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

FORM 10-Q

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

For the quarterly period ended September 30, 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 November 5, 2020, the registrant had 20,176,131 shares outstanding of its common stock, $.01 par value.

Quarterly Report on Form 10-Q
For The Quarterly Period Ended
September 30, 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 and MICRO READER are our trademarks. For convenience, these trademarks appear in this report without ® and ™ symbols, and 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, in Part II, Item 1A. "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020, as filed with the Securities and Exchange Commission on May 4, 2020, in Part II, Item 1A. "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020, as filed with the Securities and Exchange Commission on August 7, 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
AS OF

	(Unaudited) September 30, 2020	December 31, 2019
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 28,687,453**	$ 18,271,352
Accounts receivable, net of allowance for doubtful accounts of $276,210 and $62,000 as of September 30, 2020 and December 31, 2019, respectively	**3,522,498**	3,661,325
Inventories, net	**12,363,486**	9,598,030
Prepaid expenses and other current assets	**1,007,473**	693,013
TOTAL CURRENT ASSETS	**45,580,910**	32,223,720
FIXED ASSETS:		
Property, plant and equipment, net	**8,033,112**	5,933,569
Finance lease right-of-use asset, net	**248,892**	210,350
OTHER ASSETS:		
Operating lease right-of-use assets, net	**6,316,221**	7,030,744
Intangible assets, net	**3,648,495**	3,914,352
Goodwill	**5,696,679**	5,872,690
Deposits and other assets	**462,664**	543,539
TOTAL ASSETS	**$ 69,986,973**	$ 55,728,964
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 6,558,782**	$ 5,526,243
Deferred revenue	**3,865,754**	125,000
Finance lease liabilities	**57,715**	41,894
Operating lease liabilities	**710,535**	568,294
Note payable	**-**	180,249
TOTAL CURRENT LIABILITIES	**11,192,786**	6,441,680
OTHER LIABILITIES:		
Long-term operating lease liabilities	**6,448,515**	6,969,603
Long-term finance lease liabilities	**200,397**	171,953
Long-term debt, less current portion, net	**18,040,427**	17,644,149
Deferred tax liability	**165,326**	466,326
TOTAL LIABILITIES	**36,047,451**	31,693,711
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock - 10,000,000 shares authorized; none outstanding	**-**	-
Common stock - $0.01 par value; 100,000,000 shares authorized; 20,213,956 shares and 17,733,617 shares issued at September 30, 2020 and December 31, 2019, respectively	**202,139**	177,335
Additional paid-in capital	**124,622,252**	95,433,077
Accumulated deficit	**(89,967,147)**	(71,585,003)
Treasury stock - 33,290 and 0 shares at cost, at September 30, 2020 and December 31, 2019, respectively	**(150,919)**	-
Accumulated other comprehensive (loss) income	**(766,803)**	9,844
TOTAL STOCKHOLDERS' EQUITY	**33,939,522**	24,035,253
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 69,986,973**	$ 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		For the Nine Months Ended	
	September 30, 2020	September 30, 2019	**September 30, 2020**	September 30, 2019
REVENUES:				
Net product sales	**$ 8,406,457**	$ 8,510,629	**$ 17,914,623**	$ 23,381,906
R&D and grant revenue	**1,654,500**	971,980	**3,756,161**	3,528,033
License and royalty revenue	**211,521**	238,330	**572,450**	703,352
TOTAL REVENUES	**10,272,478**	9,720,939	**22,243,234**	27,613,291
COSTS AND EXPENSES:				
Cost of product sales	**7,467,746**	6,649,114	**17,512,925**	18,112,676
Research and development expenses	**2,351,880**	2,223,939	**6,233,040**	6,542,591
Selling, general and administrative expenses	**5,348,958**	4,455,588	**13,903,192**	12,565,601
Severance, restructuring and other related costs	**11,651**	-	**1,122,310**	-
Acquisition costs	-	-	**63,497**	395,612
	15,180,235	13,328,641	**38,834,964**	37,616,480
LOSS FROM OPERATIONS	**(4,907,757)**	(3,607,702)	**(16,591,730)**	(10,003,189)
OTHER INCOME:				
Interest expense, net	**(735,819)**	(195,970)	**(2,110,011)**	(183,368)
LOSS BEFORE INCOME TAXES	**(5,643,576)**	(3,803,672)	**(18,701,741)**	(10,186,557)
Income tax benefit	**104,778**	20,667	**319,597**	400,339
NET LOSS	**$ (5,538,798)**	$ (3,783,005)	**$ (18,382,144)**	$ (9,786,218)
Basic loss per share	**$ (0.28)**	$ (0.22)	**$ (0.98)**	$ (0.58)
Diluted loss per share	**$ (0.28)**	$ (0.22)	**$ (0.98)**	$ (0.58)
Weighted average number of shares outstanding, basic	**20,104,547**	16,923,695	**18,728,372**	16,912,583
Weighted average number of shares outstanding, diluted	**20,104,547**	16,923,695	**18,728,372**	16,912,583

See accompanying notes to condensed consolidated financial statements

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

	For the Three Months Ended		For the Nine Months Ended	
	September 30, 2020	September 30, 2019	**September 30, 2020**	September 30, 2019
Net loss	**$ (5,538,798)**	$ (3,783,005)	**$ (18,382,144)**	$ (9,786,218)
Other comprehensive income (loss):				
Foreign currency translation adjustments	**262,094**	(61,306)	**(776,645)**	(172,345)
Comprehensive loss	**$ (5,276,704)**	$ (3,844,311)	**$ (19,158,789)**	$ (9,958,563)

See accompanying notes to condensed consolidated financial statements

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

	For The Nine Months Ended September 30, 2020							
	Common Stock		Additional Paid-in-	Treasury Stock		Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Shares	Amount	Deficit	Income	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**
Common Stock:								
Issuance of stock, net	2,619,593	26,196	28,410,545	-	-	-	-	28,436,741
Restricted stock issued	18,858	189	(189)	-	-	-	-	-
Restricted stock compensation, net	(29,543)	(296)	262,405	-	-	-	-	262,109
Shares tendered for withholding taxes	-	-	(192,161)	(1,804)	(5,863)	-	-	(198,024)
Options:								
Exercised	5,528	55	(55)	-	-	-	-	-
Stock option compensation	-	-	122,115	-	-	-	-	122,115
Warrants exercised	253,161	2,532	(2,532)	-	-	-	-	-
Comprehensive loss	-	-	-	-	-	-	(175,447)	(175,447)
Net loss	-	-	-	-	-	(7,843,797)	-	(7,843,797)
Balance at June 30, 2020	**20,194,832**	**$ 201,948**	**$ 124,143,171**	**(33,290)**	**$ (150,919)**	**$ (84,428,349)**	**$ (1,028,897)**	**$ 38,736,954**
Common Stock:								
Restricted stock issued	19,124	191	105,561	-	-	-	-	105,752
Restricted stock compensation	-	-	275,985	-	-	-	-	275,985
Options:								
Stock option compensation	-	-	97,535	-	-	-	-	97,535
Comprehensive income	-	-	-	-	-	-	262,094	262,094
Net loss	-	-	-	-	-	(5,538,798)	-	(5,538,798)
Balance at September 30, 2020	**20,213,956**	**$ 202,139**	**$ 124,622,252**	**(33,290)**	**$ (150,919)**	**$ (89,967,147)**	**$ (766,803)**	**$ 33,939,522**

See accompanying notes to condensed consolidated financial statements

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

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

See accompanying notes to condensed consolidated financial statements

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

	September 30,2020	September 30, 2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	**$ 26,122,815**	$ 29,423,872
Cash paid to suppliers and employees	**(37,776,303)**	(35,185,776)
Cash paid for operating leases	**(797,482)**	(474,150)
Cash paid for finance leases	**(14,762)**	(4,033)
Interest and taxes, net	**(1,681,155)**	(158,120)
Net cash used in operating activities	**(14,146,887)**	(6,398,207)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Patent application costs	**(181,417)**	(346,663)
Acquisition of and deposits on fixed assets	**(3,000,763)**	(2,568,244)
Acquisitions	**-**	145,760
Net cash used in investing activities	**(3,182,180)**	(2,769,147)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of stock, net	**28,436,741**	-
Proceeds from issuance of long-term debt, net	-	18,850,000
Stimulus package loan	**2,978,315**	-
Payment of stimulus package loan	**(2,978,315)**	-
Payments of tax withholding on stock award	**(348,944)**	-
Payments on debt issuance costs	-	(186,313)
Payments on note payable	**(180,249)**	(136,232)
Payments on finance leases	**(37,166)**	(9,851)
Net cash provided by financing activities	**27,870,382**	18,517,604
Effect of exchange rate changes on cash	**(125,214)**	(6,909)
INCREASE IN CASH AND CASH EQUIVALENTS	**10,416,101**	9,343,341
Cash and cash equivalents - beginning of the period	**18,271,352**	12,524,551
Cash and cash equivalents - end of the period	**$ 28,687,453**	$ 21,867,892
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net loss	**$ (18,382,144)**	$ (9,786,218)
Adjustments:		
Depreciation and amortization	**2,057,275**	1,666,675
Benefit from deferred tax liability	**(301,000)**	(402,639)
Provision of doubtful accounts	**214,210**	-
Non-cash inventory changes	**2,530,444**	-
Share based compensation	**824,345**	1,230,966
Changes in assets and liabilities:		
Accounts receivable	**138,827**	1,995,986
Inventories	**(5,295,899)**	(558,122)
Prepaid expenses and other current assets	**(314,460)**	103,883
Deposits and other assets	**80,873**	(20,608)
Accounts payable and accrued liabilities	**559,888**	(442,725)
Deferred revenue	**3,740,754**	(185,405)
Net cash used in operating activities	**$ (14,146,887)**	$ (6,398,207)
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	**$ 472,651**	$ 430,000

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2020
(Unaudited)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. (“Chembio”) and its subsidiaries (collectively with Chembio, the “Company”) develop and commercialize point-of-care rapid tests used for the detection and diagnosis of infectious diseases, including COVID-19, sexually transmitted disease, and fever and tropical disease. Coupled with the Company's extensive scientific expertise, its novel DPP technology offers broad market applications beyond infectious disease. Chembio’s products are sold globally, directly and through distributors, to hospitals and clinics, physician offices, clinical laboratories, public health organizations, government agencies, and consumers 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 has been expanding its product portfolio based upon its proprietary DPP technology platform that provides high-quality, rapid diagnostic results in 15 to 20 minutes using a small drop of blood from the fingertip or alternative samples. Through advanced multiplexing, the DPP platform can detect up to eight, distinct test results from a single patient sample, which can deliver greater clinical value than other rapid tests. For certain applications, Chembio’s easy-to-use, highly portable, battery-operated DPP Micro Reader optical analyzer then reports accurate results in approximately 15 seconds, making it well-suited for decentralized testing where real-time results enable patients to be clinically assessed while they are still on-site. Objective results produced by the DPP Micro Reader can reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many rapid tests.

