2020							
	Common Stock		Additional Paid-in-	Treasury Stock		Accumulated		
	Shares	Amount	Capital	Shares	Amount	Deficit	AOCI	Total
Balance at December 31, 2019	17,733,617	$ 177,335	$95,433,077	-	$ -	$ (71,585,003)	$ 9,844	$24,035,253
Common Stock:								
Restricted stock issued	34,249	343	117,956	-	-	-	-	118,299
Restricted stock compensation, net	(440,631)	(4,406)	(292,495)	-	-	-	-	(296,901)
Shares tendered for withholding taxes	-	-	145,056	(31,486)	(145,056)	-	-	-
Options:								
Stock option compensation	-	-	139,449	-	-	-	-	139,449
Comprehensive loss	-	-	-	-	-	-	(863,294)	(863,294)
Net loss	-	-	-	-	-	(4,999,549)	-	(4,999,549)
Balance at March 31, 2020	17,327,235	$ 173,272	$95,543,043	(31,486)	$ (145,056)	$ (76,584,552)	$ (853,450)	$18,133,257

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

	For the three months ended March 31, 2019					
	Common Stock		Additional	Accumulated		
	Shares	Amount	Paid-in-Capital	Deficit	AOCI	Total
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
Comprehensive loss	-	-	-	-	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**

See accompanying notes to condensed consolidated financial statements

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

	March 31, 2020	March 31, 2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	**$ 6,061,411**	$ 7,869,167
Cash paid to suppliers and employees	**(10,951,402)**	(12,349,126)
Cash paid for operating leases	**(165,218)**	(281,603)
Cash paid for finance leases	**(4,211)**	-
Interest and taxes, net	**(592,540)**	6,684
Net cash used in operating activities	**(5,651,960)**	(4,754,878)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Patent application costs	**(45,057)**	(45,176)
Acquisition of and deposits on fixed assets	**(1,033,214)**	(532,296)
Net cash used in investing activities	**(1,078,271)**	(577,472)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments of tax withholding on stock award	**(145,056)**	-
Payments on note payable	**(67,321)**	(29,930)
Payments on finance lease	**(10,913)**	-
Net cash provided by financing activities	**(223,290)**	(29,930)
Effect of exchange rate changes on cash	**(79,814)**	208,407
DECREASE IN CASH AND CASH EQUIVALENTS	**(7,033,335)**	(5,153,873)
Cash and cash equivalents - beginning of the period	**18,271,352**	12,524,551
Cash and cash equivalents - end of the period	**$ 11,238,017**	$ 7,370,678
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net loss	**$ (4,999,549)**	$ (2,816,533)
Adjustments:		
Depreciation and amortization	**733,804**	355,468
Share based compensation	**(37,083)**	347,507
Change in deferred tax liability	**(138,784)**	(272,469)
Changes in assets and liabilities:		
Accounts receivable	**(1,216,518)**	(208,894)
Inventories	**(1,332,129)**	(1,992,906)
Prepaid expenses and other current assets	**(105,215)**	(366,990)
Deposits and other assets	**15,278**	(62,402)
Accounts payable and accrued liabilities	**1,009,891**	485,246
Deferred revenue	**418,345**	(222,905)
Net cash used in operating activities	**$ (5,651,960)**	$ (4,754,878)

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2020
(Unaudited)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. ("Chembio") and its subsidiaries (collectively with Chembio, the "Company") develop and commercialize rapid tests used for the detection and diagnosis of infectious diseases.

The Company has been expanding its product portfolio based upon its proprietary DPP technology, a novel, rapid diagnostic platform that uses a drop of blood from the fingertip to provide high-quality, cost-effective diagnostic results in approximately 15 minutes.

The Company's product development and commercialization efforts are focused on infectious disease testing and technology collaborations. During the three months ended March 31, 2020, the Company refocused its business strategy on the development and commercialization of the DPP COVID-19 System, which consists of a new serological test for COVID-19 and a Micro Reader analyzer. In the three months ended March 31, 2020, the Company developed, and began to manufacture in preparation for commercialization, the DPP COVID-19 System. In addition to the DPP COVID-19 System, the Company has a broad portfolio of infectious disease products, which it expects to generate an immaterial amount of revenue for the foreseeable future while it focuses on the manufacture and commercialization of the DPP COVID-19 System. Through R&D Services, the Company is developing tests for bovine tuberculosis, a rare disease in collaboration with Takeda Pharmaceutical Company Limited and a biomarker development project in collaboration with AstraZeneca plc.

Large and growing markets have been established for these types of tests, initially in high prevalence regions where they are indispensable for large-scale prevention and treatment programs. 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 globally to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments under the Company's DPP, STAT PAK, SURE CHECK and STAT-VIEW registered trademarks or under the private labels of the Company's 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 — SIGNIFICANT ACCOUNTING POLICIES:

(a) Basis of Presentation:

The accompanying unaudited condensed consolidated financial statements include the accounts of Chembio and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X issued by the Securities and Exchange Commission (the "SEC"). Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the SEC.

All adjustments contained in the accompanying unaudited condensed consolidated financial statements are of a normal recurring nature and are necessary to present fairly the financial position of the Company as of March 31, 2020. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

(b) Use of Estimates:

The preparation of the consolidated financial statements in conformity with GAAP requires management to make assumptions and estimates that affect the amounts reported in the accompanying unaudited condensed consolidated financial statements and these notes. Judgments and estimates of uncertainties are required in applying the Company's accounting policies in certain areas. Generally, matters subject to estimation and judgment include accounts receivable realization, inventory obsolescence, asset impairments, recognition of revenue pursuant to milestones, useful lives of intangible and fixed assets, stock-based compensation, business combinations, and deferred tax asset valuation allowances. Due to the inherent uncertainty involved in making estimates, actual results reported in future periods may be based upon amounts that differ from those estimates.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2020
(Unaudited)

(c) Fair Value of Financial Instruments:

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 $10.0 million and $16.0 million as of March 31, 2020 and December 31, 2019, 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 $20.0 million (carrying value of $17.8 million) and $20.0 million (carrying value of $17.6 million) as of March 31, 2020 and December 31, 2019, 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.

Fair value measurements of all financial assets and liabilities that are 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).

(d) Cash and Cash Equivalents:

Cash and cash equivalents are defined as short-term, highly liquid investments with original maturities of three months or less.

(e) Concentrations of Credit Risk:

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments and trade receivables. The Company places its temporary cash instruments with well-known financial institutions and, at times, may maintain balances in excess of the Federal Deposit Insurance Corporation insurance limit. The Company monitors the credit ratings of the financial institutions to mitigate this risk. Concentration of credit risk with respect to trade receivables is principally mitigated by the Company's ability to obtain letters of credit from certain foreign customers and its diverse customer base, both in number of customers and geographic locations.

(f) Fixed Assets:

Fixed assets are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, which range from three to seven years. Leasehold improvements are amortized over the useful life of the asset or the lease term, whichever is shorter. Deposits paid for fixed assets are capitalized and not depreciated until the related asset is placed in service.

(g) License Agreements:

The Company records up-front payments related to license agreements as prepaids and amortizes them over their respective economic life. As of both March 31, 2020 and 2019, total prepaids were $100,000.

(h) Valuation of Long-Lived Assets and Intangible Assets:

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 long-lived tangible and intangible assets was recorded for the three months ended March 31, 2020 or 2019.

(i) Revenue Recognition:

The Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. The Company recognizes revenue following the five-step model prescribed under Accounting Standards Update ("ASU") 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 revenue when (or as) the Company satisfies the performance obligation.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2020
(Unaudited)

Product Revenue

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 the product 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 excludes certain taxes from the transaction price (e.g., sales, value added and some excise taxes).

The Company's contracts with customers often include promises to transfer products or services to a customer. Determining whether products and services are considered distinct performance obligations that should be accounted for separately versus together may require judgment. Typical products sold are diagnostic tests and typical services performed are R&D studies. Revenues from product sales are recognized at a point-in-time and revenues from R&D studies are recognized ratably over the period of the agreement, unless the related performance obligations indicate otherwise.

Judgment is required to determine the stand-alone selling price ("SSP") for each distinct performance obligation. SSP is directly observable and the Company can use a range of amounts to estimate SSP, as it sells products and services separately, and can determine whether there is a discount to be allocated based on the relative SSP of the various products and services, for the various geographies.

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.

License and Royalty Revenue

The Company receives royalty revenue on sales by its licensee of products covered under patents that the Company owns. The Company does not have future performance obligations under this license arrangement. The Company records revenue based on estimates of the sales that occurred during the relevant period as a component of license and royalty revenue. The relevant period estimates of sales are based on interim data provided by the licensee 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 revenue 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 licensee.

R&D and Grant Revenue

All contracts with customers 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 Accounting Standards Codification ("ASC") Topic 958. Such contracts are further described under *Disaggregation of Revenue* below. Grants are invoiced and revenue is recognized ratably as that is the depiction of the timing of the transfer of services. The R&D study encompasses various phases of product development processes: design feasibility & planning, product development and design optimization, design verification, design validation and process validation, and pivotal studies.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2020
(Unaudited)

In June 2018, the Financial Accounting Standards Board (the "FASB") issued ASU 2018-08, Not-for-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made. This ASU clarifies the guidance presented in ASC Topic 958, "Not-for-Profit Entities," for evaluating whether a transaction is reciprocal (i.e., an exchange transaction) or nonreciprocal (i.e., a contribution) and for distinguishing between conditional and unconditional contributions. The ASU also clarified the guidance used by entities other than not-for-profits to identify and account for contributions made.

Disaggregation of Revenue

The following table disaggregates Total Revenues:

	For the Three Months Ended					
	March 31, 2020			March 31, 2019		
	Exchange Transactions	**Non-Exchange Transactions**	**Total**	Exchange Transactions	Non-Exchange Transactions	Total
Net product revenue	$ 5,716,593	$ -	$ 5,716,593	$ 6,624,285	$ -	$ 6,624,285
R&D and grant revenue	907,687	-	907,687	773,066	928,723	1,701,789
License and royalty revenue	235,304	-	235,304	216,191	-	216,191
	$ 6,859,584	$ -	$ 6,859,584	$ 7,613,542	$ 928,723	$ 8,542,265

Exchange transactions are recognized in accordance with ASC Topic 606, while non-exchange transactions are recognized in accordance with ASU 2018-08.

