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, 2021

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 October 26, 2021, the registrant had 30,045,141 shares outstanding of its common stock, $0.01 par value.

Quarterly Report on Form 10-Q
For The Quarterly Period Ended
September 30, 2021

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Chembio Diagnostics, Inc.

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

DPP, STAT-PAK, STAT-VIEW and SURE CHECK are our registered trademarks, and CHEMBIO, MICRO READER and our logo design are our trademarks. For convenience, these trademarks appear in this report without ® and ™ symbols, but that practice does not mean that we will not assert, to the fullest extent under applicable law, our rights to the trademarks.

FORWARD-LOOKING STATEMENTS

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.

Forward-looking statements 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 “Item 1A. Risk Factors” of Part II of this report. You should interpret many of the identified risks and uncertainties 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, which speak only as of the date they are made. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

PART I

Item 1. FINANCIAL STATEMENTS

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	(Unaudited) September 30, 2021	December 31, 2020
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 36,004,000**	$ 23,066,301
Accounts receivable, net of allowance for doubtful accounts of $193,535 and $296,793 at September 30, 2021 and December 31, 2020, respectively	**6,782,798**	3,377,387
Inventories, net	**16,805,669**	12,516,402
Prepaid expenses and other current assets	**1,191,678**	778,683
TOTAL CURRENT ASSETS	**60,784,145**	39,738,773
FIXED ASSETS:		
Property, plant and equipment, net	**8,744,713**	8,688,403
Finance lease right-of-use asset, net	**208,908**	233,134
OTHER ASSETS:		
Operating lease right-of-use asset, net	**6,085,655**	6,112,632
Intangible assets, net	**2,178,186**	3,645,986
Goodwill	**5,674,132**	5,963,744
Deposits and other assets	**367,396**	509,342
TOTAL ASSETS	**$ 84,043,135**	$ 64,892,014
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 10,182,488**	$ 10,042,790
Deferred revenue	**20,195**	1,606,997
Operating lease liabilities	**856,917**	642,460
Finance lease liabilities	**66,790**	58,877
Current portion of long-term debt	**300,000**	-
TOTAL CURRENT LIABILITIES	**11,426,390**	12,351,124
OTHER LIABILITIES:		
Long-term operating lease liabilities	**6,207,698**	6,327,143
Long-term finance lease liabilities	**157,251**	185,239
Long-term debt, net	**18,333,267**	18,182,158
Deferred tax liability	**-**	69,941
TOTAL LIABILITIES	**36,124,606**	37,115,605
COMMITMENTS AND CONTINGENCIES (Note 6)		
STOCKHOLDERS' EQUITY:		
Preferred stock - 10,000,000 shares authorized; none issued or outstanding	**-**	-
Common stock - $0.01 par value; 100,000,000 shares authorized; 30,086,283 shares and 20,223,498 shares issued at September 30, 2021 and December 31, 2020, respectively	**300,863**	202,235
Additional paid-in capital	**165,442,942**	124,961,514
Accumulated deficit	**(117,036,729)**	(97,106,331)
Treasury stock, 41,141 shares at cost, at September 30, 2021 and December 31, 2020	**(190,093)**	(190,093)
Accumulated other comprehensive loss	**(598,454)**	(90,916)
TOTAL STOCKHOLDERS' EQUITY	**47,918,529**	27,776,409
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 84,043,135**	$ 64,892,014

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, 2021	September 30, 2020	**September 30, 2021**	September 30, 2020
REVENUES:				
Net product sales	**$ 9,371,160**	$ 8,406,457	**$ 17,327,204**	$ 17,914,623
R&D revenue	**441**	1,444,724	**1,107,808**	3,546,385
Government grant income	**2,400,000**	209,776	**8,030,000**	209,776
License and royalty revenue	**286,843**	211,521	**779,901**	572,450
TOTAL REVENUES	**12,058,444**	10,272,478	**27,244,913**	22,243,234
COSTS AND EXPENSES:				
Cost of product sales	**7,902,819**	7,467,746	**15,490,956**	17,512,925
Research and development expenses	**3,442,044**	2,351,880	**9,102,363**	6,233,040
Selling, general and administrative expenses	**5,947,327**	5,348,958	**18,033,748**	13,903,192
Asset impairment, restructuring, severance and related costs	**396,740**	11,651	**2,440,983**	1,122,310
Acquisition costs	-	-	-	63,497
	17,688,930	15,180,235	**45,068,050**	38,834,964
LOSS FROM OPERATIONS	**(5,630,486)**	(4,907,757)	**(17,823,137)**	(16,591,730)
OTHER EXPENSE:				
Interest expense, net	**(735,336)**	(735,819)	**(2,175,188)**	(2,110,011)
LOSS BEFORE INCOME TAXES	**(6,365,822)**	(5,643,576)	**(19,998,325)**	(18,701,741)
Income tax (provision) benefit:	**(28)**	104,778	**67,928**	319,597
NET LOSS	**$ (6,365,850)**	$ (5,538,798)	**$ (19,930,397)**	$ (18,382,144)
Basic and diluted loss per share	**$ (0.24)**	$ (0.28)	**$ (0.89)**	$ (0.98)
Weighted average number of shares outstanding, basic and diluted	**26,701,546**	20,104,547	**22,361,899**	18,728,372

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, 2021	September 30, 2020	**September 30, 2021**	September 30, 2020
Net loss	**$ (6,365,850)**	$ (5,538,798)	**$ (19,930,397)**	$ (18,382,144)
Other comprehensive loss:				
Foreign currency translation adjustments	**(352,918)**	262,094	**(507,538)**	(776,645)
Comprehensive loss	**$ (6,718,768)**	$ (5,276,704)	**$ (20,437,935)**	$ (19,158,789)

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, 2021							
	Common Stock		Additional Paid-in-	Treasury Stock		Accumulated		
	Shares	Amount	Capital	Shares	Amount	Deficit	AOCI	Total
Balance at December 31, 2020	**20,223,498**	**$ 202,235**	**$124,961,514**	**(41,141)**	**$ (190,093)**	**$ (97,106,331)**	**$ (90,916)**	**$27,776,409**
Common Stock:								
Restricted stock issued	62,197	622	58,909	-	-	-	-	59,531
Restricted stock compensation, net	-	-	309,010	-	-	-	-	309,010
Shares tendered for withholding taxes	-	-	(115,059)	-	-	-	-	(115,059)
Options:								
Stock option compensation	-	-	211,140	-	-	-	-	211,140
Comprehensive loss	-	-	-	-	-	-	(455,722)	(455,722)
Net loss	-	-	-	-	-	(4,500,163)	-	(4,500,163)
Balance at March 31, 2021	**20,285,695**	**$ 202,857**	**$125,425,514**	**(41,141)**	**$ (190,093)**	**$ (101,606,494)**	**$ (546,638)**	**$23,285,146**
Common Stock:								
Restricted stock issued	51,677	517	(517)	-	-	-	-	-
Restricted stock compensation, net	-	-	288,053	-	-	-	-	288,053
Shares tendered for withholding taxes	-	-	(4,454)	-	-	-	-	(4,454)
Options:								
Stock option compensation	-	-	297,791	-	-	-	-	297,791
Comprehensive loss	-	-	-	-	-	-	301,102	301,102
Net loss	-	-	-	-	-	(9,064,385)	-	(9,064,385)
Balance at June 30, 2021	**20,337,372**	**$ 203,374**	**$126,006,387**	**(41,141)**	**$ (190,093)**	**$ (110,670,879)**	**$ (245,536)**	**$15,103,253**
Common Stock:								
Issuance of stock, net	9,709,328	97,093	38,714,867	-	-	-	-	38,811,960
Restricted stock issued	3,331	33	18,385	-	-	-	-	18,418
Restricted stock compensation, net	-	-	399,548	-	-	-	-	399,548
Options:								
Exercised	36,252	363	85,192	-	-	-	-	85,555
Stock option compensation	-	-	218,563	-	-	-	-	218,563
Comprehensive loss	-	-	-	-	-	-	(352,918)	(352,918)
Net loss	-	-	-	-	-	(6,365,850)	-	(6,365,850)
Balance at September 30, 2021	**30,086,283**	**$ 300,863**	**$165,442,942**	**(41,141)**	**$ (190,093)**	**$ (117,036,729)**	**$ (598,454)**	**$47,918,529**

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		
	Shares	Amount	Capital	Shares	Amount	Deficit	AOCI	Total
Balance at December 31, 2019	**17,733,617**	**$ 177,335**	**$ 95,433,077**	**-**	**$ -**	**$ (71,585,003)**	**$ 9,844**	**$ 24,035,253**
Common Stock:								
Restricted stock issued	34,249	343	117,956	-	-	-	-	118,299
Restricted stock compensation, net	(440,631)	(4,406)	(292,495)	-	-	-	-	(296,901)
Shares tendered for withholding taxes	-	-	145,056	(31,486)	(145,056)	-	-	-
Options:								
Stock option compensation	-	-	139,449	-	-	-	-	139,449
Comprehensive loss	-	-	-	-	-	-	(863,294)	(863,294)
Net loss	-	-	-	-	-	(4,999,549)	-	(4,999,549)
Balance at March 31, 2020	**17,327,235**	**$ 173,272**	**$ 95,543,043**	**(31,486)**	**$ (145,056)**	**$ (76,584,552)**	**$ (853,450)**	**$ 18,133,257**
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
Warrant 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, net	-	-	275,985	-	-	-	-	275,985
Options:								
Stock option compensation	-	-	97,535	-	-	-	-	97,535
Comprehensive loss	-	-	-	-	-	-	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 CASH FLOWS
FOR THE NINE MONTHS ENDED
(Unaudited)