All DPP tests are developed and manufactured in the United States and are the subject of a range of domestic and global patents and patents pending.

During the nine months ended September 30, 2020, the Company refocused its business strategy on the development and commercialization of the DPP COVID-19 IgM/IgG System, which consists of a new serological test for COVID-19 and a Micro Reader analyzer. In the nine months ended September 30, 2020, the Company developed, received regulatory approval in the US, Brazil and Europe, and commercialized the DPP COVID-19 IgM/IgG System, which provided numerical readings for both IgM and IgG levels of antibodies to the virus, and began developing its strategy for a portfolio of products both related to and expanding beyond COVID-19. On June 16, 2020, the U.S. FDA Food and Drug Administration (the "FDA") revoked the Company’s Emergency Use Authorization ("EUA") for the DPP COVID-19 System in the U.S., and the Company immediately began developing a revised version. The Company submitted an application for EUA to the FDA for its new rapid antibody test system, DPP SARS-CoV-2 IgM/IgG on September 8, 2020.

On July 6, 2020, the Company received a $628,071 grant from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, Division of Research Innovation and Ventures ("BARDA") to assist the Company in developing a COVID-19 point-of-care antigen system using Chembio’s proprietary DPP technology and submitting an application for EUA to the FDA for the system. On October 15, 2020, Chembio submitted the EUA application for the DPP SARS-CoV-2 Antigen test system, which was designed to detect SARS-CoV-2 antigens in only 20 minutes. The DPP SARS-CoV-2 Antigen test system consists of a DPP SARS-CoV-2 Antigen test cartridge, a DPP Micro Reader optical analyzer and a minimally-invasive nasal swab.

In addition to its DPP COVID-19 rapid test products, the Company has a broad portfolio of infectious disease products, which it expects to generate a diminished amount of revenue for the foreseeable future both due to the impact of the global COVID-19 pandemic and while it focuses on the development, manufacture, and commercialization of DPP COVID-19 products. Through Research & Development (“R&D”) Services, the Company is developing tests in collaboration with Takeda Pharmaceutical Company Limited.

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.

Through R&D Services, the Company develops tests for third parties using its DPP platform and, in limited cases, other platforms in projects that the Company believes have the potential to create value for the rest of its business. In addition, the Company routinely enters into arrangements with governmental and non-governmental organizations for the funding of certain 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 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 Chembio’s Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the SEC.

The Company’s future working capital needs will depend on many factors, including the rate of its business and revenue growth, the timing of its continuing automation of U.S. manufacturing, and the timing of its investment in research and development as well as sales and marketing. If the Company is unable to increase its revenues and manage its expenses in accordance with its operating plan, it may need to reduce the level or slow the timing of the growth plans contemplated by its operating plan, which would likely curtail or delay the growth in its business contemplated by its operating plan and could impair or defer its ability to achieve profitability and generate cash flow, or to seek to raise additional funds through debt or equity financings, strategic relationships, or other arrangements.

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 September 30, 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, asset impairments, recognition of revenue including variable consideration and 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.

(c) Fair Value of Financial Instruments:

The carrying values for cash and cash equivalents, accounts receivable, accounts payable, 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 $21.0 million and $16.0 million as of September 30, 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 $18.0 million) and $20.0 million (carrying value of $17.6 million) as of September 30, 2020 and December 31, 2019, respectively, is a Level 2 fair value measurement under the hierarchy, and the carrying value approximates fair value.

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, and include restricted cash of $2.3 million and $0 as of September 30, 2020 and December 31, 2019, respectively.

The Company is contractually obligated to maintain the restricted cash balance on deposit with a bank as security for the bank's issuance of a guarantee on behalf of the Company for its performance under purchase orders from and related advance payments by a customer. The Company expects that the restriction will be released within the next twelve months.

(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) 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 nine months ended September 30, 2020 or 2019.

(h) 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.

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 and returns. 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, market events and trends, and the specific facts and circumstances of each arrangement. The transaction price, which includes variable consideration reflecting the impact of discounts, allowances and returns 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 revenue and 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 licensees.

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, which 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, is also recognized ratably.

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					
	September 30, 2020			September 30, 2019		
	Exchange Transactions	**Non-Exchange Transactions**	**Total**	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	**$ 8,406,457**	**$ -**	**$ 8,406,457**	$ 8,510,629	$ -	$ 8,510,629
R&D and grant revenue	**1,444,724**	**209,776**	**1,654,500**	880,458	91,522	971,980
License and royalty revenue	**211,521**	**-**	**211,521**	238,330	-	238,330
	$ 10,062,702	**$ 209,776**	**$ 10,272,478**	$ 9,629,417	$ 91,522	$ 9,720,939

	For the Nine Months Ended					
	September 30, 2020			September 30, 2019		
	Exchange Transactions	**Non-Exchange Transactions**	**Total**	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	**$ 17,914,623**	**$ -**	**$ 17,914,623**	$ 23,381,906	$ -	$ 23,381,906
R&D and grant revenue	**3,546,385**	**209,776**	**3,756,161**	2,272,454	1,255,579	3,528,033
License and royalty revenue	**572,450**	**-**	**572,450**	703,352	-	703,352
	$ 22,033,458	**$ 209,776**	**$ 22,243,234**	$ 26,357,712	$ 1,255,579	$ 27,613,291

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		For the Nine Months Ended	
	September 30, 2020	September 30, 2019	**September 30, 2020**	September 30, 2019
Africa	**$ 1,874,518**	$ 1,250,063	**$ 3,310,603**	$ 6,009,103
Asia	**168,052**	505,379	**650,659**	746,025
Europe & Middle East	**2,887,209**	1,629,965	**6,698,382**	4,880,744
Latin America	**4,618,560**	4,296,903	**7,515,523**	9,981,874
United States	**724,139**	2,038,629	**4,068,067**	5,995,545
	$ 10,272,478	$ 9,720,939	**$ 22,243,234**	$ 27,613,291

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 September 30, 2020, the Company reported $3,865,754 in deferred revenue, of which $2.0 million is expected to be recognized during the three months ending December 31, 2020, and the remainder over the next 12 months.

(i) Inventories:

Inventories consisted of the following at:

	September 30, 2020	December 31, 2019
Raw materials	**$ 6,633,884**	$ 2,901,319
Work in process	**2,180,108**	793,343
Finished goods	**3,549,494**	5,903,368
	$ 12,363,486	$ 9,598,030

(j) 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 nine months ended September 30, 2020 and 2019 reflected the potential dilution from the exercise or conversion of other securities into common stock, if dilutive.

There were 634,851 and 650,093 restricted shares awards outstanding as of September 30, 2020 and 2019, respectively, that were not included in the calculation of diluted income per share for the three and nine months ended September 30, 2020 and 2019, because their effect would have been anti-dilutive. There were 950,997 and 672,472 weighted-average options outstanding as of September 30, 2020 and 2019, respectively, that were not included in the calculation of diluted income per share for the three and nine months ended September 30, 2020 and 2019, respectively, because their effect would have been anti-dilutive.

(k) 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.

(l) 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 September 30, 2020, there were 694,000 options expired, forfeited or exercised, and at September 30, 2020, 56,000 options were outstanding. No Equity Award Units are 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 September 30, 2020, there were 479,375 Equity Award Units expired, forfeited or exercised. At September 30, 2020, 299,564 Equity Award Units were outstanding, and 0 Equity Award Units are available to be issued under the SIP14. Following the approval of the 2019 Plan (defined below), any Equity Award Units outstanding under the SIP14 remain subject to and be paid under the SIP14, and any shares subject to outstanding awards under the SIP14 that expire, terminate, or are surrendered or forfeited for any reason without issuance of shares automatically become available for issuance under the 2019 Plan.

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, are 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 units, or other stock-based awards 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 September 30, 2020, 489,294 2019 Equity Units has been exercised or forfeited. At September 30, 2020, 1,230,286 2019 Equity Units were outstanding, and 1,311,096 2019 Equity Units were available to be awarded under the 2019 Plan.

(m) Stock-Based Compensation:

The fair value of restricted stock and performance/restricted stock unit awards are determined on the date of grant or the date of issuance, as applicable. Stock-based compensation expense for stock options is calculated using the Black-Scholes valuation model. Stock based compensation is reduced for actual forfeitures in the period in which the forfeiture occurs and generally recognized on a straight-line basis over the service period of the grant. During the three and nine months ended September 30, 2020, 16,314 and 486,488 shares of restricted stock were forfeited, respectively. During the three and nine months ended September 30, 2020, 83,127 and 123,127 options were forfeited, respectively.