The following table disaggregates revenues by geographic location of the customer:

	For the Three Months Ended	
	March 31, 2020	March 31, 2019
Africa	$ 883,515	$ 2,416,300
Asia	363,288	121,898
Europe & Middle East	1,639,782	2,143,221
Latin America	2,116,395	1,280,473
United States	1,856,604	2,580,373
	$ 6,859,584	$ 8,542,265

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, 2019, the Company reported $125,000 in deferred revenue, all of which was earned and recognized as R&D and grant revenue during the three months ended March 31, 2020. At March 31, 2020, the Company reported $543,345 in deferred revenue that is expected to be recognized during the quarter ending June 30, 2020.

(j) Inventories:

Inventories consisted of the following:

	March 31, 2020	December 31, 2019
Raw materials	**$ 3,439,546**	$ 2,901,319
Work in process	**959,371**	793,343
Finished goods	**6,531,242**	5,903,368
	$ 10,930,159	$ 9,598,030

(k) Loss Per Share:

Basic loss per share is computed by dividing net loss attributable to holders of Chembio's common stock ("common stock") by the weighted-average number of shares of common stock outstanding for the period excluding unvested restricted stock. Diluted loss per share for the three months ended March 31, 2020 and 2019 reflected the potential dilution from the exercise or conversion of other securities into common stock, if dilutive.

There were 1,345,124 and 705,301 weighted-average number of options outstanding as of March 31, 2020 and 2019, respectively, that were not included in the calculation of diluted per common share equivalents for the three months ended March 31, 2020 and 2019, respectively, because the effect would have been anti-dilutive.

There were 550,000 and 0 warrants issued and outstanding as of March 31, 2020 and 2019, respectively, that were not included in the in the calculation of diluted per common share equivalents for the three months ended March 31, 2020 and 2019, respectively, because the effect would have been anti-dilutive.

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(l) Research and Development:

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) Equity Plans:

Effective June 3, 2008, Chembio's stockholders voted to approve the 2008 Stock Incentive Plan (the "SIP"), with 625,000 shares of common stock available to be issued. At the Annual Stockholder Meeting on September 22, 2011 Chembio's stockholders voted to approve an increase to the shares of common stock issuable under the SIP by 125,000 to 750,000. Under the terms of the SIP, which expired during 2018, the Board of Directors of Chembio (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 (collectively, "Equity Award Units"). The awards became vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through March 31, 2020, there were 86,875 options expired, forfeited or exercised, and at March 31, 2020, 99,132 options were outstanding and no Equity Award Units were available to be issued under the SIP.

Effective June 19, 2014, Chembio's stockholders voted to approve the 2014 Stock Incentive Plan (the "SIP14"), with 800,000 shares of common stock available to be issued. Under the terms of the SIP14, 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. Cumulatively through March 31, 2020, there were 25,000 Equity Award Units expired, forfeited or exercised. At March 31, 2020, 441,980 Equity Award Units were outstanding, and 216,442 Equity Award Units remained available to be issued under the SIP14.

Effective June 18, 2019, Chembio'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. In addition, shares of common stock underlying any outstanding award granted under the 2019 Plan that, following the effective date of the 2019 Plan, expire, or are terminated, surrendered or forfeited for any reason without issuance of such shares, shall be available for the grant of new awards under the 2019 Plan. 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 options, stock appreciation rights, restricted stock, restricted stock unit, or other stock-based award under the 2019 Plan (collectively, "2019 Equity Units"). The 2019 Equity Units become vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through March 31, 2020, 375,000 2019 Equity Units had been forfeited. At March 31, 2020, 1,269,632 2019 Equity Units were outstanding, and 1,099,504 2019 Equity Units were available to be awarded.

(n) Stock-Based Compensation:

The fair value of restricted stock and performance/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. The fair value of restricted stock and performance and restricted stock unit awards are reduced for actual forfeitures in the period in which the forfeiture occurs and generally expensed on a straight-line basis over the service period of the grant. In the three months ended March 31, 2020, there were forfeitures of 440,631 shares of restricted stock.

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

	For the three months ended March 31,	
	2020	2019
Cost of product sales	**$ 6,300**	$ 3,491
Research and development expenses	**63,813**	59,846
Selling, general and administrative expenses	**316,788**	284,170
Severance and related costs	**(423,984)**	-
	$ (37,083)	$ 347,507

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

	For the three months ended March 31, 2020
Expected term (in years)	**6.3**
Expected volatility	**45.37%**
Expected dividend yield	**0%**
Risk-free interest rate	**1.33%**

The following table provides stock option activity for the three months ended March 31, 2020:

Stock Options	Number of Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contract Term	Aggregate Intrinsic Value
Outstanding at December 31, 2019	**642,625**	**$ 5.79**	**2.57 years**	**$ 285,925**
Granted	702,499	2.50		-
Exercised	-	-		-
Forfeited/expired/cancelled	-	-		-
Outstanding at March 31, 2020	**1,345,124**	**$ 4.07**	**4.73 years**	**$ 2,282,345**
Exercisable at March 31, 2020	**525,958**	**$ 5.25**	**2.16 years**	**$ 425,925**

The information in the above table and elsewhere in these notes does not reflect certain options that were received by Chembio's former chief executive officer and that had vested as of the time of his resignation on January 3, 2020. The Board's Compensation Committee has determined that the former chief executive officer failed to exercise such options in a timely manner prior to their expiration. The former chief executive officer has asserted that he continues to have the right to exercise those options to acquire 266,666 shares of common stock for an aggregate exercise price of $943,126.

The following table summarizes information about stock options outstanding at March 31, 2020:

	Stock Options Outstanding				Stock Options Exercisable		
Range of Exercise Prices	Number of Shares	Average Remaining Contract Term (Years)	Weighted-Average Exercise Price	Aggregate Intrinsic Value	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
$1 to$ 2.79999	672,616	6.96	$ 2.36	$ 1,856,420	-	$ -	$ -
$2.8 to $4.59999	250,000	0.95	3.42	425,925	250,000	3.42	425,925
$4.6 to $6.39999	167,758	2.98	5.82	-	119,125	5.84	-
$6.4 to $8.19999	207,875	3.81	7.31	-	138,083	7.22	-
$8.2 to $12	46,875	3.35	11.45	-	18,750	11.45	-
Total	1,345,124	4.73	$ 4.07	$ 2,282,345	525,958	$ 5.25	$ 425,925

As of March 31, 2020, there was $1,054,914 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 2.80 years. The total fair value of shares vested during the three months ended March 31, 2020 and 2019 was $182,932 and $204,567, respectively.

The following table summarizes information about restricted stock, restricted stock units and performance stock units outstanding as of March 31, 2020:

	Number of Shares & Units	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2019	545,986	$ 7.47
Granted	597,997	2.44
Vested	(30,864)	3.90
Forfeited/expired/cancelled	(440,631)	6.37
Outstanding at March 31, 2020	**672,488**	**$ 3.50**

As of March 31, 2020, there was $2,100,929 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 2.09 years.

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(o) 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 operating segment. Net product revenue by geographic area were as follows:

	For the three months ended March 31,	
	2020	2019
Africa	**$ 883,515**	$ 2,416,300
Asia	**363,288**	121,098
Europe & Middle East	**1,175,089**	1,178,025
Latin America	**2,116,396**	1,280,473
United States	**1,178,305**	1,628,389
	$ 5,716,593	$ 6,624,285

Property, plant and equipment by geographic area were as follows:

	March 31, 2020	December 31, 2019
Asia	**$ 377,020**	$ 393,299
Europe & Middle East	**173,614**	165,029
Latin America	**2,938**	60,527
United States	**6,105,707**	5,314,714
	$ 6,659,279	$ 5,933,569

(p) Accounts Payable and Accrued Liabilities:

Accounts payable and accrued liabilities consisted of:

	March 31, 2020	December 31, 2019
Accounts payable – suppliers	**$ 3,833,750**	$ 3,144,098
Accrued commissions and royalties	**655,549**	931,760
Accrued payroll	**233,610**	231,753
Accrued vacation	**392,034**	410,199
Accrued bonuses	**152,489**	215,000
Accrued severance	**395,096**	-
Accrued expenses – other	**873,606**	593,433
TOTAL	**$ 6,536,134**	$ 5,526,243

In the three months ended March 31, 2020, the Company recognized $1 million in severance expense related to the departure of Chembio's former chief executive officer.

(q) Goodwill, Long-Lived Assets and Intangible Assets:

The following table reflects changes in goodwill:

Beginning balance at December 31, 2019	$ 5,872,690
Change in foreign currency exchange rate	(379,645)
Balance at March 31, 2020	$ 5,493,045

Intangible assets consisted of the following:

		March 31, 2020			December 31, 2019		
	Weighted-Average Remaining Useful Life	**Cost**	**Accumulated Amortization**	**Net Book Value**	Cost	Accumulated Amortization	Net Book Value
Intellectual property	6	$ 1,417,400	$ 333,814	$ 1,083,586	$ 1,418,681	$ 299,232	$ 1,119,449
Developed technology	6	1,886,880	326,794	1,560,086	1,922,682	266,550	1,656,132
Customer contracts/relationships	7	1,232,099	294,481	937,618	1,325,521	270,902	1,054,619
Trade names	8	107,972	33,404	74,568	114,946	30,794	84,152
		$ 4,644,351	$ 988,493	$ 3,655,858	$ 4,781,830	$ 867,478	$ 3,914,352

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Intellectual property, developed technology, customer contracts/relationships and trade names are amortized over 10, 7, 10 and 11 years, respectively. Amortization expense for the three months ended March 31, 2020 and 2019 was approximately $144,661 and $139,000, respectively. Amortization expense, subject to changes in currency exchange rates, is expected to be $560,877 per year from 2020 through 2024, and total $992,976 for all of the years thereafter.

(r) 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 rate for the three months ended March 31, 2020 was 1.6%, compared to the effective tax rate of 8.8% for the three months ended March 31, 2019. The Company's effective tax rates for both periods were affected primarily by a full valuation allowance on domestic net deferred tax assets and a benefit from foreign net operating losses.

(s) 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.

(t) 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 have been immaterial.

(u) Acquisition Costs:

Acquisition costs include period expenses, primarily professional services, related to acquisition activities. For the three months ended March 31, 2020 and 2019, the Company recognized $63,497 and $395,612 in acquisition costs related to its acquisition of Orangelife and opTricon GmbH, respectively.

(v) Recently Issued Accounting Standards:

Recently Adopted

ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13")

In June 2016, the FASB issued ASU 2016-13. ASU 2016-13 provides guidance on measurement of credit losses on financial instruments that changes the impairment model for most financial assets and certain other instruments, including trade and other receivables, held-to-maturity debt securities and loans, and that requires entities to use a new, forward-looking "expected loss" model that is expected to generally result in the earlier recognition of allowances for losses. The guidance became effective for annual periods beginning after December 15, 2019, including interim periods within those years. The Company has evaluated the effects of this standard and determined that the adoption did not have a material impact on the Company's consolidated financial statements.