	September 30,2021	September 30, 2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	**$ 22,355,958**	$ 26,122,815
Cash paid to suppliers and employees	**(43,732,182)**	(37,776,303)
Cash paid for operating leases	**(1,049,198)**	(797,482)
Cash paid for finance leases	**(15,358)**	(14,762)
Interest and taxes, net	**(1,709,704)**	(1,681,155)
Net cash used in operating activities	**(24,150,484)**	(14,146,887)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Patent application costs	**(32,648)**	(181,417)
Acquisition of and deposits on fixed assets	**(1,387,601)**	(3,000,763)
Net cash used in investing activities	**(1,420,249)**	(3,182,180)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of stock, net	**38,811,960**	28,436,741
Stimulus package loan	**-**	2,978,315
Stimulus package loan payment	-	(2,978,315)
Payments on note payable	-	(180,249)
Payments of tax withholding on stock award	**(119,513)**	(348,944)
Payments on finance lease	**(45,680)**	(37,166)
Net cash (used in) provided by financing activities	**38,646,767**	27,870,382
Effect of exchange rate changes on cash	**(138,335)**	(125,214)
(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	**12,937,699**	10,416,101
Cash and cash equivalents - beginning of the period	**23,066,301**	18,271,352
Cash and cash equivalents - end of the period	**$ 36,004,000**	$ 28,687,453
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net loss	**$ (19,930,397)**	$ (18,382,144)
Adjustments:		
Depreciation and amortization	**2,186,684**	2,057,275
Share based compensation	**1,802,056**	824,345
Non-cash inventory adjustments	**926,499**	2,530,444
Benefit from deferred tax liability	**(69,941)**	(301,000)
Impairment of long-lived assets	**1,273,945**	-
Provision (recovery of) doubtful accounts	**(103,258)**	214,210
Changes in assets and liabilities:		
Accounts receivable	**(3,302,153)**	138,827
Inventories	**(5,215,766)**	(5,295,899)
Prepaid expenses and other current assets	**(412,995)**	(314,460)
Deposits and other assets	**141,946**	80,873
Accounts payable and accrued liabilities	**139,698**	559,888
Deferred revenue	**(1,586,802)**	3,740,754
Net cash used in operating activities	**$ (24,150,484)**	$ (14,146,887)
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	**$ -**	$ 472,651

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2021
(Unaudited)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. ("Chembio") and its subsidiaries (collectively with Chembio, the "Company") develop and commercialize point-of-care tests used for the rapid detection and diagnosis of infectious diseases, including sexually transmitted disease, insect vector and tropical disease, COVID-19 and other viral and bacterial infections, enabling expedited treatment. Coupled with its extensive scientific expertise, the Company's novel DPP technology offers broad market applications beyond infectious disease. The Company'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, STAT-VIEW and SURE CHECK registered trademarks or under the private labels of the Company's marketing partners.

The Company's future working capital needs will depend on many factors, including the rate of its business and revenue growth, the availability and cost of human, material and other resources required to build and deliver products in accordance with its existing or future product orders, the timing of its continuing automation of 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 (see Note 2(a) — Basis of Presentation). 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.

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, 2020, as filed with the SEC.

Going Concern Considerations

Revenues during the three months ended September 30, 2021 did not meet the Company's expectations. The Company's increase in cash and cash equivalents over the first nine months of 2021 reflected its issuance of common stock in at-the-market offerings for net proceeds of $38.8 million (see Note 5 - Stockholder's Equity). The Company continued to experience market, clinical trial and regulatory complications in seeking to develop and commercialize a portfolio of COVID-19 test systems during the continuing, but evolving, uncertainty of the COVID-19 pandemic. In the three months ending on September 30, 2021, the Company continued to incur significant expenses in connection with pending legal matters (see Note 6(f) – Commitments, Contingencies, and Concentrations: Litigation), delayed achievement of milestones associated with government grant income, investments in inventory, and the continuing automation of manufacturing.

The Company performed an assessment to determine whether there were conditions or events that, considered in the aggregate, raised substantial doubt about the Company's ability to continue as a going concern within one year after the date the accompanying unaudited condensed consolidated financial statements are being issued. Initially, this assessment did not consider the potential mitigating effect of management's plans that had not been fully implemented. Because, as described below, substantial doubt was determined to exist as the result of this initial assessment, management then assessed the mitigating effect of its plans to determine if it is probable that the plans (1) would be effectively implemented within one year after the date the accompanying unaudited condensed consolidated financial statements are issued and (2) when implemented, would mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern.

During the three months ended September 30, 2021, the Company undertook measures to increase its total revenues and improve its liquidity position. In particular, the Company received significant purchase orders from two customers (the "July Purchase Orders"). The Company had pursued the July Purchase Orders for an extended period of time. The July Purchase Orders consist of the following:

- On July 20, 2021, the Company received a $28.3 million purchase order from Bio-Manguinhos for the purchase of DPP SARS-CoV-2 Antigen tests for delivery during 2021 to support the urgent needs of Brazil's Ministry of Health in addressing the COVID-19 pandemic. Bio-Manguinhos, a subsidiary of the Oswaldo Cruz Foundation, is responsible for the development and production of vaccines, diagnostics and biopharmaceuticals, primarily to meet the demand of Brazil's national public health system.
- On July 22, 2021, the Company received a $4 million purchase order from the Partnership for Supply Chain Management, supported by The Global Fund, for the purchase of HIV 1/2 STAT-PAK Assays for shipment to Ethiopia into early 2022.

These measures and other plans and initiatives have been designed to provide the Company with adequate liquidity to meet its obligations for at least the twelve-month period following the date the accompanying unaudited condensed consolidated financial statements are being issued. The Company's execution of those measures and its other plans and initiative continue to depend, however, on factors and uncertainties that are beyond the Company's control, or that may not be addressable on terms acceptable to the Company or at all. The Company considered in particular how:

- Limitations of the Company's staffing, supply chain and liquidity have impaired, and are expected to continue to impair, the Company's ability to fulfill at least $11.5 million of the July Purchase Order from Bio-Manguinhos by December 31, 2021, the end of the existing shipment schedule under the order.

- Earlier delays in clinical trials, which reflected the impact of the COVID-19 vaccination rollout and the related decline in positivity rates at clinical trials on the Company's clinical plan enrollment levels, and continuing requirements of achievement of regulatory approvals may limit the Company's ability to achieve a portion of the revenue- and cash-generating milestones under a $12.7 million award granted pursuant to the Company's contract dated December 2, 2020 with the Biomedical Advanced Research and Development Authority (part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response) ("BARDA"), which contract will, unless extended by BARDA, expire on December 2, 2021.

- The ongoing healthcare and economic impacts of the COVID-19 pandemic on the global customer base for the Company's non-COVID-19 products continue to negatively affect the timing and rate of recovery of the Company's revenues from those products by, for example, decreasing the allocation of funding for HIV testing, thereby continuing to adversely affect the Company's liquidity.

- Although the Company has entered into agreements to distribute third-party COVID-19 products in the United States, its ability to sell those products could be constrained because of staffing and supply chain limitations affecting the suppliers of those products.

The Company further considered how these factors and uncertainties could impact its ability over the next year to meet the obligations specified in the Credit Agreement with the Lender (each as defined in Note 7 – Long-Term Debt). Those obligations include a covenant requiring minimum total revenue amounts for the twelve months preceding each quarter end. For the next year, the minimum total revenue requirements range from $40.3 million for the twelve months ending December 31, 2021 to $45.6 million for the twelve months ending September 30, 2022. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. In such an event, there can be no assurance that the Company would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, the Company would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. The Company's inability to raise additional capital on acceptable terms in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for its operations, could have a material adverse effect on its business, prospects, results of operations, liquidity and financial condition.

Accordingly, management determined the Company could not be certain that the Company's plans and initiatives would be effectively implemented within one year after the date on which the accompanying unaudited condensed consolidated financial statements are being issued. Without giving effect to the prospect of raising additional capital pursuant to the ATM Agreement (as defined in Note 5(a) – Stockholders' Equity: Common Stock), increasing product revenue in the near future or executing other mitigating plans, many of which are beyond the Company's control, it is unlikely that the Company will be able to generate sufficient cash flows to meet its required financial obligations, including its debt service and other obligations due to third parties. The existence of these conditions raises substantial doubt about the Company's ability to continue as a going concern for the twelve-month period following the date on which the accompanying unaudited condensed consolidated financial statements are being issued.

The accompanying unaudited condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates continuity of operations, realization of assets and the satisfaction of liabilities in the normal course of business for the twelve-month period following the date the accompanying unaudited condensed consolidated financial statements are issued. As such, the accompanying unaudited condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of assets and their carrying amounts, or the amount and classification of liabilities that may result should the Company be unable to continue as a going concern.