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	**2020**	2019
Cost of product sales	**$ -**	$ 2,691	**$ 6,300**	$ 8,479
Research and development expenses	**126,333**	56,251	**281,070**	172,346
Selling, general and administrative expenses	**350,871**	447,646	**960,959**	1,050,141
Severance and related costs	**-**	-	**(423,984)**	-
	$ 477,204	$ 506,588	**$ 824,345**	$ 1,230,966

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

	For the Nine Months Ended September 30, 2020
Expected term (in years)	6.3
Expected volatility	45.37%
Expected dividend yield	0.00%
Risk-free interest rate	1.33%

The following table provides stock option activity for the nine months ended September 30, 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**	**3 years**	**$ 285,925**
Granted	702,499	2.50		-
Exercised	(36,000)	6.30		95,976
Forfeited/expired/cancelled	(358,127)	2.44		-
Outstanding at September 30, 2020	**950,997**	**$ 4.09**	**5 years**	**$ -**
Exercisable at September 30, 2020	**205,583**	**$ 7.59**	**3 years**	**$ -**

The following table summarizes information about stock options outstanding at September 30, 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	636,364	6.46	$ 2.36	$ -	-	$ -	$ -
$2.8 to $4.59999	-	-	-	-	-	-	-
$4.6 to $6.39999	59,883	3.42	5.56	-	30,000	5.51	-
$6.4 to $8.19999	207,875	3.30	7.31	-	147,458	7.28	-
$8.2 to $12	46,875	2.85	11.45	-	28,125	11.45	-
Total	950,997	5.40	$ 4.09	$ -	205,583	$ 7.59	$ -

As of September 30, 2020, there was $775,947 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 2.35 years. The total fair value of shares vested during the nine months ended September 30, 2020 and 2019 was $172,145 and $295,412, respectively.

The following table summarizes information about restricted stock, restricted stock units and performance stock units outstanding as of September 30, 2020:

	Number of Shares & Units	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2019	545,986	$ 7.47
Granted	642,081	2.68
Vested	(66,728)	3.62
Forfeited/expired/cancelled	(486,488)	6.43
Outstanding at September 30, 2020	**634,851**	**$ 3.43**

As of September 30, 2020, there was $1,391,802 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 1.94 years.

(n) 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 was as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	**2020**	2019
Africa	**$ 1,874,518**	$ 1,250,063	**$ 3,310,603**	$ 6,009,103
Asia	**168,052**	505,379	**650,659**	746,025
Europe & Middle East	**1,451,486**	1,027,147	**3,360,648**	2,946,813
Latin America	**4,618,560**	4,296,904	**7,515,523**	9,981,874
United States	**293,841**	1,431,136	**3,077,190**	3,698,091
	$ 8,406,457	$ 8,510,629	**$ 17,914,623**	$ 23,381,906

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

	September 30, 2020	December 31, 2019
Asia	**$ 342,485**	$ 393,299
Europe & Middle East	**161,173**	165,029
Latin America	**12,512**	60,527
United States	**7,516,942**	5,314,714
	$ 8,033,112	$ 5,933,569

(o) Accounts Payable and Accrued Liabilities:

Accounts payable and accrued liabilities consisted of:

	September 30, 2020	December 31, 2019
Accounts payable – suppliers	**$ 3,586,917**	$ 3,144,098
Accrued commissions and royalties	**511,110**	931,760
Accrued payroll	**274,218**	231,753
Accrued vacation	**488,002**	410,199
Accrued bonuses	**575,479**	215,000
Accrued severance	**145,096**	-
Accrued expenses – other	**977,960**	593,433
TOTAL	**$ 6,558,782**	$ 5,526,243

(p) 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	(176,011)
Balance at September 30, 2020	$ 5,696,679

Intangible assets consisted of the following:

		September 30, 2020			December 31, 2019		
	Weighted Average Remaining Useful Life	**Cost**	**Accumulated Amortization**	**Net Book Value**	Cost	Accumulated Amortization	Net Book Value
Intellectual property	**5**	**$ 1,586,043**	**$ 420,818**	**$ 1,165,225**	$ 1,418,681	$ 299,232	$ 1,119,449
Developed technology	**5**	**2,009,962**	**487,637**	**1,522,325**	1,922,682	266,550	1,656,132
Customer contracts/relationships	**7**	**1,270,152**	**380,277**	**889,875**	1,325,521	270,902	1,054,619
Trade names	**7**	**111,568**	**40,498**	**71,070**	114,946	30,794	84,152
		$ 4,977,725	**$ 1,329,230**	**$ 3,648,495**	$ 4,781,830	$ 867,478	$ 3,914,352

Intellectual property, developed technology, customer contracts/relationships and trade names are amortized over 10, 7, 10, and 11 years, respectively. Amortization expense for the nine months ended September 30, 2020 and 2019 was $149,222 and $378,691, respectively. Amortization expense, subject to changes in currency exchange rates, is expected to be approximately $598,000 per year from 2020 through 2024, and total $1,107,056 for all remaining years combined.

(q) 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 and nine months ended September 30, 2020 was 1.9% and 1.7%, compared to the effective tax rate of 0.5% and 3.9% for the three and nine months ended September 30, 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.

(r) 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.

(s) 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.

(t) Acquisition Costs:

Acquisition costs include period expenses, primarily professional services, related to acquisition activities. For the nine months ended September 30, 2020 and 2019, the Company recognized $63,497 and $395,612 in acquisition costs related to its acquisition of Orangelife Comercio e Industria Ltda. ("Orangelife") and opTricon GmbH, respectively.

(u) 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 became effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. 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 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 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 2020-06 - Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity

On August 5, 2020, the FASB issued ASU 2020-06, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The ASU is part of the FASB's simplification initiative, which aims to reduce unnecessary complexity in U.S. GAAP. ASU 2020-06 simplifies the guidance in U.S. GAAP on the issuer's accounting for convertible debt instruments, requires entities to provide expanded disclosures about "the terms and features of convertible instruments" and how the instruments have been reported in the entity's financial statements. It also removes from ASC 815-40-25-10 certain conditions for equity classification and amends certain guidance in ASC 260 on the computation of EPS for convertible instruments and contracts on an entity's own equity. An entity can use either a full or modified retrospective approach to adopt the ASU's guidance. The ASU's amendments are effective for smaller public business entities fiscal years beginning after December 15, 2023. The Company is currently evaluating the impact of adopting ASU 2020-06 on its consolidated financial statements.

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.

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.

(w) Severance, restructuring and other related costs:

During the nine months ended September 30, 2020, the Company recognized $0.7 million in net severance expenses related to the departure of Chembio's former chief executive officer and the elimination of certain positions as part of its multi-faceted expense reduction program to reduce operating expenses. The Company undertook actions to adjust the size and composition of the organization, including by removing positions that were non-essential in light of its new business strategy, and to remove other expenses, all of which the Company expects will provide savings throughout, and after, 2020.

In light of market dynamics, the Company retrenched its Malaysian operations, including the termination of employment of its Malaysian workforce. The Company will maintain its Malaysian subsidiary and sustain the product registrations that were obtained throughout southeast Asia, with the benefit of having that entity and the WHO prequalification certified facility.

Based on these activities, the Company took restructuring actions totaling $0.4 million to realign and resize its production capacity and cost structure. All expenses have been paid as of September 30, 2020.

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 that 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 the Company's products 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 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 estimated fair value of the fixed assets based on the net book value of Orangelife, which approximated fair value. The estimated fair value of the trade name, customer contracts/relationships and contingent earnouts were based on discounted cash flows using management estimates.

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 is 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 unaudited 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 – COMMITMENTS, CONTINGENCIES, AND CONCENTRATIONS:

(a) Concentrations:

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

	For the Three Months Ended				For the Nine Months Ended				Accounts Receivable as of	
	September 30, 2020		September 30, 2019		**September 30, 2020**		September 30, 2019		**September 30, 2020**	Dec. 31, 2019
	Sales	**% of Sales**	Sales	% of Sales	**Sales**	**% of Sales**	Sales	% of Sales		
Customer 1	**$ 4,226,040**	**50.3%**	$ 3,966,142	46.6%	**$ 6,523,416**	**36.4%**	$ 10,012,644	42.8%	**$ 1,622,866**	$ 941,962
Customer 2	**$ 1,071,513**	**12.7%**	$ -	-	**$ -**	-	$ -	-	**$ -**	$ -
Customer 3	**$ 963,671**	**11.5%**	$ -	-	**$ -**	-	$ -	-	**$ 17,510**	$ -

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

The following table discloses purchases the Company made form vendors in excess of 10% of the Company's net purchases for the periods indicated:

	For the Three Months Ended				For the Nine Months Ended				Accounts Payable as of	
	September 30, 2020		September 30, 2019		**September 30, 2020**		September 30, 2019		**September 30, 2020**	Dec. 31, 2019
	Purchases	**% of Purchases**	Purchases	% of Purchases	**Purchases**	**% of Purchases**	Purchases	% of Purchases		
Vendor 1	**$ 501,562**	**15.4%**	$ -	-	**$ 1,600,916**	**12.3%**	$ -	-	**$ 178,395**	$ -

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 FDA 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 September 30, 2020, the Company had 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 September 30, 2020:

2020	$ 191,250
2021	765,000
2022	400,000

(d) Pension Plan:

The Company has a 401(k) plan established for its 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. For the nine months ending September 30, 2020 and 2019, matching contribution expenses totaled $71,154, and $74,600, respectively.

(e) Leases:

The Company leases facilities in New York, Germany, Malaysia, and Brazil, and certain equipment.

The Company's facility leases generally include optional renewal periods. Upon entering into a new facility 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 facility 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.