ASU 2018-13, Fair Value Measurement - Disclosure Framework (Topic 820) ("ASU 2018-13")
In August 2018, the FASB issued ASU 2018-13. ASU 2018-13 improves the disclosure requirements on fair value measurements. The updated guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted for any removed or modified disclosures. The Company has evaluated the effects of this standard and determined that the adoption did not have a material impact on the Company's consolidated financial statements.

Not Yet Adopted

ASU 2020-04, Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting

In March 2020, the FASB issued ASC Topic 848. ASC Topic 848 provides relief for impacted areas as it relates to impending reference rate reform. ASC Topic 848 contains optional expedients and exceptions for applying GAAP to debt arrangements, contracts, hedging relationships, and other areas or transactions that are impacted by reference rate reform. This guidance is effective for upon issuance for all entities and elections of certain optional expedients are required to apply the provisions of the guidance. The Company continues to assess all potential impacts of the standard and will disclose the nature and reason for any elections that the Company makes.

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ASU 2017-4, Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment ("ASU 2017-4")

In January 2017, the FASB issued ASU 2017-4. ASU 2017-4 simplifies the subsequent measurement of goodwill and eliminates Step 2 from the goodwill impairment test. ASU 2017-4 is effective for annual and interim goodwill tests beginning after December 15, 2019. The Company's measurement period is October 1 and is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements.

ASU 2019-12, Simplifications to Accounting for Income Taxes ("ASU 2019-12")

In December 2019, the FASB issued ASU 2019-12. ASU 2019-12 removes certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including deferred taxes for goodwill and allocating taxes for members of a consolidated group. ASU 2019-12 is effective for all entities for fiscal years beginning after December 15, 2020, and earlier adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2019-12 on its consolidated financial statements.

NOTE 3 – ACQUISITION:

Orangelife

On November 25, 2019, pursuant to a quota purchase agreement, the Company acquired all of the outstanding equity securities of Orangelife Comercio e Industria Ltda. ("Orangelife"), a privately held Brazilian company, which is an original equipment manufacturer of point-of-care tests approved by the Brazilian Health Surveillance Agency (Agência Nacional de Vigilância Sanitária, or "ANVISA") for infectious diseases that include human immunodeficiency virus ("HIV"), Hepatitis C, Zika, Chikungunya and Dengue Fever. Orangelife tests are manufactured in its Rio de Janeiro facility, which is ISO-certified and approved by ANVISA to produce Class II/III/IV medical devices. The purchase price includes the following consideration:

- $150,000 in cash and 153,707 shares of common stock.
- Issuance of 316,456 shares of common stock to the founder and former chief executive officer of Orangelife, based on the transfer and approval of registration of certain of our product in Brazil prior to November 25, 2022. All of the shares may be deliverable in the event of change in control of Chembio. The number of shares issued was subject to adjustments based upon Orangelife's working capital at closing. The fair value of the shares on the date of the acquisition was recorded in equity and was valued at $1.2 million.

The purchase consideration is subject to routine post-closing adjustments. The acquisition of Orangelife allowed the Company to expand its commercial presence by offering its products to the state, private and pharmacy markets in Brazil, in addition to providing local support to its long-time customer Bio-Manguinhos, a subsidiary of the Oswaldo Cruz Foundation (Fiocruz), which oversees development and production of vaccines, diagnostics, and biopharmaceuticals to meet the demands of Brazil's national public health system. The results of Orangelife's operations have been reflected in the consolidated financial statements since November 25, 2019.

The acquisition was accounted for using the purchase method of accounting. The following table summarizes the allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed on the closing date of November 25, 2019:

	Amount
Net current assets	$ 320,293
Property, plant and equipment and other assets	226,035
Inventory	289,205
Goodwill	986,058
Deferred tax liability	(50,000)
Other intangible assets (estimated useful life):	
Trade name (0.5 years)	5,000
Customer contracts / relationships (5 years)	195,000
Total consideration	$ 1,971,591

The Company calculated the fair value of the fixed assets based on the net book value of Orangelife as that approximates fair value. The trade name, customer contracts/relationships and contingent earnouts were based on discounted cash flows using management estimates.

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As a result of the consideration paid exceeding the fair value of the net assets acquired, goodwill in the amount of $986,058 was recorded in connection with this acquisition, none of which will be deductible for tax purposes. In addition, the Company recorded $200,000 in intangible assets associated with the addition of Orangelife's trade name and customer base.

The following represents pro forma operating results for the year ended December 31, 2019 as if the operations of Orangelife had been included in the Company's consolidated statements of operations effective as of January 1, 2019. This pro forma financial information is unaudited and presented for illustrative purposes only and is not necessarily indicative of the operating results that would have occurred if the acquisition of Orangelife and the other transactions contemplated by this acquisition had been completed as of January 1, 2019, nor is it necessarily indicative of the future operating results of the Company and Orangelife on a combined and consolidated basis.

	Unaudited Pro Forma December 31, 2019
Total revenues	$ 35,157,248
Net loss	$ (13,654,001)
Net loss per common share	$ (0.80)
Diluted net loss per common share	$ (0.80)

NOTE 4 – STOCKHOLDERS' EQUITY:

(a) Common Stock

During the first three months of 2020 and 2019, there were no options exercised.

(b) Preferred Stock

The Company has 10,000,000 shares of preferred stock authorized, none of which are outstanding. These shares can become issuable upon an approved resolution by the Board and the filing of a Certificate of Designation with the State of Nevada.

(c) Treasury Stock

The Company has 31,486 shares of treasury stock for restricted stock awards, remitted to satisfy tax withholding requirements.

(d) Options, Restricted Stock and Restricted Stock Units

The Board or its Compensation Committee may grant options, restricted stock, and restricted stock units pursuant to equity incentive plans that have been approved by Chembio's stockholders.

(e) Warrants

As of March 31, 2020, the Company has 550,000 warrants outstanding to purchase shares of common stock as further discussed in Note 7 – Warrants.

NOTE 5 – COMMITMENTS, CONTINGENCIES, AND CONCENTRATIONS:

(a) Concentrations:

The following table discloses product sales the Company had to the only customer that purchased in excess of 10% of the Company's net product sales for the periods indicated:

	For the three months ended				Accounts Receivable as of	
	March 31, 2020		March 31, 2019		March 31, 2020	December 31, 2019
	Sales	% of Sales	Sales	% of Sales		
Customer 1	$ 1,640,073	28.7%	$ 3,966,142	47%	$ 1,875,176	$ 3,499,340

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

For the three months ended March 31, 2020 and 2019, there were no vendors that sold to the Company in excess of 10% of the Company's total purchases.

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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. A change in suppliers, however, could cause a delay in manufacturing, either from the logistic and regulatory implications of changing suppliers or from product attributable changes to new components, any of which could result in a possible loss of sales and 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, the 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, the Company 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 monetary penalties, injunctions, and criminal prosecution.

(c) Employment Contracts:

As of March 31, 2020, the Company has multi-year contracts with two key employees that include salaries presently aggregating $765,000 per year. The contracts expire in December 2020 and December 2022. The following table is a schedule of future minimum salary commitments related to those contracts as of March 31, 2020:

2020	$ 573,750
2021	765,000
2022	400,000

(d) Pension Plan:

Chembio has a 401(k) plan established for the Company's employees whereby the Company 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 $28,120 and $24,030 for the three months ended March 31, 2020 and 2019, respectively.

(e) Leases:

The Company's leases are limited to its facilities in New York, Germany, Malaysia and Brazil and certain equipment. As of March 31, 2020, the Company had nine 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 asset and lease liability. During the first quarter of 2019, the Company entered into a new lease agreement for its new headquarters in Hauppauge, New York. The right-of-use asset acquired in exchange for right-of-use liabilities was approximately $6.5 million.

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 non-lease 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 were as follows:

	Three months ended March 31	
	2020	**2019**
Operating lease expense	**$ 463,857**	$ 287,428
Finance lease cost		
Amortization of right-of-use assets	**$ 12,398**	$ -
Interest on lease liabilities	**4,211**	-
Total finance lease expense	**$ 16,609**	$ -

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Supplemental cash flow information related to leases was as follows.

	Three months ended March 31,	
	2020	**2019**
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	**$ 165,218**	$ 281,603
Operating cash flows for finance leases	**$ 4,211**	$ -
Financing cash flows for finance leases	**$ 10,913**	$ -
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	**$ -**	$ 7,200,993
Finance leases	**$ 27,641**	$ -

Supplemental balance sheet information related to leases was as follows:

	March 31, 2020	**March 31, 2019**
Finance Leases		
Finance lease right of use asset	$ 262,075	$ -
Accumulated depreciation	(35,770)	-
Finance lease right of use asset, net	$ 226,305	$ -
Weighted-Average Remaining Lease Term		
Operating leases	9 years	10 years
Finance leases	4 years	0 years
Weighted-Average Discount Rate		
Operating leases	8.64%	8.52%
Finance leases	7.50%	N/A%

During the three months ended March 31, 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, New York, for which the Company remains primarily responsible until April 2020.

At the time of the initial 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 entered into a credit agreement for a $20 million term loan as described on Note 6 - Long Term Debt.

Maturities of lease liabilities were as follows.

	March 31, 2020		**March 31, 2019**	
	Operating Leases	**Finance Leases**	**Operating Leases**	**Finance Leases**
2019 and 2020	$ 1,039,942	$ 47,232	$ 1,287,593	$ -
2021	1,209,787	62,976	998,071	-
2022	1,057,757	62,976	1,026,044	-
2023	1,026,272	62,976	1,011,085	-
2024	1,018,875	35,207	1,018,875	-
Thereafter	5,773,890	620	5,773,888	-
Total lease payments	$ 11,126,523	$ 271,987	$ 11,115,556	$ -
Less: imputed interest	3,589,622	40,700	4,134,841	-
Total	$ 7,536,901	$ 231,287	$ 6,980,715	$ -

(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.

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(Unaudited)

NOTE 6 – LONG-TERM DEBT:

In September 2017, Chembio 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 Chembio 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, Chembio began making monthly payments of principal and interest of approximately $20,150, at an annual rate of 12% over a 24-month period. The remaining balance was classified short-term as of December 31, 2019.

On September 3, 2019, Chembio 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, Chembio may use the proceeds (i) for general working capital purposes and other permitted corporate purposes, (ii) to refinance certain of Chembio'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 Chembio'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. On March 31, 2020 the interest rate was 11.25%.