(b) Significant Accounting Policies:

During the nine months ended September 30, 2021, there have been no significant changes to the Company's summary of significant accounting policies contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the SEC.

(c) Fair Value of Financial Instruments:

The carrying values for cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities, 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 $32.5 million and $14.8 million as of September 30, 2021 and December 31, 2020, 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 $18.6 million) and $20.0 million (carrying value of $18.2 million) as of September 30, 2021 and December 31, 2020, respectively, is a Level 2 fair value measurement under the hierarchy. The face value of the Company's debt approximates the recorded value, as the rate is based upon the current rates available to the Company for similar financial instruments.

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

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

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

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

(d) Cash and Cash Equivalents:

Cash and cash equivalents are defined as short-term, highly liquid investments with original maturities of three months or less at date of purchase, and include restricted cash of $0 and $1.0 million as of September 30, 2021 and December 31, 2020, 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 which the Company received advance payments by a customer. During the three months ended September 30, 2021, the Company fulfilled substantially all of the remaining shipments under the agreements, and restricted funds were released.

(e) Loss Per Share:

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period excluding unvested restricted stock. Diluted loss per share for the three and nine months ended September 30, 2021 and 2020 reflects the potential dilution from the exercise or conversion of other securities into common stock, if dilutive.

There were 1,786,324 and 1,034,124 shares of common stock subject to options outstanding as of September 30, 2021 and 2020, respectively, that were not included in the calculation of diluted per common share equivalents for the three and nine months ended September 30, 2021 and 2020, respectively, because the effect would have been anti-dilutive.

There were 811,038 and 619,385 shares of common stock that were restricted stock or were subject to restricted stock units or performance stock units as of September 30, 2021 and 2020, respectively, that were not included in the calculation of diluted per common share equivalents for the three and nine months ended September 30, 2021 and 2020, respectively, because the effect would have been anti-dilutive.

(f) Income 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, 2021 was 0% and 0.34% respectively, compared to the effective tax rate of 1.9% and 1.7% for both the three and nine months ended September 30, 2020, respectively. 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.

(g) Recently Issued Accounting Standards Affecting the Company:

Recently Adopted

ASU 2020-10, Codification Improvements

In October 2020, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2020-10, which clarifies various topics in the FASB's Accounting Standards Codification ("ASC"), including the addition of existing disclosure requirements to the relevant disclosure sections. This update improves consistency by amending the ASC to include all disclosure guidance in the appropriate disclosure sections and clarifies application of various provisions in the ASC by amending and adding new headings, cross referencing to other guidance, and refining or correcting terminology. The Company adopted the standard effective December 31, 2020 and determined that the adoption did not have a material impact on the Company's 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 upon issuance for all entities and elections of certain optional expedients are required to apply the provisions of the guidance. The Company adopted the standard effective January 1, 2021 and determined that the adoption did not have a material impact on the Company's consolidated financial statements.

ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes

In December 2019, the FASB issued ASU 2019-12. This standard simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in Topic 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill and allocating consolidated income taxes to separate financial statements of entities not subject to income tax. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, with early adoption permitted. Upon adoption, the Company must apply certain aspects of this standard retrospectively for all periods presented while other aspects are applied on a modified retrospective basis through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. The Company adopted the standard effective January 1, 2021 and determined that the adoption did not have a material impact on the Company's consolidated financial statements.

ASU 2021-01—Reference Rate Reform (Topic 848)

In January 2021, the FASB issued ASU 2021-01, which refines the scope of ASC Topic 848 and clarifies some of its guidance as part of the monitoring of global reference rate reform activities. The ASU permits entities to elect certain optional expedients and exceptions when accounting for derivative contracts and certain hedging relationships affected by changes in the interest rates used for discounting cash flows, for computing variation margin settlements, and for calculating price alignment interest (PAI3) in connection with reference rate reform activities under way in global financial markets (the "discounting transition"). ASU 2021-01 expands the scope of ASC Topic 848 to include all affected derivatives and give market participants the ability to apply certain aspects of the contract modification and hedge accounting expedients to derivative contracts affected by the discounting transition. In addition, ASU 2021-01 adds implementation guidance (codified in ASC 848-10-55-1) to clarify which optional expedients in ASC Topic 848 may be applied to derivative instruments that do not reference LIBOR or a reference rate that is expected to be discontinued, but that are being modified as a result of the discounting transition. The Company adopted the standard effective January 1, 2021 and determined that the adoption did not have a material impact on the Company's consolidated financial statements.

Not Yet Adopted

ASU 2021-04 - Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options

In May 2021, the FASB issued ASU 2021-04, which is the final guidance that requires issuers to account for modifications or exchanges of freestanding equity-classified written call options (e.g., warrants) that remain equity classified after the modification or exchange based on the economic substance of the modification or exchange. Under the guidance, an issuer determines the accounting for the modification or exchange based on whether the transaction was done to issue equity, to issue or modify debt, or for other reasons. The guidance is applied prospectively and is effective for all entities for fiscal years beginning after 15 December 2021, and interim periods within those fiscal years. Early adoption is permitted. The Company plans to adopt the standard effective January 1, 2022 and has determined that the adoption is not expected to have a material impact on the Company's consolidated financial statements.

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

In August 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 GAAP. ASU 2020-06 simplifies the guidance in 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 earnings per share 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 continues to assess the potential impacts of the standard.

NOTE 3 — REVENUE:

Disaggregation of Revenue

The following table disaggregates total revenues:

	For the three months ended					
	September 30, 2021			September 30, 2020		
	Exchange Transactions	**Non-Exchange Transactions**	**Total**	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	**$ 9,371,160**	**$ -**	**$ 9,371,160**	$ 8,406,457	$ -	$ 8,406,457
R&D revenue	**441**	**-**	**441**	1,444,724	-	1,444,724
Government grant income	**-**	**2,400,000**	**2,400,000**	-	209,776	209,776
License and royalty revenue	**286,843**	**-**	**286,843**	211,521	-	211,521
	$ 9,658,444	**$ 2,400,000**	**$ 12,058,444**	$ 10,062,702	$ 209,776	$ 10,272,478

	For the nine months ended					
	September 30, 2021			September 30, 2020		
	Exchange Transactions	**Non-Exchange Transactions**	**Total**	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	**$ 17,327,204**	**$ -**	**$ 17,327,204**	$ 17,914,623	$ -	$ 17,914,623
R&D revenue	**1,107,808**	**-**	**1,107,808**	3,546,385	-	3,546,385
Government grant income	**-**	**8,030,000**	**8,030,000**	-	209,776	209,776
License and royalty revenue	**779,901**	**-**	**779,901**	572,450	-	572,450
	$ 19,214,913	**$ 8,030,000**	**$ 27,244,913**	$ 22,033,458	$ 209,776	$ 22,243,234

Exchange transactions are recognized in accordance with ASC Topic 606, Revenue from Contracts with Customers, while non-exchange transactions are recognized in accordance with ASU 2018-08, Not-For-Profit Entities (Topic 958): Clarifying the Scope and Accounting Guidance for Contributions Received and Contributions Made.

During the three and nine months ended September 30, 2021, the Company recognized government grant income totaling $2.4 million and $8.0 million, which was awarded under a contract the Company entered into with BARDA on December 2, 2020.

The following table disaggregates total revenues by geographic location:

	For the three months ended		**For the nine months ended**	
	September 30, 2021	September 30, 2020	**September 30, 2021**	September 30, 2020
Africa	**$ 1,293,405**	$ 1,874,518	**$ 4,104,619**	$ 3,310,603
Asia	**208,750**	168,052	**479,297**	650,659
Europe & Middle East	**1,132,961**	2,887,209	**4,539,444**	6,698,382
Latin America	**5,698,920**	4,618,560	**6,444,456**	7,515,523
United States	**3,724,408**	724,139	**11,677,097**	4,068,067
	$ 12,058,444	$ 10,272,478	**$ 27,244,913**	$ 22,243,234

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 June 30, 2021, the Company reported $0.4 million in deferred revenue, substantially all of which was earned and recognized during the three months ended September 30, 2021, with the remaining amount expected to be recognized in the three months ending December 31, 2021.

NOTE 4 — INVENTORY:

Inventories are presented net of reserves and consisted of the following:

	September 30, 2021	December 31, 2020
Raw materials	**$ 7,549,851**	$ 5,955,215
Work in process	**7,244,946**	2,549,516
Finished goods	**2,010,872**	4,011,671
	$ 16,805,669	$ 12,516,402

During the three and nine months ended September 30, 2021, the Company recognized a charge of $0.1 million and $0.9 million, respectively, related to the write-down of inventory for products that were not salable, including as the result of the Company's periodic review of the current status and future benefits of inventory.

NOTE 5 — STOCKHOLDERS' EQUITY:

(a) Common Stock

During the three and nine months ended September 30, 2021 and 2020, options were exercised for the purchase of 36,252 and 0, respectively, shares of common stock.

On July 19, 2021, Chembio entered into an At the Market Offering Agreement (the "ATM Agreement") with Craig-Hallum Capital Group LLC ("Craig-Hallum"), pursuant to which Chembio may sell from time to time, at its option, up to an aggregate of $60,000,000 of shares of common stock through Craig-Hallum, as sales agent. During the three months ended September 30, 2021, Chembio issued and sold pursuant to the ATM Agreement a total of 9,709,328 shares of common stock at a volume-weighted average price of $4.2011 per share for gross proceeds of $40.8 million and net proceeds, after giving effect to placement fees and other transaction costs, of $38.8 million. Additional shares of common stock may be issued and sold pursuant to the ATM Agreement for gross proceeds of up to $19.2 million.