The Company's facility leases generally include fixed rental payments with defined annual increases. While certain of the Company's facility leases are gross leases, the majority of the Company's facility 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 September 30,		**Nine Months Ended September 30,**	
	2020	2019	**2020**	2019
Operating lease expense	**$ 405,989**	$ 425,757	**$ 1,258,797**	$ 1,108,016
Finance lease cost				
Amortization of right-of-use assets	**$ 15,571**	$ 11,686	**$ 42,657**	$ 11,686
Interest on lease liabilities	**5,395**	4,033	**14,762**	4,033
Total finance lease expense	**$ 20,966**	$ 15,719	**$ 57,419**	$ 15,719

Supplemental cash flow information related to leases was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	**2020**	2019
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows for operating leases	**$ 340,205**	$ 158,050	**$ 797,482**	$ 474,150
Operating cash flows for finance leases	**5,395**	4,033	**14,762**	4,033
Financing cash flows for finance leases	**13,587**	9,851	**37,166**	9,851
Right-of-use assets obtained in exchange for lease obligations:				
Operating leases	**-**	-	**-**	6,697,896
Finance leases	**$ 5,486**	$ -	**$ 73,600**	$ 222,036

Supplemental balance sheet information related to leases was as follows:

	September 30, 2020	September 30, 2019
Finance Leases		
Finance lease right of use asset	**$ 315,153**	$ 233,722
Accumulated depreciation	**(66,261)**	(11,686)
Finance lease right of use asset, net	**$ 248,892**	$ 222,036
Weighted-Average Remaining Lease Term		
Operating leases	**9.1 years**	9.9 years
Finance leases	**4.0 years**	4.8 years
Weighted-Average Discount Rate		
Operating leases	**8.60%**	8.51%
Finance leases	**8.18%**	7.00%

During the three months ended March 31, 2019, the Company executed an operating sublease related to its former Holbrook, New York facility. The sublease ran conterminously with the base lease, for which the Company was primarily responsible until the end of the lease term in 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 5 - Long Term Debt.

Maturities of lease liabilities were as follows:

	September 30, 2020		September 30, 2019	
	Operating Leases	**Finance Leases**	Operating Leases	Finance Leases
2019 and 2020	**$ 342,462**	**$ 19,226**	$ 158,050	$ 13,884
2021	**1,209,787**	**76,904**	813,443	55,536
2022	**1,057,757**	**76,904**	998,071	55,536
2023	**1,026,272**	**76,904**	1,026,044	55,536
2024	**1,018,875**	**49,136**	1,011,085	55,536
Thereafter	**5,773,888**	**5,750**	6,792,762	27,767
Total lease payments	**$ 10,429,041**	**$ 304,824**	$ 10,799,455	$ 263,795
Less: imputed interest	**3,269,991**	**46,712**	3,837,507	39,924
Total	**$ 7,159,050**	**$ 258,112**	$ 6,961,948	$ 223,871

(f) Litigation:

Employee Litigation

John J. Sperzel III, 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 Sperzel's attempt to exercise the options following the thirty day period was not valid. Chembio intends to vigorously defend against any claim by Mr. Sperzel that he continues to have a right to exercise any options.

Stockholder Litigation

Putative Stockholder Securities Class Action Litigation

As of November 3, 2020, four purported securities class action lawsuits had been filed by alleged stockholders of Chembio, and were pending, in the United States District Court for the Eastern District of New York:

- *Sergey Chernysh v. Chembio Diagnostics, Inc., Richard L. Eberly, and Gail S. Page*, filed on June 18, 2020, which is referred to as the Chernysh case;
- *James Gowen v. Chembio Diagnostics, Inc., Richard L. Eberly, and Gail S. Page*, filed on June 22, 2020, which is referred to as the Gowen case;
- *Anthony Bailey v. Chembio Diagnostics, Inc. Richard J. Eberly, Gail S. Page, and Neil A. Goldman*, filed on July 3, 2020, which is referred to as the Bailey case; and
- *Special Situations Fund III QP, L.P., Special Situations Cayman Fund, L.P., and Special Situations Private Equity Fund, L.P. v. Chembio Diagnostics, Inc., Richard Eberly, Gail S. Page, Robert W. Baird & Co. Inc. and Dougherty & Company LLC*, filed August 17, 2020, which is referred to as the Special Situations Funds case.

The plaintiffs in each of the cases allege violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 thereunder. The Special Situations Funds complaint also asserts claims under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933 relating to Chembio's May 2020 public offering. The claims asserted in the complaints are based on purportedly false and misleading statements and omissions concerning the performance of the DPP COVID-19 IgM/IgG System. The complaints collectively seek, among other things, an award of damages in an amount to be proven at trial, as well as an award of reasonable costs, including attorneys' fees and expenses, expert fees, pre-judgement and post-judgment interest, and such other relief as the court deems just and proper. The Special Situations Funds complaint also asserts that members of the putative Section 11 class who continue to hold Chembio common stock have the right to rescind their purchases and recover the consideration paid. Chembio and the plaintiffs in the four cases have entered into court-approved stipulations relieving the defendants of the obligation to respond to the complaints in those cases pending the designation of a lead plaintiff pursuant to the Private Securities Litigation Reform Act of 1995. Two motions for appointment as lead plaintiff are currently pending for determination by the court; no date has been set for a hearing on any of those motions.

On July 1, 2020, an alleged stockholder of Chembio filed a purported class action lawsuit in the United States District Court for the Eastern District of New York captioned *Ken Hayes v. Chembio Diagnostics, Inc., Richard L. Eberly, Gail S. Page, Katherine L. Davis, Mary Lake Polan, and John G. Potthoff*, which is referred to as the Hayes case. The Hayes complaint purported to state claims for violations of Section 14(a) of the Exchange Act and Rule 14a-9 thereunder, declaratory relief, and state law claims for breach of fiduciary duty for alleged misstatements of material information in the proxy statement disseminated in advance of Chembio's Annual Meeting of Stockholders held on July 28, 2020. On July 8, 2020, Chembio filed an amended proxy statement correcting, among other things, the issues raised in the Hayes complaint. On July 23, 2020, (a) Chembio and the plaintiff entered into a stipulation to the dismissal of the Hayes action, with prejudice as to the claims of the named plaintiff subject to plaintiff's reservation of the right to apply for an award of attorneys' fees and expenses from Chembio in certain circumstances, and (b) the plaintiff filed a notice dismissing his claims, with prejudice, as to the individual defendants. On July 27, 2020, the court entered an order closing the Hayes case and providing that plaintiff would have until September 28, 2020 to move to reopen the case if the attorneys' fee issue had not been resolved. Chembio subsequently resolved the attorneys' fee issue amicably with the plaintiff.

Putative Stockholder Derivative Litigation

On September 11, 2020, a putative stockholder derivative action was filed purportedly on Chembio's behalf in the United States District Court for the Eastern District of New York captioned *Karen Wong, derivatively on behalf of Chembio Diagnostics, Inc., Plaintiff v. Richard L. Eberly, Gail S. Page, Neil A. Goldman, Javan Esfandiari, Katherine L. Davis, Mary Lake Polan, and John G. Potthoff, Defendants, and Chembio Diagnostics, Inc., Nominal Defendant*, which is referred to as the Wong complaint. The Wong complaint purports to assert a claim for violation of Section 14(a) of the Exchange Act and Rule 14a-9 thereunder based on ostensibly false and misleading statements and omissions in the proxy statement disseminated in advance of Chembio's 2020 Annual Meeting of Stockholders concerning Chembio's rapid COVID-19 antibody tests. The Wong complaint also asserts claims against the individual defendants for purported breaches of fiduciary duties owed to Chembio and unjust enrichment.

The Wong complaint requests a declaration that the individual defendants have breached or aided and abetted the breach of their fiduciary duties to Chembio, an award of damages to Chembio, restitution, and an award of the plaintiff's costs and disbursements in the action, including reasonable attorneys' and experts' fees, costs and expenses, and improvements to Chembio's corporate governance and internal procedures. Pursuant to a stipulation by which the individual defendants in the Wong action agreed to waive service of process, the court ordered that the time for defendants to answer or otherwise respond to the complaint be extended to November 19, 2020. The parties subsequently entered into a stipulation for a stay of proceedings in the Wong action pending final disposition of motions to dismiss the pending putative class action litigation, subject to certain conditions. The court entered an order granting the requested stay on November 3, 2020.

NOTE 5 – 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 note payable was fully repaid during the three months ended September 30, 2020.

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 June 30, 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.

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.

As of September 30, 2020, the loan balance, net of unamortized discounts and debt issuance costs, was $18.0 million, and Chembio was in compliance with its cash balance loan covenant, but not in compliance with its revenue loan covenant. Chembio obtained a written waivers from the Lender with respect to Chembio’s failure to meet the revenue loan covenant for the three months ended June 30, 2020 and three months ended September 30, 2020. 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 6 – 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 was exercisable for cash or on a net, or "cashless," basis, and the exercise price of the Warrant was 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 and the balances recorded in the Company's Stockholders' Equity for the Warrant, net of allocated issuance costs, was $1.2 million.

During the nine months ended September 30, 2020, the Warrant was exercised in full on a cashless basis and the Lender received a total of 253,161 shares of common stock from the net exercise.

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 unaudited 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 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, Part II, Item1A. "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020, as filed with the Securities and Exchange Commission on May 4, 2020, Part II, Item1A. "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020, as filed with the Securities and Exchange Commission on August 7, 2020 and Part II, Item1A. "Risk Factors" of this report for a discussion of factors that could cause our actual results to differ materially from our expectations.

Overview of Nine Months Ended September 30, 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 or alternative sample types 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 nine months ended September 30, 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.

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

- We acquired three regulatory approvals of the DPP COVID-19 IgM/IgG 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 IgM/IgG System to help identify persons who have recovered from COVID-19 IgM/IgG, 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 IgM/IgG 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 commercial shipments of the DPP COVID-19 IgM/IgG System to customers in the United States.
- We strengthened our balance sheet by raising $28.4 million in a secondary public offering in May 2020.
- We established a non-exclusive distribution relationship with Thermo Fisher Scientific's healthcare channel for the distribution of Chembio's DPP COVID-19 IgM/IgG System in the U.S.