No principal repayments are due under the Credit Agreement prior to September 30, 2022, unless Chembio 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 11 months from September 2022 through July 2023, and all remaining principal is payable at maturity on September 3, 2023. Chembio 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 March 31, 2020, the loan balance, net of unamortized discounts and debt issuance costs, was $17.8 million, and Chembio was in compliance with its loan covenants. Chembio's obligations under the Credit Agreement are secured by a first priority, perfected lien on substantially all of its property and assets, including its equity interests in subsidiaries.

NOTE 7 – WARRANTS:

In connection with entering into the Credit Agreement, on September 3, 2019, Chembio issued to the Lender a seven-year warrant (the "Warrant") to purchase up to 550,000 shares of 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 as stockholder's equity. Its fair value was estimated using a Black-Scholes option-pricing model using the following assumptions:

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

On the date of grant, the fair value of the Warrant was determined to be approximately $1.4 million at $2.49 per share.

The balance recorded in the Company's Stockholders' Equity for the Warrant, net of allocated issuance costs, was $1.2 million.

As of March 31, 2020, the Warrant had not been exercised and remained outstanding.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2020
(Unaudited)

NOTE 8 – SUBSEQUENT EVENTS:

On April 20, 2020, the Company entered into an agreement with the U.S Small Business Administration for a loan of $3 million under the Paycheck Protection Program. The loan bears a 1% interest rate and has a two-year term beginning on the date of disbursement. Principal and interest is due at maturity.

On April 24, 2020, the Company was awarded a grant of $1.0 million from Empire State Development to be used as working capital for the development and production of IgG/IgM serology tests for COVID-19 for sale in the State of New York.

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

The following discussion and analysis should be read in conjunction with our audited consolidated financial statements and related notes included elsewhere in this report. In addition to historical information, the following discussion contains forward-looking statements that involves risks, uncertainties and assumptions. See "Forward-Looking Statements and Statistical Estimates" on page 3 of this report. Please read Part II, Item 1A. "Risk Factors" of this report for a discussion of factors that could cause our actual results to differ materially from our expectations.

Overview of Three Months Ended March 31, 2020

We develop, manufacture and commercialize diagnostic tests used for the detection and diagnosis of infectious diseases. We have been expanding our product portfolio based upon our proprietary DPP technology, a novel, rapid diagnostic platform that uses a drop of blood from the fingertip to provide high-quality, cost-effective results in approximately 15 minutes. Our products are sold globally to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals, and retail establishments.

The global COVID-19 pandemic significantly affected our operating results for the three months ended March 31, 2020. We anticipated that, in addition to the business disruption and general economic effects caused by the pandemic, a substantial portion of the funding that would otherwise have been available for testing for infectious diseases addressed by our diagnostic tests, such as the human immunodeficiency virus or HIV, would be redirected to testing for the novel coronavirus that causes COVID-19. In February 2020 we began the process of shifting substantially all of our resources to leverage our DPP lateral flow technology to address the acute and escalating need for an accurate diagnostic test for COVID-19. The diminished focus on our existing product portfolio, as well as the extensive economic disruption caused by the COVID-19 pandemic, was reflected in our first quarter results as compared to the prior year period, as total revenue decreased 19.7% to $6.9 million and product sales decreased 13.7% to $5.7 million.

In the latter half of the first quarter of 2020, we developed, and began to manufacture for commercialization, the DPP COVID-19 System, which consists of our new serological test for COVID-19 and our Micro Reader analyzer. The DPP COVID-19 System can provide discrete, numerical readings for IgM and IgG antibody levels in approximately 15 minutes from a simple fingerstick drop of blood. Our actions in the first-quarter have led to several subsequent key achievements:

- We acquired three regulatory approvals of the DPP COVID-19 System in our targeted global testing market: an Emergency Use Authorization, or EUA, granted by the U.S. Food and Drug Administration, or FDA, in April 2020; an approval for emergency use issued by Brazil's Agência Nacional de Vigilância Sanitária, or ANVISA, in April 2020, and a CE Marking for the European Union obtained in early May 2020.
- Stony Brook Medicine selected the DPP COVID-19 System to help identify persons who have recovered from COVID-19, for use in an FDA-approved investigation to determine if those persons' convalescent blood plasma can help treat patients with an active COVID-19 infection.
- We began shipping the DPP COVID-19 System to fulfill a $4 million purchase order from Bio-Manguinhos, a long-standing customer that is a subsidiary of the foundation responsible for the development and production of vaccines, diagnostics and biopharmaceuticals for Brazil's national public health system.
- We initiated a limited number of commercial shipments of the DPP COVID-19 System to customers in the United States.

In order to address challenging economic conditions and accelerate implementation of our new business strategy, we have initiated a program to reduce operating expenses and better align our costs with revenues. For a further description of this program, see "—Expense Reduction Program" below. Our cash and cash equivalents totaled $11.2 million at March 31, 2020, compared to $18.3 million at December 31, 2019.

In light of the significant changes in our business and operations implemented during the three months ended March 31, 2020, we have set forth below under "—Business Update" information to supplement the disclosures made under "Item 1. Business" of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the Securities and Exchange Commission on March 13, 2020, or our 2019 Form 10-K.

Business Update

DPP COVID-19 System

We believe we have a proven track record in rapidly responding to global health emergencies. Building upon our extensive experience in developing and manufacturing high-quality HIV tests, we received EUAs for DPP tests related to the global outbreak of Ebola, which began in 2014, and Zika, which commenced in 2015. When the novel coronavirus emerged, we were confident that we could leverage our DPP platform and our scientific and operational expertise to create an antibody test that could detect and diagnose the presence, or former presence, of antibodies generated in response to the virus. DPP technology is an advanced, versatile lateral flow testing platform with the capability to multiplex, or detect multiple biomarkers, from a single patient sample. The speed with which we were able to develop a test for COVID-19 illustrates the DPP platform's applicability to new and emerging infectious diseases.

During three months ended March 31, 2020 we refocused our business strategy to apply our DPP technology to address the escalating need for COVID-19 diagnostic tests, including tests that can be performed both close to the patient and at a laboratory or hospital. In February 2020 we began the process of shifting substantially all of our resources to the development and commercialization of the DPP COVID-19 System, which consists of our new serological test for COVID-19 and our Micro Reader analyzer. In the latter half of the first quarter of 2020, we developed and in preparation for commercialization, began to manufacture the DPP COVID-19 System.

The DPP COVID-19 System detects antibodies in the blood that are produced by the body in response to a novel coronavirus infection. Detection of an acute infection, as determined by the level of IgM antibodies, helps determine if a patient is still infectious. As the infection progresses, the body typically begins to produce IgG antibodies. The IgG antibody levels increase, while IgM antibody levels decrease and eventually disappear. IgG antibodies remain, evidencing the earlier infection. It is not currently known how long IgG antibodies to coronavirus remain in the body.

The DPP COVID-19 System offers discrete detection of IgM and IgG antibodies, with high sensitivity and specificity, from a simple fingerstick drop of blood after approximately 15 minutes of reaction time. Using our portable Micro Reader analyzer, the DPP COVID-19 System produces numerical results in approximately 15 seconds. Numerical readings of each of the IgM and IgG antibodies can assist in identifying patients who have been exposed to the novel coronavirus, even patients who exhibit mild, or no, symptoms. Numerical results reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many other serological tests. Because the reader processing requires approximately 15 seconds and is independent of the processing of tests, the DPP COVID-19 System can process more than 200 tests per hour, making it appropriate for high-volume applications.

Key Developments

While we have been focusing on a test for COVID-19 for only a short time, we have achieved several key developments that we believe demonstrate the potential utility and marketability of the DPP COVID-19 System.

Shipment to Brazil. In March 2020 we received a $4 million purchase order for DPP COVID-19 Systems from Bio-Manguinhos, a long-standing customer that is a subsidiary of the foundation responsible for the development and production of vaccines, diagnostics and biopharmaceuticals for Brazil's national public health system. In April 2020 we began shipping DPP COVID-19 Systems to Bio-Manguinhos to fulfill this purchase order.

Issuance of EUA. On April 14, 2020, the FDA issued an EUA for emergency use of the DPP COVID-19 System pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act of 1938. EUA authority allows the FDA, following a declaration of emergency or threat-justifying authorization of emergency use by the Secretary of Health and Human Services, to authorize the introduction into interstate commerce of drugs, devices, or biologics intended for use in an actual or potential emergency involving a biological, chemical, radiological, or nuclear agent. Under this authority, the FDA may authorize such products to be used in an emergency to diagnose, treat or prevent serious or life-threatening diseases or conditions caused by such agents when appropriate findings are made concerning the nature of the emergency, the availability of adequate and approved alternatives, and the quality of available data concerning the effectiveness of the medical product under consideration for emergency use. On February 4, 2020, the Secretary of Health and Human Services determined that the novel coronavirus presented a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and declared that circumstances existed justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus that causes COVID-19. On February 29, 2020, the FDA issued immediately in effect guidance for clinical laboratories, commercial manufacturers and FDA staff to provide a policy to help accelerate the availability of COVID-19 diagnostic tests, and updated that guidance on March 16, 2020 to provide more specific detail to laboratories and commercial manufacturers developing COVID-19 diagnostic tests. To date, the FDA has issued several EUAs for serological tests for use in detecting COVID-19-related antibodies. On May 4, 2020, the FDA further updated its COVID-19 diagnostic test guidance to require EUA submissions for all serology tests that were previously marketed under FDA enforcement discretion following submission of a notification to FDA. FDA policies regarding diagnostic tests, therapies and other products used to diagnose, treat or mitigate COVID-19 remain in flux as the FDA responds to new and evolving public health information and clinical evidence.

Selection for Use in FDA-Approved Study. In April 2020, Stony Brook Medicine selected the DPP COVID-19 System to assist in the recruitment of patients who have recovered from COVID-19 infections. Stony Brook Medicine is conducting a study intended to determine if convalescent blood plasma from people who have recovered from COVID-19 can help treat hospitalized patients with active COVID-19 infection. Stony Brook University Hospital has received FDA approval to offer convalescent blood plasma treatment to its patients through a randomized, controlled study and is expected to enroll up to 500 patients from the Long Island, New York area. The DPP COVID-19 System is being used to confirm that patients enrolled in the study had been infected with COVID-19 and now have adequate levels of IgG antibodies to make them eligible to donate convalescent plasma.

Initial Shipments in United States. We made our initial commercial shipments of the DPP COVID-19 System to U.S. customers late in April 2020.