(b) Preferred Stock

The Company has 10,000,000 shares of preferred stock authorized and none issued or outstanding. These shares can become issuable upon an approved resolution by the board of directors of Chembio (the "Board") and the filing of a Certificate of Designation with the state of Nevada.

(c) Treasury Stock

The Company has 41,141 shares of common stock held as treasury stock, which were acquired upon the vesting of restricted stock awards related to the tax withholding requirements paid on behalf of employees.

(d) Options, Restricted Stock, Restricted Stock Units and Performance Stock Units

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

NOTE 6 — COMMITMENTS, CONTINGENCIES, AND CONCENTRATIONS:

a) Concentrations:

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

	For the three months ended				For the nine months ended				Accounts Receivable as of	
	September 30, 2021		September 30, 2020		**September 30, 2021**		September 30, 2020		**September 30, 2021**	December. 31, 2020
	Sales	**% of Sales**	Sales	% of Sales	**Sales**	**% of Sales**	Sales	% of Sales		
Customer 1	**$5,434,186**	**58.0%**	$4,226,040	50.3%	**$5,724,171**	**33.04%**	$6,523,416	36.4%	**$ 3,183,367**	$ 1,622,866
Customer 2	**1,196,217**	**12.8%**	*	*	**2,347,832**	**13.55%**	*	*	**1,264,639**	*
Customer 3	*****	*****	1,071,513	12.7%	*****	*****	*	*	*****	*
Customer 4	*****	*****	963,671	11.5%	*****	*****	*	*	**17,510**	*

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

The following table discloses product purchases the Company had to each vendor 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, 2021		September 30, 2020		**September 30, 2021**		September 30, 2020		**September 30, 2021**	December 31, 2020
	Purchases	**% of Purchases**	Purchases	% of Purchases	**Purchases**	**% of Purchases**	Purchases	% of Purchases		
Vendor 1	**$1,678,250**	**34.4%**	$ *	*	**$2,339,182.00**	**18.8%**	$ *	*	**$ 1,651,866**	$ *
Vendor 2	*	*	501,562	15.4%	*	*	1,600,916	12.3%	*	178,395

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

The Company currently buys materials that are purchased under intellectual property rights agreements and are important components in its products. Management believes that other suppliers could provide similar materials on comparable terms. 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 loss of sales and adversely affect operating results.

b) Governmental Regulation:

All of the Company's existing and proposed diagnostic products are regulated by the U.S. Food and Drug Administration (the "FDA"), the U.S. Department of Agriculture, certain other U.S. federal, state and local agencies, and 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 money penalties, injunctions, and criminal prosecution.

c) Employment Contracts:

The Company has multi-year contracts with two key employees. The contracts call for salaries presently aggregating $843,292 per year. The contracts expire in December 2021 and December 2022. The following table is a schedule of future minimum salary commitments:

2021	$ 210,823
2022	460,000

d) Benefit Plan:

The Company has a 401(k) plan established for its employees whereby it matches 40% of the first 5% of salary (or up to 2% of salary) that an employee contributes to the plan. Matching contribution expenses totaled $35,533 and $21,747 for the three months ended September 30, 2021 and 2020, respectively. Matching contribution expenses totaled $100,922 and $71,154 for the nine months ended September 30, 2021 and 2020, 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 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 leases generally include fixed rental payments with defined annual increases. While certain of the Company's leases are gross leases, the majority of the Company's leases are net leases in which the Company makes separate payments to the lessor based on the lessor's property and casualty insurance costs, the property taxes assessed on the property, and a portion of the common area maintenance where applicable. The Company has elected the practical expedient not to separate lease and nonlease components for all of the Company's facility leases.

Effective May 2021, the Company permanently discontinued its operations in Malaysia. Impairment charges for the Malaysian facility right-of-use asset recorded during the three and nine months ended September 30, 2021 was $0 and $0.1 million, respectively.

The components of lease expense were as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	**2021**	2020
Operating lease expense	**$ 398,089**	$ 405,989	**$ 1,208,885**	$ 1,258,797
Finance lease cost				
Amortization of right-of-use assets	**$ 17,038**	$ 15,571	**$ 49,834**	$ 42,657
Interest on lease liabilities	**5,047**	5,395	**15,358**	14,762
Total finance lease expense	**$ 22,085**	$ 20,966	**$ 65,192**	$ 57,419

Supplemental cash flow information related to leases was as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	**2021**	2020
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows for operating leases	**$ 353,009**	$ 340,205	**$ 1,049,198**	$ 797,482
Operating cash flows for finance leases	**5,047**	5,395	**15,358**	14,762
Financing cash flows for finance leases	**15,859**	13,587	**45,680**	37,166
Right-of-use assets obtained in exchange for lease obligations:				
Operating leases	**$ -**	$ -	**$ 616,100**	$ -
Finance leases	-	5,486	**25,609**	73,600

Supplemental balance sheet information related to leases was as follows:

	September 30, 2021	September 30, 2020
Finance Leases		
Finance lease right-of-use asset	**$ 340,762**	$ 315,153
Accumulated depreciation	**(131,854)**	(66,261)
Finance lease right-of-use asset, net	**$ 208,908**	$ 248,892
Weighted-Average Remaining Lease Term		
Operating leases	**7.7 Years**	9.1 Years
Finance leases	**3.1 Years**	4.0 Years
Weighted-Average Discount Rate		
Operating leases	**8.41%**	8.60%
Finance leases	**8.74%**	8.18%

Maturities of lease liabilities were as follows:

	September 30, 2021		September 30, 2020	
	Operating Leases	**Finance Leases**	Operating Leases	Finance Leases
2020 and 2021	**$ 355,335**	**$ 20,906**	$ 342,462	$ 19,226
2022	**1,447,249**	**83,624**	1,209,787	76,904
2023	**1,221,017**	**83,624**	1,057,757	76,904
2024	**1,018,875**	**55,856**	1,026,272	76,904
2025	**1,049,442**	**12,471**	1,018,875	49,136
Thereafter	**4,724,446**	**1,679**	5,773,888	5,750
Total lease payments	**$ 9,816,364**	**$ 258,160**	$ 10,429,041	$ 304,824
Less: imputed interest	**2,751,749**	**34,119**	3,269,991	46,712
Total	**$ 7,064,615**	**$ 224,041**	$ 7,159,050	$ 258,112

f) Litigation:

SEC Investigation

The SEC is conducting a non-public, fact-finding investigation relating to the public offering of common stock that Chembio completed in May 2020 (the "May 2020 Offering") and to the FDA's revocation in June 2020 of an emergency use authorization for the DPP COVID-19 IgM/IgG system that was issued by the FDA in April 2020. Chembio received subpoenas from the SEC in July 2020 and April 2021 seeking the production of documents in connection with this investigation. In addition, the SEC delivered subpoenas in April 2021 to five of Chembio's employees (including its three executive officers, who consist of its Chief Executive Officer and President, its Executive Vice President and Chief Financial Officer, and its Executive Vice President and Chief Scientific and Technology Officer). An additional subpoena was issued in June 2021 to Chembio's former Interim Chief Executive Officer and Executive Chair. Each subpoena requested the production of documents relating to the same matters as are the subject of the subpoenas Chembio received. Chembio and the six individuals are cooperating fully in the SEC's investigation and expect to continue to do so.

The SEC's letters transmitting the subpoenas expressly provide that the inquiry does not mean that the SEC or its staff have concluded that anyone has violated the federal securities laws or have a negative opinion of any person, entity or security. The Company cannot predict the scope, duration or outcome of the investigation or the impact, if any, of the investigation on its results of operations.

Legal Proceedings

Stockholder Litigation

Putative Stockholder Securities Class-Action Litigation

In 2020 four purported securities class-action lawsuits were filed in the United States District Court for the Eastern District of New York by alleged stockholders of Chembio:

- Sergey Chernysh v. Chembio Diagnostics, Inc., Richard L. Eberly and Gail S. Page, filed on June 18, 2020;
- James Gowen v. Chembio Diagnostics, Inc., Richard L. Eberly and Gail S. Page, filed on June 22, 2020;
- Anthony Bailey v. Chembio Diagnostics, Inc., Richard L. Eberly, Gail S. Page and Neil A. Goldman, filed on July 3, 2020; 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 L. Eberly, Gail S. Page, Robert W. Baird & Co. Inc. and Dougherty & Company LLC, filed August 17, 2020.

The plaintiffs in each of the above cases alleged claims under Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act"), Rule 10b-5 thereunder and Section 20(a) of the Exchange Act. Special Situations Fund III QP, L.P., Special Situations Cayman Fund, L.P. and Special Situations Private Equity Fund, L.P. (collectively, the "Special Situations Funds") also asserted claims under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933 (the "Securities Act") relating to the May 2020 Offering.