In addition, in June 2020 our DPP platform received further U.S. regulatory approval upon the FDA's granting of a 510(k) for our DPP Zika IgM System, which includes both a test for Zika IgM antibodies and a Micro Reader. The development and regulatory submission of the DPP Zika IgM System was funded by the Biomedical Advanced Research and Development Authority, part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (BARDA). The DPP Zika IgM System had previously received an EUA from the FDA. This was the first 510(k) that includes our Micro Reader, which is the same device used with DPP COVID-19 IgM/IgG Systems (as such term is defined below) and DPP HIV-Syphilis Systems, the latter which received approval from the FDA for a PMA at the beginning of October 2020.

However, later in June 2020 the FDA revoked our EUA for the DPP COVID-19 IgM/IgG System, which we refer to as the Revocation, after which we focused on revising the COVID-19 System for antibodies (serology) in anticipation of resubmitting it to the FDA for an EUA. Additionally, as announced in early July 2020, we were developing the DPP SARS-CoV-2 Antigen system, for antigen detection, and together with the DPP SARS-CoV-2 IgM/IgG system, the DPP SARS-CoV-2 Systems, with the support of a $0.6 million award from the Biomedical Advanced Research and Development Authority or BARDA, which is part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services. The DPP SARS-CoV-2 Antigen system consists of a DPP SARS-CoV-2 Antigen test cartridge, a DPP Micro Reader and a minimally-invasive nasal swab.

On September 8, 2020, we submitted our revised DPP SARS-CoV-2 IgM/IgG System to the FDA for an EUA. On October 15, 2020, we submitted our DPP SARS-CoV-2 Antigen system to the FDA for an EUA.

The diminished focus on our existing product portfolio and extensive economic disruption caused by the COVID-19 pandemic, exacerbated by the Revocation in June 2020 and the related impact on product returns and our manufacturing operations, was reflected in our results for the nine months ended September 30, 2020 as compared to the prior year period, as total revenue decreased 19% to $22.2 million and product sales decreased 23% to $17.9 million.

In order to address challenging economic conditions and accelerate implementation of our new business strategy, we are executing 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 $28.7 million at September 30, 2020, compared to $18.3 million at December 31, 2019.

DPP COVID-19 Products

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 and was awarded a 510(k) in June 2020 as discussed above. 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 the presence of antibodies indicative of recent infection or past infection 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 serology and antigen tests for COVID-19 illustrates the DPP platform's applicability to new and emerging infectious diseases.

During the nine months ended September 30, 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 IgM/IgG 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 IgM/IgG System.

During the second quarter of 2020, prior to the Revocation, we focused on responding to a substantial number of commercial leads for the DPP COVID-19 IgM/IgG System, establishing and servicing qualified new customers, building a distributor relationship with Thermo Fisher Scientific's healthcare channel, and manufacturing product to meet demand.

During the third quarter of 2020, we focused on completing the submission of our new DPP SARS-CoV-2 IgM/IgG system to the FDA for EUA, and on the development of our DPP SARS-CoV-2 Antigen system, which was submitted to the FDA for EUA on October 15, 2020.

The DPP SARS-CoV-2 IgM/IgG 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. As the IgG antibody levels increase, the IgM antibody levels will 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 SARS-CoV-2 IgM/IgG 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. Our portable Micro Reader analyzer then reports accurate results in approximately 15 seconds. Objective results produced by the Micro Reader reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many other serological tests. The DPP platform is portable, provides accurate results from fingerstick blood or other samples, and can detect multiple biomarkers simultaneously and discretely. At the same time, the easy-to-use testing workflow is scalable. Clinicians can run multiple tests at the same time because cartridges are only required to be inserted in the Micro Reader for 15 seconds to obtain results following the 15-minute test incubation period.

The DPP SARS-CoV-2 Antigen System was submitted for an application for EUA from the FDA with the support of BARDA on October 15, 2020. It consists of a DPP SARS-CoV-2 Antigen Assay and Micro Reader and minimally invasive nasal swab to detect SARS-CoV-2 antigens in approximately 20 minutes. Antigen tests are important in the overall response against COVID-19 as they can be provided on a decentralized basis, closer to the point of care, at lower cost and with faster results than alternative molecular test options.

Key Developments

While we have been focusing on tests for COVID-19 for a relatively short time, we have achieved several key developments that we believe demonstrate the potential utility and marketability of the DPP SARS-CoV-2 Systems.

Shipments to Brazil. In March 2020 we received a $4 million purchase order for DPP COVID-19 IgM//IgG System 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 IgM/IgG 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 IgM/IgG 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 many 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 IgM/IgG 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 received Investigational New Drug approval from the FDA 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 was used to confirm that patients enrolled in the study were infected with COVID-19 and had 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 IgM/IgG System to U.S. customers late in April 2020 and continued to ship product until receipt of the Revocation.

Revocation of EUA. On June 16, 2020, the FDA stated that it was revoking our EUA for the DPP COVID-19 IgM/IgG System, based in part on the performance of our system in the NCI's methodology for the evaluation of COVID-19 serology tests. The FDA's original letter of authorization for the EUA required our participation in a National Institutes of Health/National Cancer Institute (NCI) study. However, the letter stated that the NCI submission and evaluation would only be used to revise our product labeling. After we learned of the results of the NCI study -- but before the FDA took action with respect to the EUA -- we engaged in a number of communications with the FDA about the results of the NCI study and other topics.

Despite the Revocation, we continue to be excited about our opportunities in the market for DPP SARS-CoV-2 Systems, as follows:

- We stand behind the real-world clinical data, including that which we submitted to the FDA, in connection with the DPP COVID-19 IgM/IgG System EUA, and
- The FDA's recent identification of the performance criteria for COVID-19 serology tests clarified our path forward in working to revise the DPP SARS-CoV-2 IgM/IgG system to meet or exceed current FDA requirements.

Regarding the real-world clinical data for our original DPP COVID-19 IgM/IgG System, including the data we submitted to the FDA in connection with our system's EUA:

- We acknowledge the policy change that led the FDA to create performance criteria and rely on the NCI study for those purposes.
- On April 15, 2020, the DPP COVID-19 IgM/IgG System was granted an EUA. Subsequently, the FDA announced the adoption of a performance review process based in part on a NCI methodology for the evaluation of COVID 19 serology tests. The NCI report acknowledges that this process, which evaluates COVID-19 serology test sensitivity and specificity using a panel of pre-selected samples, may not be indicative of either performance in the real-world or performance of finger stick blood as used in the Chembio system.

- In addition, the NCI study does not invalidate the real-world clinical data that we submitted to the FDA, including that compiled by Chembio as well as independent evaluators at two university medical centers.
- The importance of our system's real-world performance has been highlighted by a number of customers.

Revised Serology Test EUA Submission

On September 8, 2020, we submitted an application for EUA to the FDA for the new DPP SARS-CoV-2 IgM/IgG system. On September 14, the FDA notified us that the System could not follow the FDA's Notification pathway. The DPP SARS-CoV-2 IgM/IgG system is in the FDA's queue for review.

Antigen Test EUA Submission

On October 15, 2020, we submitted the DPP SARS-CoV-2 Antigen system for an application for EUA from the FDA.

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 SARS-CoV-2 Systems are 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 SARS-CoV-2 Systems are portable, uses fingerstick blood sample, nasal swab or other samples, can produce accurate results, and requires approximately 15 minutes for test processing (or 20 minutes in the case of our DPP SARS-CoV-2 Antigen system) 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 IgM/IgG 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 Systems. 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 categorized 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 many 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 SARS-CoV-2 Systems, based on the DPP SARS-CoV-2 Systems' portability, accuracy, speed, cost-effectiveness and ease of use.

If we are granted an EUA for the revised DPP SARS-CoV-2 IgM/IgG system or the DPP SARS-CoV-2 Antigen system and, until the FDA authorized waived status under CLIA, we will focus our sales efforts on target hospitals, moderately complex physician office labs, urgent care clinics 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 SARS-CoV-2 Systems, as our legacy products. As described above under "—DPP SARS-CoV-2 Systems," in the nine months ended September 30, 2020 we continued the process of shifting substantially all of our resources to the development and commercialization of the DPP SARS-CoV-2 Systems. As a result, and as illustrated by our results for the nine months ended September 30, 2020, we expect to generate a diminished amount of revenue from our legacy products for the foreseeable future, while we continue to focus on the regulatory approval, manufacture, and commercialization of the DPP SARS-CoV-2 Systems. Thereafter, we intend to recommence the development, marketing, manufacture, and sale of the legacy product portfolio consistent with market demand.

On October 1, 2020, the FDA approved the Premarket Approval (PMA) application for the DPP HIV-Syphilis System. The system includes the DPP HIV-Syphilis assay, a multiplex single-use test, and the DPP Micro Reader optical analyzer, and we began offering it in the United States immediately.

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

- enhanced sensitivity and specificity;
- advanced multiplexing; and
- when used with our Micro Reader, accurate 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 COVID-19 IgM/IgG System		✓
DPP HIV 1/2 Assay	✓	✓
DPP HIV-Syphilis System	✓	✓
DPP Syphilis Screen & Confirm Assay		✓
DPP ZCD IgM/IgG System		✓
DPP Dengue NS1 Antigen System		✓
DPP Dengue IgM/IgG System		✓
DPP Zika IgM System	✓	✓
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 recently launched 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 received FDA approval of our PMA on October 2, 2020. When appropriate, 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, Dengue, lassa, leptospirosis, Marburg, Rickettsia and Zika. Though certain of these have not been commercialized, our legacy products include tests using our DPP platform to detect all of the aforementioned fever and tropical diseases, as stand-alone or multiplex tests.

Our investments in these products are attracting international attention. In April 2020, we received a second $1.5 million purchase order from UNICEF for multiplex Zika, Chikungunya and Dengue (DPP ZCD) Systems, including tests and Micro Readers. The orders follow the successful completion of conditions set forth in the previously announced long term arrangement (LTA). Along with the firm purchase commitment of $1.5 million, the LTA includes additional potential purchases of up to $2.0 million, for a total potential amount of up to $3.5 million. Along with the previous UNICEF order for our multiplex Zika IgM/IgG System announced in February 2020, the combined LTAs contemplate up to $7.0 million in potential orders. Shipments under these orders commenced during the quarter ended June 30, 2020 and are scheduled for delivery through 2021.