Targeted Uses and Customers

By changing the way people interact and function in everyday life, the COVID-19 pandemic has created new types of customer needs and has expanded the use cases for diagnostic testing. We believe the DPP COVID-19 System is well-positioned to address both existing and emerging markets by, for example, monitoring infection progression in individuals to improve clinical outcomes, surveilling community populations to determine herd immunity, and facilitating evaluation of potential therapeutic treatments and potential vaccine development processes. Because the DPP COVID-19 System is portable, uses a fingerstick blood sample, produces numerical results, and requires approximately 15 minutes for test processing and approximately 15 seconds for results processing, we believe tests can be conducted in a wide variety of settings, including on a decentralized basis without significant infrastructure.

Because the EUA issued by the FDA for emergency use of the DPP COVID-19 System was limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, to perform moderate and high complexity tests, we are working with the FDA to identify and understand the requirements and guidelines that would be applicable to receiving a certificate of waiver under CLIA with respect to the DPP COVID-19 System. CLIA generally regulates laboratories that test human specimens and ensures laboratories produce accurate, reliable, and timely patient test results, regardless of where the test is performed. As defined by CLIA, waived tests are categoried as simple laboratory examinations and procedures that have an insignificant risk of an erroneous result. A CLIA-waived test can be performed as a point-of-care test at any laboratory with a Certificate of Waiver without need for a highly trained laboratory technician to administer the test, which makes the test more accessible and economical. This would include physician offices, health clinics and urgent care centers, pharmacies and nursing homes. In the event that FDA approves our application for waived status under CLIA, we anticipate that a diverse customer base will be interested in using the DPP COVID-19 System, based on the DPP COVID-19 System's portability, accuracy, speed, cost-effectiveness and ease of use.

Until FDA authorizes the DPP COVID-19 System's waived status under CLIA, we are currently focusing our sales efforts on target hospitals and state and city health departments authorized to perform moderate and high complexity tests in regions that have been most effected by the pandemic. Outside the known health care arena, we anticipate there will be increasing interest from larger institutions and employers as the world evaluates its path back to work and whether individuals may have been exposed to COVID 19 and may have immunity.

Legacy Infectious Disease Product Portfolio

We are a leading provider of diagnostic tests for infectious diseases with a broad portfolio of infectious disease products. We refer to our infectious disease products, other than the DPP COVID-19 System, as our legacy products. As described above under "—DPP COVID-19 System," in the three months ended March 31, 2020 we began the process of shifting substantially all of our resources to the development and commercialization of the DPP COVID-19 System. As a result, we expect to generate an immaterial amount of revenue from our legacy products for the foreseeable future, while we continue to focus on the manufacture and commercialization of the DPP COVID-19 System. Thereafter, we intend to recommence the development, marketing, manufacture and sale of the legacy product portfolio consistent with market demand.

Our legacy infectious disease products are based on our DPP technology. They require only a single drop of blood from the fingertip and provide results in approximately 15 minutes. These products feature:

- enhanced sensitivity and specificity;
- advanced multiplexing; and
- when used with our Micro Reader, numerical results processed in approximately 15 seconds.

Regulatory Approvals

We have obtained FDA approvals and, directly or through our partners, international regulatory approvals for legacy infectious disease tests as follows:

Product	U.S.	International
DPP HIV 1/2 Assay	✓	✓
DPP HIV-Syphilis System	Pending FDA Approval	✓
DPP Syphilis Screen & Confirm Assay		✓
DPP ZCD IgM/IgG System		✓
DPP Dengue NS1 Antigen System		✓
DPP Dengue IgM/IgG System		✓
DPP Zika IgM System	✓ EUA	✓
DPP Zika IgM/IgG System		✓
DPP Chikungunya System		✓
DPP Ebola Antigen System	✓ EUA	
DPP Leishmaniasis Assay		✓
HIV 1/2 STAT-PAK Assay	✓	✓
Chagas STAT-PAK Assay		✓
SURE CHECK HIV 1/2 Assay	✓	✓
SURE CHECK HIV Self-Test		✓

Historically, we have sought to leverage our FDA approvals and, directly or through our partners, international regulatory approvals for infectious disease tests as follows:

- our registration of existing and new products in unchartered countries and regions, such as selected countries in Latin America and Southeast Asia;
- our entry into new market segments, such as international HIV self-testing; and
- advances in our product pipeline in infectious disease with key products, including a multiplex test for HIV and Syphilis targeted for sale in the United States and tests for Chikungunya, Dengue and Zika for sale internationally.

Legacy Products

Our legacy products include both stand-alone and multiplex tests for sexually transmitted infectious diseases, such as HIV and Syphilis. HIV and Syphilis continue to be major global public health issues. According to estimates of the World Health Organization, or WHO:

- HIV has claimed more than 35 million lives, including 770,000 in 2018. Approximately 37.9 million people were living with HIV at the end of 2018, and 1.7 million were newly infected during 2018.
- There were 18.0 million prevalent cases of Syphilis as of 2012, and 5.6 million new infections were estimated to occur annually.
- Elimination of mother-to-child transmission, or MTCT, of both HIV and Syphilis is a global health priority. In 2013, 1.9 million pregnant women were infected with Syphilis worldwide. Congenital syphilis contributes significantly to infant mortality, accounting for 305,000 annual perinatal deaths worldwide in 2013. Globally, more than 1.4 million pregnant women were infected with HIV as of 2015, and MTCT of HIV is estimated to have resulted in over 150,000 infant cases in 2015.

We have sought to address the global concerns related to HIV and Syphilis co-infection through the development of a novel, multiplex test for both HIV and Syphilis. We developed a DPP HIV-Syphilis multiplex test and received regulatory approvals covering a number of international markets, including Brazil, Europe, Malaysia and Mexico. In February 2020, we received a "not approvable" letter from the FDA with respect to our Premarket Approval, or PMA, application on our DPP HIV-Syphilis multiplex test for commercial use in the United States. The FDA requested the repeat of the reproducibility study, as one of the sites in the trial reported greater variability compared to the other sites. We completed and submitted the repeat study to the FDA in April 2020 and are awaiting its formal review. When appropriate and subject to issuance of the PMA, we will continue the pursuit of the associated CLIA waiver. We believe we continue to be well-positioned to be the first company to introduce a multiplex, rapid test for HIV and Syphilis in the United States.

Our legacy products also include tests for selected fever and tropical diseases such as Chagas, Ebola, Leishmaniasis and Zika. The market for lateral flow tests for mosquito-borne diseases includes established markets for diseases such as Dengue and Malaria, which WHO estimates collectively account for more than 600 million annual infections worldwide. There are also a number of emerging markets for lateral flow tests for infectious diseases such as Burkholderia, Chikungunya, lassa, leptospirosis, Marburg, Rickettsia and Zika. Our legacy products in development include tests using our DPP platform to detect all of the aforementioned fever and tropical diseases, as stand-alone or multiplex tests.

Third-Party Funding

Since 2015, we have received over $12.2 million of funding from some of the world's leading health organizations, which has helped us accelerate the expansion of our pipeline of infectious disease tests. Our collaborators have included: the Bill & Melinda Gates Foundation; The Paul G. Allen Family Foundation, or Paul Allen Foundation; The Oswaldo Cruz Foundation (Fiocruz); and the Foundation for Innovative New Diagnostics, or FIND, as well as U.S. government agencies such as the Centers for Disease Control and Prevention, or CDC, the Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services, or BARDA, and the U.S. Department of Agriculture.

Legacy Products Under Development

Several tests in our infectious disease pipeline are approaching commercialization, and several have received initial regulatory approvals:

Product	Collaborator	Phase I Feasibility	Phase II Development	Phase III Verification & Validation	Phase IV Clinical & Regulatory	Phase V Commercial Launch
DPP HIV-Syphilis System (US)	Self-funded	✓	✓	✓	✓	PMA[/510(k)] pending
DPP Dengue IgM/IgG System (International)	Self-funded	✓	✓	✓	✓	CE and ANVISA
DPP Dengue NS1 Antigen System (International)	Self-funded	✓	✓	✓	✓	CE and ANVISA pending
DPP Chikungunya IgM/IgG System (International)	Self-funded	✓	✓	✓	✓	CE and ANVISA
DPP Zika Chikungunya Dengue IgM/IgG System (International)	Self-funded	✓	✓	✓	✓	CE and ANVISA
DPP Zika IgM System (US)	BARDA	✓	✓	✓	✓	FDA-EUA
DPP Ebola Antigen System	CDC	✓	✓	✓	✓	FDA-EUA
DPP Fever Assay Asia	FIND	✓	✓	✓	✓	Field studies ongoing
DPP Fever Assay Africa	Paul Allen Foundation	✓	✓	✓		
DPP Fever Assay Malaysia	Self-funded	✓	✓	✓	✓	Field studies ongoing

Sales Channels

We believe our deep experience with infectious diseases, including our development of tests that can multiplex as many as eight different diseases with a single drop of blood and deliver numerical results with our Micro Readers, illustrates our ability to expand our DPP technology into a broader range of tests. Our initial focus for the DPP COVID-19 System is in the United States and in fulfilling existing orders from Brazil, but we expect to expand our sales efforts to include Europe and elsewhere, as demand determines.

There is a diverse customer base interested in using the DPP COVID-19 System. This potential group includes various hospital departments, state and city health departments, ambulatory surgery centers, physician offices, health clinics and urgent care centers, pharmacies, and nursing homes. Outside the known health care arena, we anticipate there will be increasing interest from larger institutions and employers as the world evaluates its path back to work and whether individuals may have been exposed to COVID-19 and may have immunity. We are focusing our initial sales efforts for the DPP COVID-19 System principally on hospitals and state and city health departments in the regions that have been most affected by the pandemic, while monitoring existing and escalating demand throughout the United States and internationally.

Our broader infectious disease portfolio of products is sold globally, both directly and through distributors, to hospitals and clinics, physician offices, clinical laboratories, public health organizations, government agencies and consumers. Historically, we marketed and sold our products only in a small number of countries and regions. While we are focusing substantially on the market for the DPP COVID-19 System, we intend to maintain our relationships with the United Nations Children's Fund or UNICEF and other organizations and agencies that influence market decisions for our legacy products and products under development.

Manufacturing

We historically manufactured our tests using a manual assembly process. Our number of full-time equivalent employees in manufacturing increased from 230 as of December 31, 2019 to 240 as of March 31, 2020, as the result of preparing to increase production capacity for the tests included in the DPP COVID-19 System. This increase was offset in part by our implementation of an expense reduction program (see “—Expense Reduction Program” below). In April 2020, we initiated a retrenchment of our Malaysian facility that will be completed during the second quarter of 2020 and that included termination of employment of our Malaysian workforce. We now manufacture all of our tests in the United States and Brazil and all of our Micro Readers in Germany.