Chembio and the plaintiffs entered into Court-approved stipulations relieving Chembio and the other defendants of the obligation to respond to the complaints in these cases pending the designation of a lead plaintiff pursuant to the Private Securities Litigation Reform Act of 1995. Eight motions for appointment as lead plaintiff were filed by various prospective lead plaintiffs. However, all but two of these motions were withdrawn or otherwise abandoned, leaving before the Court two motions for appointment as lead plaintiff — one filed by the Special Situations Funds and one by Municipal Employees' Retirement System of Michigan. By order entered December 29, 2020, Magistrate Judge Lindsay consolidated the cases and appointed the Special Situations Funds and Municipal Employees' Retirement System of Michigan (together, the "Lead Plaintiffs"), as co-lead plaintiffs and their respective counsel as co-lead counsel. The consolidated cases are now pending under the caption "In re Chembio Diagnostics, Inc. Securities Litigation."

The Lead Plaintiffs filed their Consolidated Amended Complaint (the "CAC") on February 12, 2021. In summary, the CAC purports to allege claims based on assertedly false and misleading statements and omissions concerning the performance of the DPP COVID-19 IgM/IgG System, as well as an asserted failure to timely disclose that the emergency use authorization that had been granted by the FDA with respect to the DPP COVID-19 IgM/IgG System "was — or was at an increased risk of — being revoked." The CAC names as defendants Chembio, Richard L. Eberly, Gail S. Page, Neil A. Goldman, Javan Esfandiari, Katherine L. Davis, Mary Lake Polan, John Potthoff and the underwriters for the May 2020 Offering, Robert W. Baird & Co., Inc. and Dougherty & Company LLC.

The CAC purports to assert five counts under the Securities Act and the Exchange Act. Counts I through III are brought under the Securities Act, allegedly on behalf of a purported class consisting of all persons who purchased Chembio common stock directly in or traceable to the May 2020 Offering pursuant to Chembio's shelf registration statement on Form S 3 (File No. 333-227398) and the related prospectus, as supplemented by a prospectus supplement dated May 7, 2020 (the "Securities Act Class"). Count I purports to allege a claim for violation of Section 11 of the Securities Act against all defendants other than Messrs. Eberly and Esfandiari. Count II purports to allege a claim for violation of Section 12 of the Securities Act against all defendants other than Messrs. Eberly and Esfandiari. Count III purports to allege a claim under Section 15 of the Securities Act against Ms. Davis, Dr. Polan, Dr. Potthoff, Ms. Page and Mr. Goldman.

Counts IV and V allege claims under the Exchange Act on behalf of a purported class consisting of all persons who purchased Chembio common stock on the open market from March 12, 2020 through June 16, 2020 (the "Exchange Act Class"). Count IV purports to allege a claim for violation of Section 10(b) of the Exchange Act and Rule 10b-5 thereunder against Chembio, Mr. Eberly, Ms. Page, Mr. Goldman and Mr. Esfandiari. Count V purports to allege a claim under Section 20(a) of the Exchange Act against Mr. Eberly, Ms. Page, Mr. Goldman and Mr. Esfandiari.

The Lead Plaintiffs seek, on behalf of the Securities Act Class and the Exchange Act Class, 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-judgment and post-judgment interest, and such other relief as the Court deems just and proper. The Lead Plaintiffs also seek rescission "or a rescissory measure of damages" on behalf of the Securities Act Class as to Count II.

Pursuant to an order entered by the Court on January 29, 2021, any defendant wishing to move against the amended complaint was required to file, by February 18, 2021, a letter requesting a pre-motion conference. On that date, the defendants submitted letters to the Court requesting a pre-motion conference regarding anticipated motions to dismiss the CAC, and the Lead Plaintiffs responded on February 24, 2021. In its January 29, 2021 order, the Court indicated that it would consider a briefing schedule on motions to dismiss after it had received and reviewed the parties' correspondence.

On March 5, 2021, the Court entered an order in which it advised the parties that it had determined a pre motion conference was not necessary and established a briefing schedule on the defendants' anticipated motions to dismiss. However, the defendants subsequently agreed with the Lead Plaintiffs' counsel to a modification of the schedule, which was then approved by the Court. Pursuant to that schedule, defendants' motions and supporting papers were filed on March 26, 2021, the Lead Plaintiffs' opposition papers were filed on April 16, 2021, and the defendants' reply papers were filed on April 30, 2021. The defendants' motions remain pending before the Court. At this stage of the litigation, the Company is not able to predict the probability of a favorable or unfavorable outcome.

Putative Stockholder Derivative Litigation

On September 11, 2020, a putative stockholder derivative action 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 (the "Wong complaint") was filed purportedly on Chembio's behalf in the United States District Court for the Eastern District of New York. 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 concerning the Company's rapid COVID-19 antibody test in the proxy statement disseminated in advance of Chembio's Annual Meeting of Stockholders held on July 28, 2020. The Wong complaint also asserts claims against the individual defendants for purported breaches of fiduciary duties owed to Chembio, as well as 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 us, 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 regarding compliance with laws. Pursuant to a stipulation by which the individual defendants named in the Wong complaint 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 action relating to the Wong complaint 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. At this stage of the litigation, the Company is not able to predict the probability of a favorable or unfavorable outcome.

Employee Litigation

On March 19, 2021, John J. Sperzel III, Chembio's former chief executive officer, filed a fifteen-count complaint in the United States District Court for the Eastern District of New York. The complaint was filed following the dismissal of an action previously filed by Mr. Sperzel in the United States District Court in Maine, which was dismissed for lack of personal jurisdiction over Chembio. In summary, the complaint filed in the Eastern District of New York alleges that Chembio wrongfully refused to allow Mr. Sperzel 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 allegedly vested as of the date of his separation from Chembio, on January 3, 2020. The complaint alleges that under the terms of the applicable stock incentive plans, Mr. Sperzel had thirty days after the date on which he ceased to qualify as an "Eligible Person" under the plans within which to exercise the options, and asserts that by reason of his alleged continued service to us, he remained an "Eligible Person" and ostensibly retained the right to exercise the options. The Compensation Committee of the Board determined that the options expired on February 3, 2020, thirty days after Mr. Sperzel's separation from Chembio, and that a purported attempt by Mr. Sperzel to exercise the options after that date was not valid.

Count I of the complaint purports to allege that Chembio breached Mr. Sperzel's separation agreement by refusing to allow him to exercise the stock options. Counts II through XI of the complaint purport to allege claims for breach of each of ten separate stock option agreements, collectively asserting damages of "at least" $3,190,198. Count XII of the complaint alleges a breach of Mr. Sperzel's separation agreement based on Chembio's purported failure to pay Mr. Sperzel consulting fees to which he claims to be entitled for consulting services allegedly performed following his separation. Count XIII of the complaint alleges a claim for breach of an implied covenant of good faith and fair dealing under Nevada common law based on the allegation that Chembio prevented Mr. Sperzel from obtaining the benefits of the stock option agreements and separation agreement. Mr. Sperzel alleges that he suffered damages in excess of $3 million as a result of the purported breach of the covenant of good faith and fair dealing. Count XIV of the complaint purports to assert a claim for quantum meruit, alleging that "it is reasonable for Sperzel to expect payment in exchange for ... services" he assertedly provided to us and, based on allegations that upon his separation Mr. Sperzel was not informed as to the pending expiration of the stock options he later sought to exercise, that Chembio has been unjustly enriched. Finally, Count XV of the complaint seeks a declaratory judgment that Mr. Sperzel is relieved from performance under his separation agreement due to asserted material breaches of the agreement based on the allegations summarized above. The complaint seeks compensatory damages in an unspecified amount, a declaration, as described above, and an award of Mr. Sperzel's costs and expenses in the litigation, including reasonable attorneys' fees, expert costs and disbursements. The complaint requests a trial by jury. In recently served initial disclosures, Mr. Sperzel claims entitlement to recover damages in a total amount not less than $10 million, together with prejudgment interest at the rate of 9% per annum.

On May 20, 2021, Chembio filed its answer and affirmative defenses denying the material allegations of Mr. Sperzel's complaint. Chembio and Mr. Sperzel are presently engaged in discovery. Under the present case schedule, all discovery is expected to be completed by April 28, 2022. At this stage of the litigation, the Company is not able to predict the probability of a favorable or unfavorable outcome.

Other

From time to time the Company may become involved in legal proceedings or may be subject to claims arising in the ordinary course of its business. Although the results of litigation and claims cannot be predicted with certainty, the Company currently believes that the final outcome of these ordinary course matters will not have a material adverse effect on its business, operating results, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources, and other factors.

NOTE 7 — LONG-TERM DEBT:

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

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

The Credit Agreement contains financial covenants requiring that the Company (i) maintain aggregate unrestricted cash of not less than $3,000,000 at all times and (ii) achieve specified minimum rolling four-quarter total revenue amounts as of September 30, 2019 and the last day of each calendar quarter thereafter. The minimum total revenue amounts, which range from $32.0 million to $50.1 million, were developed for purposes of the Credit Agreement and do not reflect the internal estimates and plans used by Chembio's management and the Board to understand and evaluate the Company's operating performance, to establish budgets, and to establish operational goals for managing the Company's business.

As of September 30, 2021, the loan balance, net of unamortized discounts and debt issuance costs, was $18.6 million, and the Company was in compliance with its loan covenants.