Our DPP ZCD System can accurately detect three unique viral infections, all of which are transmitted by the same type of mosquito, have similar symptoms and are often associated with co-infections. We believe that testing for these viruses in combination will be critical in addressing these co-circulating pathogens. This novel multiplex test will enhance both surveillance capabilities and clinical response efforts, providing significant advantages over current lab-based tests by allowing healthcare providers to take rapid action.

Our multiplex DPP ZCD System allows simultaneous and discrete detection of antibodies for both active (IgM) and prior exposure (IgG) to Zika, Chikungunya and Dengue viruses. The DPP ZCD System has received approval from ANVISA in Brazil and is CE Marked.

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 approved
DPP Dengue IgM/IgG System	Self-funded	✓	✓	✓	✓	CE and ANVISA
DPP Dengue NS1 Antigen System	Self-funded	✓	✓	✓	✓	CE and ANVISA pending
DPP Chikungunya IgM/IgG System	Self-funded	✓	✓	✓	✓	CE and ANVISA
DPP Zika Chikungunya Dengue IgM/IgG System	Self-funded	✓	✓	✓	✓	CE and ANVISA
DPP Ebola Antigen System	CDC	✓	✓	✓	✓	FDA-EUA
DPP Fever Assay Asia	FIND	✓	✓	✓	✓	
DPP Fever Assay Africa	Paul Allen Foundation	✓	✓	✓		
DPP Fever Assay Malaysia	Self-funded	✓	✓	✓	✓	

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 accurate 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 Systems 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 SARS-CoV-2 Systems. 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 SARS-CoV-2 Systems principally on hospitals, physician offices with moderately complex labs, urgent care clinics 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 SARS-CoV-2 Systems, 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.

To support our commercial efforts and support future growth, we are also adding to our marketing and customer service teams in a manner that is aligned with our growth expectations.

Manufacturing

In April 2020, we initiated a retrenchment of our Malaysian facility that was 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 process of automating some of our manufacturing processes and expanding our manufacturing capacity in the United States. 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 SARS-CoV-2 Systems" above, since February 2020 we have been shifting resources to develop and commercialize the DPP SARS-CoV-2 Systems. Accordingly, and in connection with receipt of an EUA from the FDA for the DPP COVID-19 IgM/IgG 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 IgM/IgG 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 IgM/IgG System, the ultimate duration of which we continue to evaluate, we worked to scale both our manual and automated processes for the assembly of tests for the DPP COVID-19 IgM/IgG System. We have designed, and will seek to implement, a capacity growth plan intended to ramp production. 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 novel 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 Pharmaceutical 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.
- In July 2020, we were selected to conduct a second research and development services program for Takeda utilizing our DPP technology and Micro Reader analyzers.

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	✓	✓			
DPP (undisclosed biomarker)	Takeda	✓				
DPP SARS-CoV-2 Antigen System	BARDA	✓	✓			
COVID-19 Test	LumiraDx	✓	✓			
Infectious Disease Portfolio	LumiraDx	✓	✓			

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 Systems

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 SARS-CoV-2 Systems. 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 antigen 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. In addition, during the time period between the Revocation and resubmission we anticipate for EUA, competitors have gained progress in their commercialization efforts, and customers have gained experience in using competitive product.

We believe we will be able to compete successfully based upon (a) the capabilities and attributes of the DPP SARS-CoV-2 Systems, which can provide, for a competitive price, rapid and accurate test results for IgM and IgG antibodies (in the case of the serology test) or SARS-CoV-2 antigens (in the case of the antigen test) 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 nine months ended September 30, 2020, we implemented a multi-faceted expense reduction program to reduce operating expenses and facilitate profitable growth. 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 SARS-CoV-2 Systems.

Based on these activities, the Company recorded a restructuring charge ranging of $0.4 million during the nine months ended September 30, 2020.

Consolidated Results of Operations

Three Months Ended September 30, 2020 Versus Three Months Ended September 30, 2019

Our results of operations for the three months ended September 30, 2020 and 2019 were as follows (dollars in thousands):

	September 30, 2020		September 30, 2019	
TOTAL REVENUES	**$ 10,272**	**100%**	$ 9,721	100%
OPERATING COSTS AND EXPENSES:				
Cost of product sales	**7,468**	**73%**	6,649	68%
Research and development expenses	**2,352**	**23%**	2,224	23%
Selling, general and administrative expenses	**5,349**	**52%**	4,456	46%
Severance and restructuring costs	**12**	**0%**	-	0%
	15,181		13,329	
LOSS FROM OPERATIONS	**(4,909)**		(3,608)	
OTHER EXPENSE, NET	**(735)**		(196)	
LOSS BEFORE INCOME TAXES	**(5,644)**	**(55)%**	(3,804)	(39)%
Income tax benefit	**105**		21	
NET LOSS	**$ (5,539)**		$ (3,783)	

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during the three months ended September 30, 2020 were $10.3 million, an increase of $0.5 million, or 6%, compared to the three months ended September 30, 2019. As discussed above, in the third quarter, we executed steps to implement our new business model and focus our resources on the development and commercialization of COVID-19 testing products. At the same time, the customers of our legacy infectious disease tests also focused much of their resources on COVID-19 management. Our revenues during the three months ended September 30, 2020 included $2.7 million that was previously not recognized during the second quarter of 2020 due to the hurdle that required a high degree of confidence that it is probable that a significant reversal in revenue would not have occured for shipments of the DPP COVID-19 IgM/IgG System outside the U.S.

The Revocation continued to have a significant negative impact on our product revenues by triggering the recall of unused DPP COVID-19 IgM/IgG Systems from customers in the U.S. during the second quarter of 2020, precluding the sale of the systems within the U.S. during the third quarter of 2020, and also deferring certain customer opportunities for the DPP SARS-CoV-2 Systems outside the U.S.

Gross Product Margin

Cost of product sales is primarily composed of material, labor, manufacturing overhead, depreciation and amortization, and other operating expenses. Gross product margin is net product sales less cost of product sales, and gross product margin percentage is gross product margin as a percentage of net product sales. Gross product margin during the three months ended September 30, 2020 decreased by $0.9 million, or 50%, from the comparable period of 2019. The following schedule calculates gross product margin (dollars in thousands):

	For the Three Months Ended September 30		**Favorable/(Unfavorable)**	
	2020	2019	**$ Change**	**% Change**
Net product sales	**$ 8,406**	$ 8,511	$ (105)	1.2%
Less: Cost of product sales	**(7,468)**	(6,649)	(819)	12.3%
Gross product margin	**$ 938**	$ 1,862	$ (924)	49.6%
Gross product margin percentage	**11.2%**	21.9%		

In 2020 and continuing during the third quarter of 2020 we have invested in developing and offering products that will address the COVID-19 pandemic and which we expect will have average selling prices greater than those of our legacy products. We have also advanced our investment in automation that we believe will reduce our reliance on manual labor and contribute to improved product margins. The $0.9 million decrease in gross product margin from the third quarter of 2019 to the third quarter of 2020 was nearly entirely comprised of unfavorable product margins, principally reflecting the following:

- The Revocation in June 2020 precluded planned sales of COVID-19 IgM/IgG Systems to customers in the United States in both the second and third quarter of 2020 and resulted in the deferral in the third quarter of certain customer opportunities for sales of COVID-19 IgM/IgG Systems outside the United States, which negatively impacted our sales mix as follows: (a) significantly lower sales in the United States, where we have our highest average selling prices, and (b) outside the United States, a higher mix of sales in geographic regions with lower average selling prices;
- We experienced operational inefficiencies, including those triggered by the Revocation and activities related to qualifying automated lines for production of certain products, which resulted in increased cost of product sales as we substantially shifted our production from COVID-19 products to legacy products; and,
- Our recognition of net revenue in the amount of $2.7 million from shipments of DPP COVID-19 IgM/IgG Systems outside the United States that had been deferred from the second quarter, for which the cost of product sales was recorded during the second quarter, offset the above items.

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 September 30		Favorable/(Unfavorable)	
	2020	2019	**$ Change**	**% Change**
Clinical and regulatory affairs	$ 258	$ 333	$ 75	22.5%
Other research and development	2,094	1,891	(203)	10.7%
Total research and development	$ 2,352	$ 2,224	$ (128)	5.8%

The increase in R&D costs for the three months ended September 30, 2020 compared to the three months ended September 30, 2019 was primarily associated with the cost related to the development of the DPP SARS-CoV-2 Systems.

Selling, General and Administrative Expense

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

The $0.9 million, or 20%, increase in selling, general and administrative expense for the three months ended September 30, 2020 compared to the three months ended September 30, 2019 is primarily related to legal costs arising subsequent to the Revocation, offset in part by restructuring cost savings at our Malaysia facility and other areas.

Other (Expense) Income, 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 September 30, 2020 compared to comparable period in 2019 due to interest accruing on a long-term debt agreement that was executed as of September 3, 2019, of which $20 million (carrying value of $18 million) was outstanding at September 30, 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 September 30, 2020, we recognized a tax benefit of $0.1 million related to losses generated by our foreign subsidiaries. As of September 30, 2020 and 2019, our U.S. deferred tax assets included a full valuation allowance.