In 2018, we began the process of automating some of our manufacturing processes and expanding our manufacturing capacity in the United States. During 2018, we took delivery of our first automated manufacturing line. This automated manufacturing line provided DPP test production for Brazil and is capable of assembling various configurations of DPP tests. The first automated line has an annual capacity of between five and ten million tests, depending on the test configuration, and uses vision-guided, robotic operation to improve inspection and quality control. During 2019, we took delivery of our second and third automated manufacturing lines, which are undergoing commissioning and regulatory approvals. We initiated the process of automating our U.S. manufacturing processes because we believe the reduced variable costs associated with automated manufacturing lines will improve product gross margins.

As described under “—Business Update—DPP COVID-19 System” above, since February 2020 we have been shifting resources to develop and commercialize the DPP COVID-19 System. Accordingly, and in connection with receipt of an EUA from the FDA for the DPP COVID-19 System, during the three months ended March 31, 2020 we began the process of shifting substantially all of our test manufacturing capacity to the DPP COVID-19 System. This shift included investment totaling approximately $0.8 million to increase tooling capacity, advance our automated manufacturing, and begin recruiting additional workers to expand capacity and supplement absenteeism associated with employee self-quarantines as the result of the COVID-19 pandemic.

During the initial period of expected high demand for COVID-19 tests such as the DPP COVID-19 System, the ultimate duration of which we continue to evaluate, we are working to scale both our manual and automated processes for the assembly of tests for the DPP COVID-19 System. We are focused on scaling our manufacturing operations to target a manufacturing capacity of one million tests in May 2020, subject to continued test demand and supply chain reliability. Thereafter, we will, to the extent feasible, seek to cost-effectively scale our manufacturing capacity to respond to market demand. We have designed, and will seek to implement, a capacity growth plan intended to ramp production each month to reach a target run rate of two million per month by the end of the third quarter of 2020. Our actual growth in capacity will be tied to market demand, and our ability to ramp capacity will be subject to our ability to fund, manage and execute our internal manufacturing requirements and to continue to have the necessary support of our supply chain and other vendors.

Research & Development Services

Our commercially available products employ either our proprietary DPP technology or traditional lateral flow technology. In recent years, we have, while concurrently developing our own products, executed a strategy to leverage DPP intellectual property, as well as our scientific and operational expertise, through our Research & Development Services program of collaborative projects.

Research & Development Services develops tests for third parties using our DPP platform and, in limited cases, other platforms in projects that we believe have the potential to create value for the rest of our business. Research and development, or R&D, costs related to these collaborations are fully funded by our collaborators. We believe that, in addition to providing revenue to support our R&D organization, these activities further validate the DPP platform's ability to provide superior diagnostic performance compared with products that utilize traditional lateral flow technology. The projects also expand the know-how of our R&D team, which we seek to leverage in the development of our own products.

Examples of projects performed by Research & Development Services include the following:

- In January 2015 we entered into an agreement with the Concussion Science Group Division of Perseus Science Group LLC, or Perseus, to develop a rapid diagnostic test for traumatic brain injury utilizing both our DPP and optical analyzer technologies.
- In October 2017 we signed a biomarker development project agreement with AstraZeneca plc, or AstraZeneca, utilizing both our DPP and optical analyzer technologies.
- In April 2018, we entered into a collaboration agreement with LumiraDx to develop new rapid diagnostic tests for infectious diseases. Under terms of the agreement, we receive funding from LumiraDx, subject to satisfying certain milestones, to develop certain new rapid infectious disease tests. Following the regulatory approval and commercialization of tests in accordance with the agreement, we will both sell reagents to, and receive royalty payments from, LumiraDx on sales of all products developed through this collaboration.
- In July 2019 we entered into a collaboration agreement with Shire, a subsidiary of Takeda, to develop a novel rapid diagnostic test to detect an undisclosed biomarker.
- In March 2020 we completed the technical feasibility phase for a potential companion/compatible diagnostic test being developed in collaboration with Shire. The program is focused within Takeda's Rare Diseases Therapeutic Area Unit, which aspires to transform the treatment of rare diseases in immunology, hematology, metabolic and lysosomal storage disorders. Based on the progress, in March 2020 Takeda provided the next tranche of funding for the next phase of the program.
- We entered into agreements with LumiraDx in March 2020 (as amended in April 2020) to, among other things, develop a diagnostic test for the detection of the COVID-19 virus and IgM and IgG antibodies on the LumiraDx platform.

We believe leading global healthcare organizations and others have chosen to collaborate with us based on our deep scientific expertise with our DPP technology platform and capabilities, our successful record of developing DPP tests with a diverse set of collaborators, including global commercial companies, governments and non-governmental organizations, and our extensive experience in obtaining regulatory approvals from various regulatory authorities in the United States, Brazil , the European Union and Mexico, as well as prequalifications from WHO.

The following table illustrates the status of work within our Research & Development Services program:

Product	Collaborator	Phase I Feasibility	Phase II Development	Phase III Verification &Validation	Phase IV Clinical/ Regulatory	Phase V Commercial Launch
DPP Rare Disease (undisclosed biomarker)	Takeda	✓	✓			
COVID-19 Test	LumiraDx	✓	✓			
Infectious Disease Portfolio	LumiraDx	✓	✓			
DPP Biomarker Development Project (undisclosed biomarker)	AstraZeneca	✓	✓	✓		CE Mark*
DPP TBI	Perseus	✓	✓			

* For use in pharmaceutical research

Competition

General

Many of our competitors are significantly larger than us, and they may have market presence, engineering, technical and marketing capabilities and financial, personnel and other resources substantially greater than our own. Important competitive factors include product quality, analytical performance, ease of use, price, customer service and reputation. Industry competition is based on these and the following additional factors:

- patent protection;
- scientific expertise;
- ability to develop and market products and processes;
- ability to obtain required regulatory approvals;
- ability to manufacture cost-effective products that meet applicable regulatory requirements;
- access to adequate capital; and
- ability to attract and retain qualified personnel.

Our ability to develop and market other products is in large measure dependent on our having additional resources and collaborative relationships. Some of our product development efforts have been funded by a third party on a project or milestone basis. We believe our proprietary know-how relating to our DPP technology has been instrumental in obtaining collaborations. We believe our patent protection enhances our ability to develop new, more profitable collaborative relationships.

DPP COVID-19 System

Competition is, and will likely continue to be, particularly intense in the market for COVID-19 diagnostic tests. Numerous companies in the United States and internationally have announced their intention to offer new products, services and technologies that could be used in substitution for the DPP COVID-19 System. Many of those competitors are significantly larger, and have substantially greater financial, engineering and other resources, than our company. Existing and potential competitors in the market for COVID-19 diagnostic tests include developers of both serological and molecular tests.

We expect competition to continue to increase as other established and emerging companies enter the market, as customer requirements evolve, and as new products, services and technologies are introduced. The entrance of new competitors is being encouraged by governmental authorities, who are offering funding to support development of testing solutions for COVID-19. For example, on April 29, 2020, the U.S. National Institutes of Health announced it would be using a portion of its $1.5 billion in federal stimulus funding to fund a $500 million national challenge designed to help the agency identify the best candidates for an at-home or point-of-care test for COVID-19. Some of our existing or new competitors may have strong relationships with current and potential customers, including governmental authorities, and, as a result, may be able to respond more quickly to new or changing regulatory requirements, new or emerging technologies, and changes in customer requirements.

We believe we will be able to compete successfully based upon (a) the capabilities and attributes of the DPP COVID-19 System, which can provide, for a competitive price, rapid and accurate test results for both IgM and IgG antibodies through portable, close-to-the-patient tests and analyzers, (b) our extensive experience in developing rapid tests to respond to the HIV crisis and the Ebola and Zika global outbreaks.

Expense Reduction Program

During the three months ended March 31, 2020, we began implementing a multi-faceted expense reduction program to reduce operating expenses and facilitate profitable growth.[1] We undertook actions to adjust the size and composition of our organization, including by removing positions that were non-essential in light of our new business strategy, and to remove other expenses, all of which we expect will provide savings throughout, and after, 2020. Certain actions were taken with a view to facilitating our new focus on the development, manufacture and commercialization of the DPP COVID-19 System.

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2 Is there anything quantitative that can be said? Otherwise, the sole focus is going to be on the restructuring charge.

In light of market dynamics, we also initiated a retrenchment of our Malaysian operations, including the termination of employment of our entire Malaysian workforce. We will maintain our Malaysian subsidiary and sustain the product registrations that were obtained throughout southeast Asia, with the benefit of having that entity to preserve the opportunity to restart operations there in the future when market conditions warrant.

Based on these activities, the Company expects to report a restructuring charge ranging from $0.3 million to $0.6 million for the three months ended June 30, 2020.

Consolidated Results of Operations

Three Months Ended March 31, 2020 Versus Three Months Ended March 31, 2019

Our results of operations for the three months ended March 31, 2020 and 2019 were as follows (dollars in thousands):

	March 31, 2020		March 31, 2019	
TOTAL REVENUES	**$ 6,860**	**100%**	$ 8,542	100%
OPERATING COSTS AND EXPENSES:				
Cost of product sales	**4,374**	**64%**	5,012	59%
Research and development expenses	**1,959**	**29%**	2,218	26%
Selling, general and administrative expenses	**4,157**	**61%**	4,013	47%
Severance and related costs	**723**	**11%**		
Acquisition costs	**64**	**1%**	395	5%
	11,277		11,638	
LOSS FROM OPERATIONS	**(4,417)**		(3,096)	
OTHER (EXPENSE) INCOME, NET	**(662)**		7	
LOSS BEFORE INCOME TAXES	**(5,079)**	**(74)%**	(3,089)	(36)%
Income tax (benefit)	**(80)**		(272)	
NET LOSS	**$ (5,000)**		$ (2,817)	

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during the three months ended March 31, 2020 were $6.9 million, a decrease of $1.7 million, or 19.7%, compared to the three months ended March 31, 2019. The decrease in total net revenues reflected a $2.0 million decrease in product sales in Africa, Europe, and United States that we believe resulted from a diversion in funding from HIV to COVID-19, and a $0.8 million decrease in R&D revenues related to the completion of a BARDA-related program funding during 2019, offset in part by a $1.1 million increase in product revenue driven by gains in Latin America and Asia. Total revenues for the three months ended March 31, 2020 was also adversely effected by our shift in focus from offering and selling legacy products to developing and beginning to commercialize the DPP COVID-19 System.