NOTE 8 — EQUITY INCENTIVE PLAN:

(a) Equity Plans:

Effective June 3, 2008, Chembio's stockholders voted to approve the 2008 Stock Incentive Plan (the "2008 Plan"), with 625,000 shares of common stock available to be issued. At the Annual Stockholder Meeting on September 22, 2011 Chembio's stockholders voted to approve an increase to the shares of common stock issuable under the 2008 Plan by 125,000 to 750,000. Under the terms of the 2008 Plan, which expired during 2018, the Board 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, 2021, there were 714,000 options expired, forfeited or exercised, and at September 30, 2021, 36,000 options were outstanding and no Equity Award Units were available to be issued under the 2008 Plan.

Effective June 19, 2014, Chembio's stockholders voted to approve the 2014 Stock Incentive Plan (the "2014 Plan"), with 800,000 shares of common stock available to be issued. Under the terms of the 2014 Plan, the Board or its Compensation Committee has the discretion to select the persons to whom 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, 2021, there were 566,658 Equity Award Units expired, forfeited or exercised. At September 30, 2021, 212,281 Equity Award Units were outstanding and, 21,061 shares were not issued. All shares that expired, forfeited or were not issued rolled over into the 2019 Plan. No Equity Award Units remain available to be issued under the 2014 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. At the Annual Stockholder Meeting on June 25, 2021, Chembio's stockholders voted to approve an increase to the shares of common stock issuable under the SIP by 2,400,000 to 4,800,000. In addition, shares of common stock underlying any outstanding award granted under the 2019 Plan that, following the effective date of the 2019 Plan, expire, or are terminated, surrendered or forfeited for any reason without issuance of such shares, shall be available for the grant of new awards under the 2019 Plan. Under the terms of the 2019 Plan, the Board or its Compensation Committee has the discretion to select the persons to whom awards are to be granted. Awards can be in the form of options, stock appreciation rights, restricted stock, restricted stock units, performance 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, 2021, 448,584 2019 Equity Units have been cancelled or forfeited. At September 30, 2021, 2,193,355 2019 Equity Units were outstanding, and 3,051,405 2019 Equity Units were available to be awarded.

(b) Stock Compensation Expense:

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**	
	2021	2020	**2021**	2020
Cost of product sales	**$ 52,819**	$ -	**$ 124,955**	$ 6,300
Research and development expenses	**164,560**	126,333	**388,264**	281,070
Selling, general and administrative expenses	**419,152**	350,871	**1,288,837**	960,959
Severance and related costs	-	-	-	(423,984)
	$ 636,531	$ 477,204	**$ 1,802,056**	$ 824,345

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

	For the three months ended September 30, 2021	**For the nine months ended September 30, 2021**
Expected term (in years)	**6.0**	**5.0**
Expected volatility	**85.33%**	**78.28%**
Expected dividend yield	**N/A**	**N/A**
Risk-free interest rate	**1.00%**	**0.81%**

The following table provides stock option activity for the nine months ended September 30, 2021:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contract Term	Aggregate Intrinsic Value
Outstanding at December 31, 2020	**974,778**	**$ 4.12**	**2.87 years**	**$ 1,520,910**
Granted	932,135	4.72		-
Exercised	36,252	2.36		-
Forfeited	31,212	9.19		-
Expired	53,125	8.68		
Outstanding at September 30, 2021	**1,786,324**	**$ 4.25**	**7.00 years**	**$ 84,016**
Exercisable at September 30, 2021	**461,833**	**$ 4.57**	**4.05 years**	**$ 34,772**

The following table summarizes information about stock options outstanding at September 30, 2021:

	Stock Options Outstanding				Stock Options Exercisable		
Range of Exercise Prices	Number of Shares	Average Remaining Contract Term (Year)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
1 to 2.79999	603,287	5.48	$ 2.36	$ 84,016	248,372	$ 2.36	$ 34,772
2.8 to 4.59999	29,410	9.69	3.05	-	-	-	-
4.6 to 6.39999	944,430	8.91	4.81	-	14,961	5.49	-
6.4 to 8.19999	209,197	2.35	7.30	-	198,500	7.27	-
8.2 to 12	-	-	-	-	-	-	-
Total	**1,786,324**	**7.00**	**$ 4.25**	**$ 84,016**	**461,833**	**$ 4.57**	**$ 34,772**

As of September 30, 2021, there was $2,609,700 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 2.66 years. The total fair value of options vested during the nine months ended September 30, 2021 and 2020 were $335,579 and $172,145, respectively.

The following table summarizes information about restricted stock, restricted stock units and performance stock units outstanding as of September 30, 2021:

	Number of Shares & Units	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2020	603,531	$ 3.08
Granted	346,970	4.59
Vested	130,906	2.57
Forfeited	8,557	4.97
Outstanding at September 30, 2021	**811,038**	**$ 3.65**

As of September 30, 2021, there was $1,768,680 of net unrecognized compensation cost related to restricted stock, restricted stock units and performance stock units that had not vested, which is expected to be recognized over a weighted average period of approximately 1.83 years.

NOTE 9 — 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 sales by geographic area were as follows:

	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	**2021**	2020
Africa	**$ 1,293,405**	$ 1,874,518	**$ 4,104,619**	$ 3,310,603
Asia	**208,750**	168,052	**479,297**	650,659
Europe & Middle East	**1,132,520**	1,451,486	**3,431,736**	3,360,648
Latin America	**5,698,920**	4,618,560	**6,444,456**	7,515,523
United States	**1,037,565**	293,841	**2,867,096**	3,077,190
	$ 9,371,160	$ 8,406,457	**$ 17,327,204**	17,914,623

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

	September 30, 2021	December 31, 2020
Asia	**$ 122,719**	$ 326,267
Europe & Middle East	**117,227**	147,692
Latin America	**32,975**	14,719
United States	**8,471,792**	8,199,725
	$ 8,744,713	$ 8,688,403

Effective May 2021, the Company permanently discontinued its operations in Malaysia. Impairment charges recorded for the Malaysian property, plant and equipment during the three and nine months ended September 30, 2021 were $0 and $0.1 million, respectively.

NOTE 10 — ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:

Accounts payable and accrued liabilities consisted of:

	September 30, 2021	December 31, 2020
Accounts payable – suppliers	**$ 5,978,865**	$ 5,727,781
Accrued commissions and royalties	**870,627**	807,708
Accrued payroll	**475,072**	277,908
Accrued vacation	**530,773**	417,238
Accrued bonuses	**1,138,337**	1,193,985
Accrued severance	**-**	511,681
Accrued expenses – other	**1,188,814**	1,106,489
TOTAL	**$ 10,182,488**	$ 10,042,790

NOTE 11 — GOODWILL, LONG-LIVED ASSETS and INTANGIBLE ASSETS:

The following table reflects changes in goodwill:

Beginning balance at December 31, 2020	$ 5,963,744
Change in foreign currency exchange rate	(289,612)
Balance at September 30, 2021	$ 5,674,132

Intangible assets consisted of the following at:

		September 30, 2021			December 31, 2020		
	Weighted Average Remaining Useful Life	**Cost**	**Accumulated Amortization**	**Net Book Value**	Cost	Accumulated Amortization	Net Book Value
Intellectual property	**7**	**$ 779,848**	**$ 173,650**	**$ 606,198**	$ 1,638,699	$ 472,190	$ 1,166,509
Developed technology	**4**	**1,986,811**	**775,405**	**1,211,406**	2,102,526	594,186	1,508,340
Customer contracts/relationships	**6**	**516,464**	**155,882**	**360,582**	1,323,424	423,093	900,331
Trade names	**6**	**3,875**	**3,875**	**-**	115,318	44,512	70,806
		$ 3,286,998	**$ 1,108,812**	**$ 2,178,186**	$ 5,179,967	$ 1,533,981	$ 3,645,986

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, 2021 and 2020 was $373,784 and $287,253, respectively. Amortization expense, subject to changes in currency exchange rates, is expected to average $358,771 per year from 2021 through 2025, and total $384,745 for all of the years thereafter.

Effective May 2021, the Company permanently discontinued its operations in Malaysia. Impairment charges relating to intangible assets recorded during the three and nine months ended September 30, 2021 were $0 and $1.0 million, respectively as follows: intellectual property ($0.5 million), customer contracts/relationship ($0.4 million), and trade names ($0.1 million).

NOTE 12 — ASSET IMPAIRMENT, RESTRUCTURING, SEVERANCE AND RELATED COSTS:

The Company recorded an impairment loss of $1.3 million during the second quarter of 2021, as the result of its write-off of the intangible assets, net, leasehold improvements, net and right-of-use assets for leases, net associated with its Malaysian operations that underwent a retrenchment during the second quarter of 2020. During the second quarter of 2021, the Company was informed that the World Health Organization had prioritized its review of prequalification of the manufacture of the Company's HIV 1/2 STAT-PAK Assay on its U.S. automated manufacturing processes, which would reduce the Company's reliance on manual labor that otherwise could have been performed at the Malaysian facilities had the Company re-started operations there. During July 2021, the World Health Organization approved the change notification. The products produced on the Company's automated and manual production lines at any time depend on, among other things, the timing of customer orders and the mix of products being produced.