Nine Months Ended September 30, 2020 versus Nine Months Ended September 30, 2019

The results of operations for the nine months ended September 30, 2020 and 2019 were as follows (dollars in thousands):

	September 30, 2020		September 30, 2019	
TOTAL REVENUES	**$ 22,243**	**100%**	$ 27,613	100%
OPERATING COSTS AND EXPENSES:				
Cost of product sales	**17,513**	**79%**	18,113	66%
Research and development expenses	**6,233**	**28%**	6,543	24%
Selling, general and administrative expenses	**13,903**	**63%**	12,565	46%
Severance and restructuring costs	**1,122**	**5%**	-	0%
Acquisition costs	**63**	**0%**	395	1%
	38,834		37,616	
LOSS FROM OPERATIONS	**(16,591)**		(10,003)	
OTHER EXPENSE, NET	**(2,110)**		(183)	
LOSS BEFORE INCOME TAXES	**(18,701)**	**(84)%**	(10,186)	(37)%
Income tax benefit	**319**		400	
NET LOSS	**$ (18,382)**		$ (9,786)	

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during the nine months ended September 30, 2020 were $22.2 million, a decrease of $5.4 million, or 19% compared to the nine months ended September 30, 2019. As discussed above, in the second quarter, we executed the initial steps to implement our new business model and focus our resources on the development and commercialization of COVID-19 testing products. At the same time, the customers of our legacy infectious disease tests also focused much of their resources on COVID-19 management, and in the United States and other parts of the world, many HIV clinics were closed for meaningful periods of time due to the pandemic, which limited the sale and distribution of our legacy HIV test products. The Revocation had a significant negative impact on our net product revenues by triggering the recall of unused DPP COVID-19 IgM/IgG systems from customers in the U.S. during the second quarter of 2020, and also deferring certain customer opportunities for the systems outside the U.S. Total revenues for the nine months ended September 30, 2020 was also adversely affected by our shift in focus from offering and selling legacy products to developing and beginning to commercialize the DPP COVID-19 Systems, followed by a forced re-shift in focus immediately following the Revocation to offering and selling legacy products while simultaneously developing the new DPP SARS-CoV-2 Systems.

Gross Product Margin

Cost of product sales is primarily composed of material, labor, manufacturing overhead, depreciation and amortization, and other operating expenses. Gross product margin is net product revenue less cost of product sales, and gross product margin percentage is gross product margin as a percentage of net product revenue. Gross product margin during the nine months ended September 30, 2020 decreased by $4.9 million, or 92%, from the comparable period of 2019. The following schedule calculates gross product margin (dollars in thousands):

	For the Nine Months Ended		**Favorable/(Unfavorable)**	
	September 30, 2020	**September 30, 2019**	**$ Change**	**% Change**
Net product sales	**$ 17,915**	**$ 23,382**	$ (5,467)	23.4%
Less: Cost of product sales	**17,513**	**18,113**	600	3.3%
Gross product margin	**$ 402**	**$ 5,269**	$ (4,867)	92.4%
Gross product margin percentage	**2.2%**	**22.53%**		

As noted above, in 2020 we have invested in developing and offering products that will address the COVID-19 pandemic and which we expect will have average selling prices greater than those of our legacy products. We have also advanced our investment in automation that we believe will reduce our reliance on manual labor and contribute to improved product margins. The $4.9 million decrease in gross product margin was composed of the following:

- $1.3 million unfavorable product sales volume as described under *Total Revenues*, above, together with
- $3.6 million unfavorable product margins as discussed below, principally reflecting the following:
  - We incurred the cost of product sales for COVID-19 IgM/IgG Systems that were returned by customers following the Revocation;
  - The Revocation in June 2020 precluded planned sales of COVID-19 IgM/IgG Systems to customers in the United States in both the second and third quarter of 2020 and resulted in the deferral in the third quarter of certain customer opportunities for sales of COVID-19 IgM/IgG Systems outside the United States, which negatively impacted the benefit of higher volumes on fixed overhead costs;

- We experienced operational inefficiencies, including those triggered by the Revocation and activities related to qualifying automated lines for production of certain products, which resulted in increased cost of product sales as we substantially shifted our production from COVID-19 products to legacy products; and,
- Our recognition of net revenue from shipments of DPP COVID-19 IgM/IgG Systems outside the United States that had been deferred from the second quarter offset the above items.

Research and Development

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

	For the Nine Months Ended		Favorable/(Unfavorable)	
	September 30, 2020	September 30, 2019	**$ Change**	**% Change**
Clinical and regulatory affairs	**$ 758**	$ 1,096	$ 338	30.8%
Other research and development	**5,475**	5,447	(28)	0.5%
Total Research and Development	**$ 6,233**	$ 6,543	$ 310	4.7%

The decrease in R&D costs for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 was primarily associated with the reduction in clinical trial costs related to the DPP HIV-Syphilis System during 2019, offset by costs related to the development of the DPP SARS-CoV-2 Systems.

Selling, General and Administrative Expense

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

The $1.3 million, or 11%, increase in selling, general and administrative expense for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 is primarily related to legal costs arising subsequent to the Revocation, offset in part by restructuring cost savings at our Malaysia facility and other areas.

Other (Expense) Income, net

Other expenses/income, net consists principally of interest expense, net of interest income earned on our deposits, which increased in the nine months ended September 30, 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 $18 million) was outstanding at September 30, 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 nine months ended September 30, 2020, we recognized a tax benefit of $0.3 million related to losses generated by our foreign subsidiaries. As of September 30, 2020 and 2019, our U.S. deferred tax assets included a full valuation allowance.

Liquidity and Capital Resources

During the nine months ended September 30, 2020 we have funded our business operations, including capital expenditures and working capital requirements, principally from cash and cash equivalents. Our operations used $14.1 million of cash, and we received proceeds on issuance of stock of $28.4 million (net of expenses). As of September 30, 2020, we had outstanding debt (excluding leases) in the amount of $20.0 million (carrying amount of $18 million), under a credit agreement entered into on September 3, 2019.

Chembio was in compliance with its cash balance loan covenant, but not in compliance with its revenue loan covenant as of September 30, 2020. Chembio obtained a written waiver from the Lender with respect to Chembio's failure to meet the revenue loan covenant for the period ended September 30, 2020. 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.

The Credit Agreement provides for specified quarterly minimum consolidated net revenue covenants of us and our subsidiaries for the trailing twelve-month period ended on each such calculation date during the term of the Credit Agreement. The Credit Agreement also contains covenants requiring us and our subsidiaries to maintain cash and cash equivalents held in one or more accounts subject to the first priority perfected security interests of the lenders under the Credit Agreement of not less than $3,000,000. The breach of any of these covenants would result in a default under the Credit Agreement. We failed to meet the specified quarterly minimum consolidated net revenue covenant for the periods ended June 30, 2020 and September 30, 2020, and we were required to obtain waivers from Perceptive to avoid an event of default.

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 SARS-CoV-2 Systems. We believe our existing cash and cash equivalents and our cash flow from operating activities 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 timing of a successful award of an EUA for either the DPP SARS-CoV-2 IgM/IgG system or the DPP SARS-CoV-2 Antigen system by the FDA; the rate of our business and revenue growth, particularly if we are able to resume commercialization of the DPP COVID-19 Systems; 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 we are unable to increase our revenues and manage our expenses in accordance with our operating plan, we may need to reduce the level or slow the timing of the growth plans contemplated by our operating plan, 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.

Sources of Funds

The following table sets forth selected working capital information:

	September 30, 2020
	(in thousands)
Cash and cash equivalents	$ 28,687
Accounts receivable, net of allowance for doubtful amounts	3,523
Inventories, net	12,364
Prepaid expenses and other current assets	1,007
Total current assets	44,581
Less: Total current liabilities	(11,193)
Working capital	$ 33,388

On July 5, 2020, we were awarded a contract of $0.6 million from BARDA to assist us in developing the DPP SARS-CoV-2 Antigen system and requesting an EUA from the FDA for said system, and we submitted the request for the EUA to the FDA on October 15, 2020.

Our cash and cash equivalents at September 30, 2020, which included a restricted amount of $2.3 million, was 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 and inventory balances fluctuate from period to period, which affects our cash flow from operating activities. Fluctuations vary depending on cash collections, customer mix, and the timing of shipment of our products and the invoicing of our research and development activities.

Uses of Funds

Our operations used $14.1 million of cash during the nine months ended September 30, 2020, reflecting a net loss adjusted for non-cash items of $13.1 million (which included $1.1 million of severance and restructuring costs and $0.1 million of acquisition costs), a $5.3 million increase in inventory, a $0.6 million increase in accounts payable and accrued liabilities and a $3.7 million increase in deferred revenue, offset by a $0.1 million decrease in accounts receivable.

During the nine months ended September 30, 2020, we continued to invest in manufacturing equipment, enterprise business systems, and other fixed assets, particularly in the light of our shift in business focus to our DPP COVID-19 Systems. Our capital expenditures totaled $3.2 million in the nine months ended September 30, 2020.

Off-Balance Sheet Arrangements

As of September 30, 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

The following description of our significant accounting policies and critical accounting estimates augments the disclosure set forth under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019.

Revenue Recognition

We recognize revenue for product sales in accordance with FASB ASC 606, *Revenue from Contracts with Customers*. Revenues from product sales are generally recognized when the customer obtains control of our product, which occurs at a point in time, typically upon tendering to the customer, subject to variable consideration and other provisions of ASC 606. We expense 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. We have 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. We exclude certain taxes from the transaction price (e.g., sales, value added and some excise taxes).

Product revenue reserves, which are classified as a reduction in product revenues, are generally related to discounts and returns. 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, market events and trends, and the specific facts and circumstances of each arrangement. The transaction price, which includes variable consideration reflecting the impact of discounts, allowances and returns 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 revenue and earnings in the period of adjustment.

For certain contracts, we recognize revenue from research and development, milestone and grant revenues when earned. Grants are invoiced after expenses are incurred. Revenues from projects or grants funded in advance are deferred until earned. For certain collaborative research projects, we recognize revenue by defining milestones at the inception of the agreement and applying judgement and estimates in recognizing revenue for relevant contracts.