Gross Product Margin

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

Gross product margin is net product revenue less cost of product revenue, and gross product margin percentage is gross product margin as a percentage of net product revenue. Gross product margin during the three months ended March 31, 2020 decreased by $0.3 million, or 16.7%, from the comparable period of 2019. The gross product margin reduction resulted primarily from unfavorable average selling prices due to geographic mix and, to a lesser extent, the impact of fixed overhead on our overall lower product sales volume. The following schedule calculates gross product margin (dollars in thousands):

	For the three months ended March 31		**Favorable/(unfavorable)**	
	2020	**2019**	**$ Change**	**% Change**
Net product revenue	**$ 5,717**	$ 6,624	$ (907)	13.7%
Less: Cost of product revenues	**(4,375)**	(5,012)	637	12.7%
Gross product margin	**$ 1,342**	$ 1,612	$ (270)	16.7%
Gross product margin percentage	**23.5%**	24.3%		

The $0.3 million decrease in gross product margin was composed of the following:

- $0.2 million unfavorable product sales volume as described above, offset by
- $0.1 million unfavorable geographic-related margin mix corresponding to average selling prices.

During 2019, we took delivery of our second and third automated manufacturing lines, which are undergoing commissioning and regulatory approvals. We believe the automation will reduce our reliance on manual labor and contribute to improved product gross margins.

Research and Development

This category includes costs incurred for clinical and regulatory affairs and other R&D as follows (dollars in thousands):

	For the three months ended March 31		Favorable/(unfavorable)	
	2020	2019	$ Change	% Change
Clinical and regulatory affairs	$ 323	$ 439	$ 116	$ 26.4%
Other research and development	1,636	1,779	143	8.0%
Total research and development	$ 1,959	$ 2,218	$ 259	11.7%

The decrease in R&D costs for the three months ended March 31, 2020 compared to the three months ended March 31, 2019 was primarily associated with the reduction externally funded programs, offset by costs related to the development of the DPP COVID-19 System.

Selling, General and Administrative Expense

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

The $0.1 million, or 3.6%, increase in selling, general and administrative expense for the three months ended March 31, 2020 compared to the three months ended March 31, 2019 principally reflected commissions on increased product sales in Latin America as discussed above. Severance and related costs for the three months ended March 31, 2020 consisted of $1.1 million of gross severance costs related to the resignation of our former chief executive officer, offset by the reversal of previously expensed non-cash equity compensation costs of $0.4 million with respect to equity awards held by such officer. Acquisition costs during the three months ended March 31, 2020 and 2019 resulted from the Company's acquisitions of Orangelife and opTricon GmbH in the three months ended December 31, 2019 and 2018, respectively. The $0.3 million decrease in these costs reflects to the statutory audit requirement of the pre-acquisition financial statements of opTricon GmbH that was not required for Orangelife.

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 three months ended March 31, 2020 compared to comparable period in 2019 due to interest accruing on long-term debt incurred on September 3, 2019, of which $20 million (carrying value of $17.8 million) was outstanding at March 31, 2020. For a description of this long-term debt, please see "—Liquidity and Capital Resources—Sources of Funds—Credit Agreement" below.

Income Tax Benefit

During the three months ended March 31, 2020, we recognized a tax benefit of $0.1 million related to losses generated by our foreign subsidiaries. As of March 31, 2020 and 2019, our U.S. deferred tax assets included a full valuation allowance.

Liquidity and Capital Resources

In 2020 we have funded our business operations, including capital expenditures and working capital requirements, principally from cash and cash equivalents. Our operations used $5.7 million of cash. As of March 31, 2020, we had outstanding debt (excluding leases) in the amount of $20.1 million (carrying amount of $17.8 million), consisting of loans of $20.0 million under a credit agreement entered into on September 3, 2019 and $0.1 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, particularly in the light of our shift in business focus to the DPP COVID-19 System. 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, particularly with respect to the DPP COVID-19 System; 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 our 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

The following table sets forth selected working capital information:

	March 31, 2020
	(in thousands)
Cash and cash equivalents	$ 11,238
Accounts receivable, net of allowance for doubtful amounts	4,878
Inventories, net	10,930
Prepaid expenses and other current assets	798
Total current assets	27,844
Less: Total current liabilities	(8,006)
Working capital	$ 19,838

On April 24, 2020, we were awarded a grant of $1.0 million from Empire State Development to be used as working capital for the development and production of IgG/IgM serology tests for COVID-19 for sale in the State of New York.

On April 20, 2020, we entered into an agreement with the U.S Small Business Administration for a loan of $3 million under the Paycheck Protection Program. The loan bears a 1% interest rate and has a two-year term beginning on the date of disbursement. Principal and interest is due at maturity.

Our cash and cash equivalents at March 31, 2020 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

Our operations used $5.7 million of cash during the three months ended March 31, 2020, reflecting a net loss adjusted for non-cash items of $4.4 million (which included $0.8 million of severance and related costs and $0.1 million of acquisition costs), a $1.2 million increase in accounts receivable, a $1.3 million increase in inventory, offset by a $1.0 million increase in accounts payable and accrued liabilities and a $0.5 million increase in deferred revenue.

During the three months ended March 31, 2020, we continued to invest in manufacturing equipment, leasehold improvements and other fixed assets, particularly in the light of our shift in business focus to our DPP COVID-19 System. Our capital expenditures totaled $1.0 million in the three months ended March 31, 2020.

Off-Balance Sheet Arrangements

As of March 31, 2020, 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, or the Exchange Act.

Significant Accounting Policies and Critical Accounting Estimates

There were no significant changes in our critical accounting estimates during the three months ended March 31, 2020 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 as described in subsection (v) of note 2 to the condensed consolidated financial statements included elsewhere in this report.

Recently Issued Accounting Pronouncements

A discussion of recent accounting pronouncements was included in our 2019 Form 10-K and is updated in Note 3 to the condensed consolidated financial statements included elsewhere in this report.

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 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 March 31, 2020 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 March 31, 2020, 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

John J. Sperzel, our former chief executive officer, has asserted a right to exercise certain options to purchase, for an aggregate exercise price of $943,126, a total of 266,666 shares of common stock that were vested when he resigned on January 3, 2020. Under their terms, those options were exercisable for a period of thirty days after his service to our company ended. The compensation committee of the board, acting in its discretion in accordance with the terms of the underlying equity incentive plans, has determined that Mr. Sperzel failed to exercise the options in a timely manner prior to their expiration. Chembio intends to vigorously defend against any claim by Mr. Sperzel that he continues to have a right to exercise any options.

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

ITEM 1A. RISK FACTORS

Except as set forth below, there have been no material changes to the risk factors described in the section captioned Part I, Item 1A, “Risk Factors,” in our 2019 Form 10-K. In addition to the other information set forth in this report, you should carefully consider the factors discussed in the section captioned Part I, Item 1A, Risk Factors,” in our 2019 Form 10-K, which could materially affect our business, financial condition, or future results. Moreover, you should interpret many of the risks identified in our 2019 Form 10-K as being heightened as a result of the ongoing and numerous adverse impacts of the COVID-19 pandemic. The risks described in our 2019 Form 10-K and in this report are not the only risks we face. 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/or operating results.

We are refocusing our business strategy to respond to COVID-19, which is a new and rapidly developing market, making it difficult to evaluate our business and future prospects.

The market for COVID-19 diagnostic testing is new and rapidly developing, which makes it difficult to evaluate our business and future prospects. We have encountered, and will continue to encounter, risks and difficulties frequently experienced in rapidly changing industries, including those related to:

- our ability to compete with companies that are currently in, or may in the future enter, the market for our products;
- our ability to control costs, including our operating expenses;
- our ability to successfully expand our business;
- our ability to meet customer demand;
- the amount and timing of operating expenses, particularly sales and manufacturing expenses, related to the maintenance and expansion of our business, operations and infrastructure; and
- general economic and political conditions in our markets.

Given the unpredictable nature of the COVID-19 pandemic, the potential size of this market and the timing of its development is highly uncertain. Our future success is dependent on the manner in which the market for COVID-19 diagnostics develops. If the market develops in a manner that does not facilitate the inclusion of our products, or fails to grow in the manner in which we expect, our business may not continue to grow.

We are allocating substantially all of our resources to the production of our DPP COVID-19 System for the foreseeable future, and our long-term business success could be negatively impacted by our diversion of resources from our legacy business of diagnostic testing for other infectious diseases.

We are committing substantially all of our financial and personnel resources to the development, manufacturing and commercialization of the DPP COVID-19 System. This resource allocation may negatively impact our legacy product portfolio, as we expect to spend limited funds and time on updating pre-existing products and regulatory approvals or on completing products that were in development prior to our strategic decision to focus on the DPP COVID-19 System. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could dissipate; there is no guarantee that current or anticipated demand will continue, or if demand does continue, that we will be able to produce in quantities to meet the demand. We intend to reestablish our legacy business in the future, but there can be no assurance that we will be able to successfully recommence the development and commercialization of our legacy products and products under development.

COVID-19 diagnostic tests, including our DPP COVID-19 System, are subject to changes in CLIA, FDA and other regulatory requirements.

Our DPP COVID-19 System is subject to regulations of the U.S. Food and Drug Administration, or FDA, International Organization for Standards and other regulatory requirements. The regulations regarding the manufacture and sale of our DPP COVID-19 System may be unclear and are subject to change. Newly promulgated regulations could require changes to our DPP COVID-19 System, necessitate additional procedures, or make it impractical or impossible for us to market our DPP COVID-19

System for certain uses, in certain markets, or at all. The FDA and other regulatory authorities also have the ability to impose new or additional requirements relating to our DPP COVID-19 System. The implementation of such changes or new or additional requirements may result in a substantial additional costs and could delay or make it more difficult or complicated to sell our products.

The FDA issued an Emergency Use Authorization, or EUA, for emergency use of the DPP COVID-19 System. The FDA has established certain conditions that must be met to maintain authorization under an EUA, and the FDA also has the power to revoke the EUA under which our DPP COVID-19 System is sold if it determines that the underlying health emergency no longer exists or warrants such authorization. Such revocation would preclude the sale of our COVID-19 product unless and until a further regulatory approval or authorization is obtained. We cannot predict the effect, if any, that these changes might have on our business, financial condition or results of operations.

In addition, the EUA issued by the FDA for emergency use of the DPP COVID-19 System is limited to authorized laboratories certified under CLIA to perform moderate and high complexity tests. We are currently working with the FDA to approve our application for waived status under CLIA, which would permit any laboratory with a Certificate of Waiver, including physician offices and urgent care clinics, to perform the tests. The time required to obtain marketing authorizations and other approvals from regulatory authorities is unpredictable. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can change, and does often change, during development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA policy during the period of FDA regulatory review.

Our near-term success is highly dependent on the success of our DPP COVID-19 System, and we cannot be certain that it will attain market acceptance and or be successfully commercialized in the United States or elsewhere.