In light of the uncertainty of the timing and any receipt of those regulatory approvals, the timing of progress on and results of clinical trial programs, and the timing and any receipt of product orders from the commercialization of the COVID-19 Diagnostic Test Systems and other diagnostic test systems both within and outside the United States, during the second quarter of 2021, the Company engaged the services of an independent financial advisory firm (the "Financial Advisor"). The Financial Advisor worked with management to develop a forecast model to assess the amount and timing of the Company's liquidity needs, assuming various business cases, and together with legal counsel advised the Company regarding alternative approaches to enhancing its liquidity position, participating in discussions with the Lender, and related matters. During the three and nine months ended September 30, 2021, the Company incurred $0.4 and $1.1 million, respectively, related to these restructuring matters.

In order to address challenging economic conditions and implement its business strategy, in the first quarter of 2021 the Company continued to execute a program to reduce operating expenses and better align its costs with revenues, including by eliminating positions that were no longer aligned with its strategy, and recognized severance charges of $0.1 million.

The table below represents the total costs by category:

	For the three months ended September 30, 2021	For the nine months ended September 30, 2021
Severance	$ -	$ 83,087
Restructuring costs	396,740	1,083,951
Asset impairment	-	1,273,945
	$ 396,740	$ 2,440,983

NOTE 13 — SUBSEQUENT EVENTS:

In October 2021 the U.S. Department of Justice advised the Company that the U.S. Attorney's Office for the Eastern District of New York is investigating the May 2020 Offering (see also "Litigation—SEC Investigation" under Note 6—Commitments, Contingencies, and Concentrations). The Company intends to cooperate fully in this investigation, should the Company be asked to provide documents or other materials.

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 condensed 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" above. Please read "Item 1A. Risk Factors" in Part II of this report for a discussion of factors that could cause our actual results to differ materially from our expectations.

Overview

We develop and commercialize point-of-care tests used for the rapid detection and diagnosis of infectious diseases, including sexually transmitted disease, insect vector and tropical disease, COVID-19 and other viral and bacterial infections, enabling expedited treatment.

Our product portfolio is based upon our proprietary DPP technology, a diagnostic platform that provides high-quality, cost-effective results in 15 to 20 minutes using fingertip blood, nasal swabs and other sample types. The DPP technology platform addresses the rapid diagnostic test market, which includes infectious diseases, cardiac markers, cholesterol and lipids, pregnancy and fertility, and drugs of abuse. Compared with traditional lateral flow technology, the DPP technology platform can provide enhanced sensitivity and specificity, advanced multiplexing capabilities and, with the DPP Micro Reader, quantitative results.

We target the market for rapid diagnostic test solutions for infectious diseases, which is driven by the high prevalence of infectious diseases globally, an increase in the geriatric population, growing demand for rapid test results, and advancements in multiplexing. We have a broad portfolio of infectious disease products, which prior to 2020 were focused principally on sexually transmitted disease and fever and tropical disease. In February 2020 we began the process of shifting substantially all of our resources to seek to leverage the DPP technology platform to address the acute and escalating need for diagnostic testing for COVID-19. We are continuing to pursue:

- an emergency use authorization, or EUA, from the U.S. Food and Drug Administration, or FDA, as well as 510(k) clearance from the FDA, for the DPP SARS-CoV-2 Antigen test system;
- an EUA from the FDA for the DPP Respiratory Panel; and
- a Clinical Laboratory Improvement Amendment, or CLIA, waiver from the FDA for the DPP HIV-Syphilis test system.

Our products are sold globally, directly and through distributors, to medical laboratories and hospitals, governmental and public health entities, nongovernmental organizations, medical professionals, and retail establishments. We continue to seek to expand our commercial distribution channels.

Substantial Doubt as to Going Concern Status

Factors and considerations with respect to our liquidity raised, as of September 30, 2021, substantial doubt as to our ability to continue as a going concern through one year after the date that our condensed consolidated financial statements with respect to the three and nine months ended September 30, 2021, or the Accompanying Financial Statements, are being issued. In July 2021 we received two significant customer purchase orders, or the July Purchase Orders, as described under "—Recent Events—July Purchase Orders" below, and we raised funds through "at-the-market" offerings as described under "—Recent Events —At-the-Market Offerings of Common Stock" below, both of which were intended in part to improve our liquidity position.

These measures and other plans and initiatives have been designed to provide us with adequate liquidity to meet our obligations for at least the twelve-month period following the filing date of this report, when the Accompanying Financial Statements are being issued. Our execution of those measures and our other plans and initiatives continue to depend, however, on factors that are beyond our control, or that may not be addressable on terms acceptable to us or at all. We have considered in particular how:

- Limitations of our staffing, supply chain and liquidity have impaired, and are expected to continue to impair, our ability to fulfill at least $11.5 million of the July Purchase Order from Bio-Manguinhos by December 31, 2021, the end of the existing shipment schedule under the order. Please see "—Recent Events—July Purchase Orders" below and "Because of our liquidity and operational limitations, including the availability of staffing and supply chain resources that are necessary but outside of our control, we will not be able to timely fulfill all of the requirements of the July Purchase Order from Bio-Manguinhos and it is difficult to reliably estimate the extent to which we will be able to timely meet those requirements" and "Because of our liquidity and operational limitations, we may be required to prioritize fulfillment of customer orders, including the July Purchase Orders, which could harm our relationships with customers and our reputation and thereby negatively impact our business and operating results" under "Item 1A. Risk Factors" of Part II of this report.

- Earlier delays in clinical trials, which reflected the impact of the COVID-19 vaccination rollout and the related decline in positivity rates at clinical trials on our clinical plan enrollment levels, and continuing requirements of achievement of regulatory approvals may limit our ability to achieve a portion of the revenue- and cash-generating milestones under a $12.7 million award granted pursuant to our contract dated December 2, 2020 with the Biomedical Advanced Research and Development Authority (part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response), or BARDA, which contract will, unless extended by BARDA, expire on December 2, 2021. Please see "—Liquidity and Capital Resources" below and "Our ability to receive the amount of grants remaining under our existing contracts with BARDA is limited by operational factors as well as regulatory and other factors outside our control, and we cannot assure you that we will be able to receive all, or a significant portion, of those remaining amounts before the contracts expire" under "Item 1A. Risk Factors" of Part II of this report.

- The ongoing healthcare and economic impacts of the COVID-19 pandemic on the global customer base for our non-COVID-19 products continue to negatively affect the timing and rate of recovery of our revenues from those products by, for example, decreasing the allocation of funding for HIV testing, thereby continuing to adversely affect our liquidity.

- Although we have entered into agreements to distribute third-party COVID-19 products in the United States, our ability to sell those products could be constrained because of staffing and supply chain limitations affecting the suppliers of those products.

We further considered how these factors and uncertainties could impact our ability over the next year to meet the obligations specified in the Credit Agreement and Guaranty, or the Credit Agreement, that we and certain of our subsidiaries, as guarantors, entered into with Perceptive Credit Holdings II, LP, or the Lender. Those obligations include a covenant requiring minimum total revenue amounts for the twelve months preceding each quarter end. For the next year, the minimum total revenue requirements range from $40.3 million for the twelve months ending December 31, 2021 to $45.6 million for the twelve months ending September 30, 2022. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. In such an event, there can be no assurance that we would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, we would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. Our inability to raise additional capital on acceptable terms in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for our operations, could have a material adverse effect on our business, prospects, results of operations, liquidity and financial condition.

Accordingly, management determined we could not be certain that our plans and initiatives would be effectively implemented within one year after the filing date of this report, when the Accompanying Financial Statements are being issued. Without giving effect to the prospect of raising additional capital pursuant to our at-the-market offerings, increasing product revenue in the near future or executing other mitigating plans, many of which are beyond our control, it is unlikely that we will be able to generate sufficient cash flows to meet our required financial obligations, including our debt service and other obligations due to third parties. The existence of these conditions raises substantial doubt about our ability to continue as a going concern for the twelve-month period following the filing date of this report.

The Accompanying Financial Statements have been prepared assuming we will continue as a going concern, which contemplates continuity of operations, realization of assets and the satisfaction of liabilities in the normal course of business for the twelve-month period following the filing date of this report. As such, the Accompanying Financial Statements do not include any adjustments relating to the recoverability and classification of assets and their carrying amounts, or the amount and classification of liabilities that may result should we be unable to continue as a going concern.

Please see note 2(a) to the Accompanying Financial Statements for additional information regarding our going concern assessment in connection with the Accompanying Financial Statements. You are urged to read carefully the information provided below under "—Liquidity and Capital Resources" below as well as in "Because of our liquidity limitations, we have concluded there is a substantial doubt about our ability to continue as a going concern and we may require additional capital to fund our operations, which capital may not be available to us on acceptable terms or at all," and "The failure to comply with the terms of the Credit Agreement could result in a default under its terms and, if uncured, could result in action against our pledged assets and dilution of our stockholders" under "Item 1A. Risk Factors" of Part II of this report.

Recent Events

July Purchase Orders

In July 2021 we received the July Purchase Orders, which we had been pursuing for an extended period of time and which consist of the following:

- On July 20, 2021, we received a $28.3 million purchase order from Bio-Manguinhos for the purchase of DPP SARS-CoV-2 Antigen tests for delivery during 2021 to support the needs of Brazil's Ministry of Health in addressing the COVID-19 pandemic. Bio-Manguinhos, a subsidiary of the Oswaldo Cruz Foundation (known as Fiocruz), is responsible for the development and production of vaccines, diagnostics, and biopharmaceuticals, primarily to meet demands of Brazil's national public health system.
- On July 22, 2021, we received a $4 million purchase order from the Partnership for Supply Chain Management, supported by The Global Fund, for the purchase of HIV 1/2 STAT-PAK Assays for shipment to Ethiopia into early 2022.