Recently Issued Accounting Pronouncements

A discussion of recent accounting pronouncements was included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and is updated in subsection (v) of note 2 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 September 30, 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 September 30, 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

Employee Litigation

John J. Sperzel III, 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's attempt to exercise the options following the thirty day period was not valid. Chembio intends to vigorously defend against any claim by Mr. Sperzel that he continues to have a right to exercise any options.

Stockholder Litigation

Putative Stockholder Securities Class Action Litigation

As of November 3, 2020, four purported securities class action lawsuits had been filed by alleged stockholders of our company, and were pending, in the United States District Court for the Eastern District of New York:

- *Sergey Chernysh v. Chembio Diagnostics, Inc., Richard L. Eberly, and Gail S. Page*, filed on June 18, 2020, which we refer to as the Chernysh case;
- *James Gowen v. Chembio Diagnostics, Inc., Richard L. Eberly, and Gail S. Page*, filed on June 22, 2020, which we refer to as the Gowen case;
- *Anthony Bailey v. Chembio Diagnostics, Inc. Richard J. Eberly, Gail S. Page, and Neil A. Goldman*, filed on July 3, 2020, which we refer to as the Bailey case; and
- *Special Situations Fund III QP, L.P., Special Situations Cayman Fund, L.P., and Special Situations Private Equity Fund, L.P. v. Chembio Diagnostics, Inc., Richard Eberly, Gail S. Page, Robert W. Baird & Co. Inc. and Dougherty & Company LLC*, filed August 17, 2020, which we refer to as the Special Situations Funds case.

The plaintiffs in each of the cases allege violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 thereunder. The Special Situations Funds complaint also asserts claims under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933 relating to Chembio's May 2020 public offering. The claims asserted in the complaints are based on purportedly false and misleading statements and omissions concerning the performance of the DPP COVID-19 IgM/IgG System. The complaints collectively seek, among other things, an award of damages in an amount to be proven at trial, as well as an award of reasonable costs, including attorneys' fees and expenses, expert fees, pre-judgement and post-judgment interest, and such other relief as the court deems just and proper. The Special Situations Funds complaint also asserts that members of the putative Section 11 class who continue to hold our common stock have the right to rescind their purchases and recover the consideration paid. We and the plaintiffs in the four cases have entered into court-approved stipulations relieving the defendants of the obligation to respond to the complaints in those cases pending the designation of a lead plaintiff pursuant to the Private Securities Litigation Reform Act of 1995. Two motions for appointment as lead plaintiff are currently pending for determination by the court; no date has been set for a hearing on those motions.

On July 1, 2020, an alleged stockholder of our company filed a purported class action lawsuit in the United States District Court for the Eastern District of New York captioned *Ken Hayes v. Chembio Diagnostics, Inc., Richard L. Eberly, Gail S. Page, Katherine L. Davis, Mary Lake Polan, and John G. Potthoff*, which we refer to as the Hayes case. The Hayes complaint purported to state claims for violations of Section 14(a) of the Exchange Act and Rule 14a-9 thereunder, declaratory relief, and state law claims for breach of fiduciary duty for alleged misstatements of material information in the proxy statement disseminated in advance of our Annual Meeting of Stockholders held on July 28, 2020. On July 8, 2020, we filed an amended proxy statement correcting, among other things, the issues raised in the Hayes complaint. On July 23, 2020, (a) we and the plaintiff entered into a stipulation to the dismissal of the Hayes action, with prejudice as to the claims of the named plaintiff subject to plaintiff's reservation of the right to apply for an award of attorneys' fees and expenses from us in certain circumstances, and (b) the plaintiff filed a notice dismissing his claims, with prejudice, as to the individual defendants. On July 27, 2020, the court entered an order closing the Hayes case and providing that plaintiff would have until September 28, 2020 to move to reopen the case if the attorneys' fee issue had not been resolved. We subsequently resolved the attorneys' fee issue amicably with the plaintiff.

Putative Stockholder Derivative Litigation

On September 11, 2020, a putative stockholder derivative action was filed purportedly on our company's behalf in the United States District Court for the Eastern District of New York captioned *Karen Wong, derivatively on behalf of Chembio Diagnostics, Inc., Plaintiff v. Richard L. Eberly, Gail S. Page, Neil A. Goldman, Javan Esfandiari, Katherine L. Davis, Mary Lake Polan, and John G. Potthoff, Defendants, and Chembio Diagnostics, Inc., Nominal Defendant*, which we refer to as the Wong complaint. The Wong complaint purports to assert a claim for violation of Section 14(a) of the Exchange Act and Rule 14a-9 thereunder based on ostensibly false and misleading statements and omissions in the proxy statement disseminated in advance of our Annual Meeting of Stockholders held on July 28, 2020 concerning our rapid COVID-19 antibody tests. The Wong complaint also asserts claims against the individual defendants for purported breaches of fiduciary duties owed to our company and unjust enrichment.

The Wong complaint requests a declaration that the individual defendants have breached or aided and abetted the breach of their fiduciary duties to our company, an award of damages to our company, restitution, and an award of the plaintiff's costs and disbursements in the action, including reasonable attorneys' and experts' fees, costs and expenses, and improvements to our company's corporate governance and internal procedures regarding compliance with laws. Pursuant to a stipulation by which the individual defendants in the Wong action agreed to waive service of process, the court ordered that the time for defendants to answer or otherwise respond to the complaint be extended to November 19, 2020. The parties subsequently entered into a stipulation for a stay of proceedings in the Wong action pending final disposition of motions to dismiss the pending putative class action litigation, subject to certain conditions. The court entered an order granting the requested stay on November 3, 2020.

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 Annual Report on Form 10-K for the fiscal year ended December 31, 2019. 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2019, which could materially affect our business, financial condition, or future results. Moreover, you should interpret many of the risks identified in our Annual Report on 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 Annual Report on Form 10-K for the year ended December 31, 2019 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.

For purposes of the following risk factors, we refer to our DPP COVID-19 IgM/IgG Systems and DPP COVID-19 Antigen Systems collectively as DPP COVID-19 Systems.

Risks Related to Our Business

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

Of the 171 manufacturers and commercial laboratories to receive an EUA for COVID-19 diagnostics as of July 31, 2020, 35 were for serology tests, 134 were for molecular tests, and 2 were for antigen tests. 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 antigen test. Various advances in the treatment and monitoring of patients could cause lower demand for our revised DPP SARS-CoV-2 Antigen system or for antigen testing for COVID-19 as a whole.

The failure to comply with the terms of our Credit Agreement and Guaranty could result in a default under its terms and, if uncured, could result in action against our pledged assets and dilution of our stockholders.

On September 3, 2019, we entered into a Credit Agreement and Guaranty, or Credit Agreement, with Perceptive Credit Holdings II, LP, or Perceptive. Under the Credit Agreement, we received a $20,000,000 senior secured term loan credit facility, which was drawn in full on September 4, 2019. The credit agreement is secured by a first priority, perfected lien on substantially all of our property and assets, including our equity interests in our subsidiaries.

The Credit Agreement contains covenants that restrict our ability to finance future operations or capital needs or to engage in other business activities. The Credit Agreement restricts our ability and the ability of our restricted subsidiaries to:

- incur, assume or guarantee additional Indebtedness (as defined in the Credit Agreement);
- repurchase capital stock;
- make other restricted payments including, without limitation, paying dividends and making investments;
- create liens;
- sell or otherwise dispose of assets, including capital stock of subsidiaries;
- enter into agreements that restrict dividends from subsidiaries;
- enter into mergers or consolidations; and
- enter into transactions with affiliates

The Credit Agreement provides for specified quarterly minimum consolidated net revenue covenants of us and our subsidiaries for the trailing twelve-month period ended on each such calculation date during the term of the Credit Agreement. The Credit Agreement also contains covenants requiring us and our subsidiaries to maintain cash and cash equivalents held in one or more accounts subject to the first priority perfected security interests of the lenders under the Credit Agreement of not less than $3,000,000. The breach of any of these covenants would result in a default under the Credit Agreement. We failed to meet the specified quarterly minimum consolidated net revenue covenant for the quarters ended June 30, 2020 and September 30, 2020, and we were required to obtain waivers from Perceptive in order to avoid an event of default. If we fail to meet such covenant for a future quarter, we may not be able to obtain a waiver from Perceptive, which has total discretion in deciding whether to grant a waiver, and we may incur an event of default. If an event of default occurs, Perceptive could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. If we were unable to pay such amounts, Perceptive could proceed against the collateral pledged to them. We have pledged our inventory, accounts receivable, cash, securities, other general intangibles and the capital stock of certain subsidiaries to the lenders. In such an event, we cannot assure you that we would have sufficient assets to pay amounts due under the Credit Agreement.

Risks Related to Regulations

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

Our DPP SARS-CoV-2 Systems are subject to regulations of the FDA, International Organization for Standards and other regulatory requirements, including ANVISA, Brazil’s health regulatory agency. The regulations regarding the manufacture and sale of DPP SARS-CoV-2 Systems may be unclear and are subject to change. Newly promulgated regulations could require changes to DPP SARS-CoV-2 Systems, necessitate additional procedures, or make it impractical or impossible for us to market DPP SARS-CoV-2 Systems 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 DPP SARS-CoV-2 Systems. 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, and then revoked, an EUA, for emergency use of the DPP COVID-19 IgM/IgG System. Such revocation precludes the sale of DPP COVID-19 IgM/IgG Systems in the United States 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.

We are currently working to obtain EUAs for both our DPP SARS-CoV-2 IgM/IgG system and our DPP SARS-CoV-2 Antigen system, and approvals for waived statuses 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.

ITEM 6. EXHIBITS

Number	Description
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	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	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document
104	Cover page formatted as Inline XBRL and contained in Exhibit 101

* 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: November 5, 2020

By: /s/ Richard L. Eberly
Richard L. Eberly
Chief Executive Officer and President

Date: November 5, 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: November 5, 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: November 5, 2020

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Chembio Diagnostics, Inc. for the quarterly period ended September 30, 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: November 5, 2020

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

Date: November 5, 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.