Although we have received EUA for our DPP COVID-19 System, the product may not gain broad market acceptance among physicians, healthcare payers, patients, and the medical community. We have conducted our own research into the markets for our product candidates, including our DPP COVID-19 System; however, we cannot guarantee market acceptance of our product, and have somewhat limited information on which to estimate our anticipated level of sales. Our product will require healthcare providers and doctors to accept and adopt our technology. Our industry is susceptible to rapid technological developments and there can be no assurance that we will be able to match any new technological advances. If we are unable to match the technological changes in the needs of our customers the demand for our products will be reduced. Acceptance and use of any products we market will depend upon a number of factors including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our products;
- limitation on use or warnings required by FDA in our product labeling;
- cost-effectiveness of our products relative to competing products;
- convenience and ease of administration;
- potential advantages of alternative treatment methods;
- availability of reimbursement for our products from government or other healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect virtually all of our product revenues for the foreseeable future to be generated from sales of our current products and the DPP COVID-19 System in particular, the failure of these products to find market acceptance would substantially harm our business and would adversely affect our revenue. If our DPP COVID-19 System is not as successfully commercialized as expected, we may not be able to generate sufficient revenue to become profitable. Any failure of the DPP COVID-19 System to be successfully commercialized in the United States may have a material adverse effect on our business, operating result financial condition and cash flows, and could result in a substantial decline in the price of our common stock.

Our DPP COVID-19 System may not gain wide industry acceptance, and industry adoption of alternative technology could negatively impact our ability to compete successfully.

Of the 54 test kit manufacturers and commercial laboratories to receive an EUA for COVID-19 diagnostics as of April 30, 2020, only eight use serological technology. Customers or the industry as a whole could adopt alternative technologies for testing, including molecular point-of-care testing, which could result in lower demand for our serological test. Various advances in the treatment and monitoring of patients could cause lower demand for our DPP COVID-19 System or for serological testing for COVID-19 as a whole.

The diagnostic testing market, particularly with respect to COVID-19, is highly competitive, and many of our competitors are larger, better established and have greater technical and marketing capabilities and financial and other resources than we have.

The diagnostics market, particularly with respect to COVID-19 diagnostic tests, is highly competitive and we face substantial competition based on factors such as product quality, analytical performance, ease of use, price, customer service and reputation. Industry competition is also based the following additional factors:

- patent protection;
- scientific expertise;
- ability to develop and market products and processes;
- ability to obtain required regulatory approvals;
- ability to manufacture cost-effective products that meet applicable regulatory requirements;
- access to adequate capital; and
- ability to attract and retain qualified personnel.

Numerous companies in the United States and internationally have announced their intention to offer new products, services and technologies that could be used in substitution for the DPP COVID-19 System. Many of those competitors are significantly larger, and have substantially greater financial, engineering and other resources, than us. In addition, our competitors may have or may develop products or technologies that currently or in the future will enable them to produce competitive products with greater capabilities or at lower costs than ours. If we are unable to compete effectively, we may fail to meet our strategic objectives, and our business, financial condition and operating results could be harmed.

We expect competition to with respect to testing solutions for COVID-19 to continue to increase and our success will depend on widespread market acceptance of our products.

We expect competition to continue to increase as other established and emerging companies enter the market, as customer requirements evolve, and as new products, services and technologies are introduced. The entrance of new competitors is being encouraged by governmental authorities, which are offering funding to support development of testing solutions for COVID-19. Some of our existing or new competitors may have strong relationships with current and potential customers, including governmental authorities, and, as a result, may be able to respond more quickly to new or changing regulatory requirements, new or emerging technologies, and changes in customer requirements. Our products may not compete favorably, and we may not be successful in the face of increasing competition from new products and technologies introduced by our existing competitors or new companies entering our markets. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

We depend on use of third-party suppliers, some of which may constitute our sole supply source, for certain important product components and materials presents risks that could have negative consequences for our business.

We purchase certain critical components used in our DPP product lines, including our DPP COVID-19 System from a sole source or limited number of sources. If for any reason these suppliers become unwilling or unable to supply our critical component needs, it may be difficult to find an alternate supply source in a reasonable time period or on commercially reasonable terms, if at all. The change in a critical component could also necessitate additional development work and approval by the FDA and other regulatory agencies. As a result, the termination or limitation of our relationship with one or more of these suppliers could require significant time to complete, increase our costs, and disrupt or discontinue our ability to manufacture and sell the affected products. Moreover, some of these suppliers may experience financial difficulties that could prevent them from supplying us with components or subassemblies used in the design and manufacture of our products. In addition, these suppliers may experience manufacturing delays or shut downs due to circumstances beyond their control, such as complications related to COVID-19, labor issues, political unrest or natural disasters.

Any supply chain deficiencies could materially and adversely affect our ability to fulfill customer orders and our results of operations. The availability of critical components and materials from sole- or limited source suppliers could reduce our control over pricing, quality and timely delivery, increase our costs, could disrupt our ability to manufacture and sell, and preclude us from manufacturing and selling, certain of our products into one or more markets. Any such event could have a material adverse effect on our results of operations, cash flow and business.

The COVID-19 pandemic could continue to spread rapidly and affect our suppliers and employees, and cause disruptions in current and future plans for operations and expansion.

The COVID-19 pandemic may directly and indirectly adversely impact our business, financial condition and operating results. The extent to which this will continue will depend on numerous evolving factors that are highly uncertain, rapidly changing and cannot be predicted with precision or certainty at this time.

Our business may be disrupted due to the costs incurred as a result of additional necessary actions and preparedness plans to help ensure the health and safety of our employees and continued operations, including enhanced cleaning processes, protocols designed to implement appropriate social distancing practices, and/or adoption of additional wage and benefit programs to assist employees. We may also have difficulty meeting demand for our products if our employees are affected by COVID-19, or if we do not have adequate space to produce our product with social distancing practices implemented. We also cannot predict the effect of COVID-19 pandemic on our supply chain’s reliability and costs,

In addition, our business and operations, and the operations of our suppliers, may be adversely affected by the COVID-19 pandemic. The pandemic, including the related response, could cause disruptions due to potential suspension or slowdown of activities at our third-party suppliers, or increased prices implemented by our suppliers. The adverse effect on our employees or suppliers could have an adverse impact on our business, results of operations and financial condition.

We are subject to governmental export controls that could impair our ability to compete in international markets.

The United States and various foreign governments have imposed controls, export license requirements and restrictions on the export of certain products and technologies. We must export our products in compliance with export controls in the United States, including the Commerce Department's Export Administration Regulations and various economic and trade sanctions established by the Treasury Department's Office of Foreign Assets Controls. We may not always be successful in obtaining necessary export licenses, and our failure to obtain required import or export approval for our products or limitations on our ability to export or sell our products imposed by these laws may harm our international and domestic sales and adversely affect our revenue. Noncompliance with these laws could have negative consequences, including government investigations, penalties and reputational harm.

If the United States government imposes restrictions on the export of our DPP COVID-19 System, or any of our other products, such restrictions could have a material impact on our ability to sell our products to existing or potential customers outside of the United States and harm our ability to compete internationally. Any change in export regulations or legislation, or change in the countries, persons or technologies targeted by export regulations, could decrease our ability to export or sell our products outside the United States or to existing or potential customers with international operations. Changes in our ability to sell our products outside the United States could negatively impact our business prospects and adversely affect our business and results of operations.

Third-party reimbursement policies and potential cost constraints could negatively affect our business.

The potential end-users of our products include hospitals, physicians and other healthcare providers. If these end-users do not receive adequate reimbursement for the cost of our products from their patients' healthcare insurers or payors, the use of our products could be negatively impacted. Furthermore, the net sales of our products could also be adversely affected by changes in reimbursement policies of government or private healthcare payors.

Hospitals, physicians and other healthcare providers who purchase diagnostic products in the United States generally rely on third-party payors, such as private health insurance plans, Medicare and Medicaid, to reimburse all or part of the cost of the product. Due to the overall escalating cost of medical products and services, especially in light of the COVID-19 outbreak and its straining of healthcare systems across the globe, there is increased pressure on the healthcare industry, both foreign and domestic, to reduce the cost of products and services. Given the efforts to control and reduce healthcare costs in the United States, available levels of reimbursement may change for our existing products or products under development. Third-party reimbursement and coverage may not be available or adequate in either the United States or international markets, current reimbursement amounts may be decreased in the future and future legislation, and regulation or reimbursement policies of third-party payors, may reduce the demand for our products or our ability to sell our products on a profitable basis.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared, approved, authorized, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and clear, approve, or authorize new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for medical devices or modifications to be cleared or approved, medical devices to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

ITEM 5. OTHER MATTERS

Appointment of New Director

On May 2, 2020, the board of directors appointed Richard L. Eberly, our Chief Executive Officer and President, to serve as a member of the board, commencing immediately and continuing until our 2020 Annual Meeting of Stockholders. Biographical information about Mr. Eberly can be found in Amendment No. 1 to the 2019 Form 10-K, as filed with the SEC on April 29, 2020.

Mr. Eberly will receive no additional compensation as a result of his appointment to the board.

Our employment agreement dated as of March 4, 2020 with Mr. Eberly contemplated that Mr. Eberly would be nominated for election to the board at our 2020 Annual Meeting of Stockholders. There is no other arrangement or understanding between Mr. Eberly and any other person pursuant to which he was selected to become a member of the board, and there are no transactions between us or any of our subsidiaries and Mr. Eberly that are reportable under Item 404(a) of Regulation S-K.

ITEM 6. EXHIBITS

Number	Description
10.1†	Separation and Release Agreement, dated January 7, 2020, between Chembio Diagnostics, Inc. and John J. Sperzel III
10.2†	Letter agreement dated January 17, 2020, between Chembio Diagnostics, Inc. and Gail S. Page
10.3†*	Employment Agreement, dated as of March 4, 2020 and effective as of March 16, 2020, between Chembio Diagnostics, Inc. and Richard L. Eberly
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
32ç	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

† Indicates management contract or compensatory plan or arrangement.

* Certain sensitive personally identifiable information in this exhibit was omitted by means of redacting a portion of the text and replacing it with [***].

ç The certifications attached as Exhibit 32.1 accompany the Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

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

Chembio Diagnostics, Inc.

Date: May 4, 2020

By: /s/ Richard Eberly

Richard Eberly
Chief Executive Officer and President

Date: May 4, 2020

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, Richard L. Eberly, 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: May 4, 2020

/s/ Richard L. Eberly
Richard L. Eberly
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: May 4, 2020

/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 March 31, 2020, 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: May 4, 2020

/s/ Richard L. Eberly
Richard L. Eberly
Chief Executive Officer and President
(Principal Executive Officer)

Date: May 4, 2020

/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. § 1350 and is not being filed as part of the Report or as a separate disclosure document.