Our delivery of the full number of tests covered by the July Purchase Orders, and in particular the July Purchase Order from Bio-Manguinhos, has been adversely affected by limitations of our staffing and supply chain that are largely outside of our control. Upon receiving the July Purchase Orders, we launched a broad campaign to recruit and retain manufacturing personnel and, more recently, we have temporarily implemented substantial increases in our hourly pay rates for manufacturing personnel. Our recruiting efforts have not, however, proven sufficient to overcome the tight labor market that has been impacting many U.S. companies, including employers on Long Island, New York, where our manufacturing operations are located. We have not been able to hire the number of manufacturing personnel required to meet our internal plans for delivery of all of the tests contemplated by the July Purchase Orders. Moreover, the overtime demands of seeking to produce the maximum number of tests possible with existing personnel increasingly are challenging our ability to retain manufacturing personnel. While we are seeking to leverage our automated production lines, automation cannot, on the schedule for delivering tests contemplated by the July Purchase Orders, compensate fully for the shortage of manufacturing personnel.

Our delivery of tests covered by the July Purchase Orders has also been negatively affected by limitations on production supplies. The COVID-19 pandemic has disrupted nearly every aspect of the global supply chain, including the manufacturing of some of the key supplies used in our tests. Many suppliers are experiencing shortages of required personnel as the result of the tight labor market and underlying raw material commodities. Because of the number of tests deliverable under the July Purchase Orders and the required timing of the deliveries, we have had to identify sources of supplies on a short timeframe and in a markedly increased quantity. As the result, we have been required to seek to identify new sources of materials to replace or augment our past sources. Moreover, scarcity has caused increases in the cost of some supplies. Given the ongoing labor and supply chain shortages, we expect our ability to manufacture tests covered by the July Purchase Orders will continue through at least the end of 2021, the contractual deadline for delivering tests under the July Purchase Order from Bio-Manguinhos.

During the three months ended September 30, 2021, we delivered tests constituting $5.4 million of the total $28.3 million contemplated by the July Purchase Order from Bio-Manguinhos. While we have established internal plans for delivery of additional tests contemplated by the July Purchase Order from Bio-Manguinhos, the number of uncertainties related to third parties — including the availability of required personnel and supplies — and other operational factors make it difficult for us to reliably estimate the extent to which we will be able to fulfill the July Purchase Order from Partnership for Supply Chain Management are subject to uncertainties related to third parties — including the availability of required personnel and supplies — and other operational factors similar to those affecting fulfillment of the July Purchase Order from Bio-Manguinhos, which make it difficult for us to accurately estimate the extent to which we will be able to fulfill the July Purchase Order from Partnership for Supply Chain Management on time and at an acceptable cost.

Please see “Because of our liquidity and operational limitations, including the availability of staffing and supply chain resources that are necessary but outside of our control, we will not be able to timely fulfill all of the requirements of the July Purchase Order from Bio-Manguinhos and it is difficult to reliably estimate the extent to which we will be able to timely meet those requirements” under “Item 1A. Risk Factors” of Part II of this report.

At-the-Market Offerings of Common Stock

On July 19, 2021, we entered into an At the Market Offering Agreement, or the ATM Agreement, with Craig-Hallum Capital Group LLC, or Craig-Hallum, pursuant to which we may sell from time to time, at our option, up to an aggregate of $60,000,000 of shares of common stock through Craig-Hallum, as sales agent. Any sales of shares made pursuant to the ATM Agreement will be made pursuant to our shelf registration statement on Form S-3 (File No. 333-254261) and the related prospectus previously declared effective by the SEC on May 5, 2021, as supplemented by a prospectus supplement dated July 19, 2021 that we filed with the SEC, pursuant to Rule 424(b)(5) under the Securities Act of 1933 or the Securities Act, on July 19, 2021, as such prospectus supplement may be amended or supplemented from time to time. Subject to the terms and conditions of the ATM Agreement, Craig-Hallum may sell any shares only by methods deemed to be an “at the market” offering as defined in Rule 415 under the Securities Act, including sales made directly through the Nasdaq Capital Market, by means of ordinary brokers’ transactions, in negotiated transactions, to or through a market maker other than on an exchange or otherwise, at market prices prevailing at the time of sale, at prices related to such prevailing market prices, or at negotiated prices and/or any other method permitted by law. For a further description of the terms of the ATM Agreement, please see note 5 to the Accompanying Financial Statements.

As of the filing date of this report, we have issued and sold pursuant to the ATM Agreement a total of 9,709,328 shares of common stock at a volume-weighted average price of $4.2011 per share for gross proceeds of $40.8 million and net proceeds, after giving effect to placement fees and other transaction costs, of $38.8 million. Additional shares of common stock may be issued and sold pursuant to the ATM Agreement for gross proceeds of up to $19.2 million, but we cannot provide any assurance that will be able to issue any additional shares under the ATM Agreement at an acceptable price or at all.

This report shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any offer, solicitation, or sale of any securities in any state or country in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or country.

Consolidated Results of Operations

Three Months Ended September 30, 2021 versus Three Months Ended September 30, 2020

The results of operations for the three months ended September 30, 2021 and 2020 were as follows (dollars in thousands):

	For the three months ended September 30,			
	2021		2020	
TOTAL REVENUES	**$ 12,058**	**100%**	$ 10,272	100%
OPERATING COSTS AND EXPENSES:				
Cost of product sales	**7,903**	**66%**	7,468	73%
Research and development expenses	**3,442**	**29%**	2,352	23%
Selling, general and administrative expenses	**5,947**	**49%**	5,349	52%
Asset impairment, restructuring, severance and related costs	**397**	**3%**	12	0%
	17,689		15,181	
LOSS FROM OPERATIONS	**(5,631)**		(4,909)	
OTHER EXPENSE, NET	**(735)**		(736)	
LOSS BEFORE INCOME TAXES	**(6,366)**	**(53)%**	(5,645)	(55)%
Income tax (expense) benefit	-		105	
NET LOSS	**$ (6,366)**		$ (5,540)	

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during the three months ended September 30, 2021 were $12.1 million, an increase of $1.8 million, or 17.4%, compared to the three months ended September 30, 2020. The increase in total revenues compared to the comparable quarter of 2020 reflected the benefit of government grant income totaling $2.2 million associated with our $12.7 million award from BARDA, offset by a decrease in R&D revenue of $1.4 million from the completion of the related projects; and an increase of $1 million in net product sales reflecting higher sales in Latin America, United States, and Asia, offset by lower sales in the Africa and Europe & Middle East.

Our total 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 was probable that a significant reversal in revenue would not have occurred for shipments of the DPP COVID-19 IgM/IgG System outside the United States. After reflecting the revenue recognition timing of those shipments, total revenues during the three months ended September 30, 2021 increased by $4.5 million, or 59.2%, compared to the three months ended September 30, 2020.

Gross Product Margin

Cost of product sales is primarily composed of material, labor, manufacturing overhead, depreciation and amortization, and freight and distribution costs. 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 sales.

Gross product margin during the three months ended September 30, 2021 increased by $0.5 million or 56.5%.

The following schedule calculates gross product margin (dollars in thousands):

	For the three months ended September 30,		Favorable/(unfavorable)	
	2021	2020	**$ Change**	**% Change**
Net product sales	**$ 9,371**	$ 8,406	$ 965	11.5%
Less: Cost of product sales	**(7,903)**	(7,468)	(435)	5.8%
Gross product margin	**$ 1,468**	$ 938	$ 530	56.5%
Gross product margin percentage	**15.7%**	11.2%	4.51%	

The $0.5 million increase in gross product margin was comprised of (a) $0.4 million from favorable product margins due to higher average selling prices and (b) $0.1 million from favorable product sales volume as described under "—Total Revenues" above.

Research and Development

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

	For the three months ended September 30,		Favorable/(unfavorable)	
	2021	2020	**$ Change**	**% Change**
Clinical and regulatory affairs	**$ 1,520**	$ 258	$ 1,262	$ (489.3)%
Other research and development	**1,922**	2,094	(172)	(8.2)%
Total research and development	**$ 3,442**	$ 2,352	$ 1,090	46.3%

The $1.1 million increase in research and development costs for the three months ended September 30, 2021 compared to the three months ended September 30, 2020 was primarily associated with clinical and regulatory affairs costs related to pursuing an EUA and 510(k) from the FDA for the DPP SARS-CoV-2 Antigen test system and an EUA for the DPP Respiratory Panel, each pursuant to awards from BARDA.

Selling, General and Administrative Expense

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

The $0.6 million, or 11.2%, increase in selling, general and administrative expense for the three months ended September 30, 2021 compared to the three months ended September 30, 2020 principally reflected increased costs associated with compensation costs related to our expanded U.S. commercial team, commissions, and insurance, offset by a decrease in legal services.

Asset Impairment, Restructuring, Severance and Related Costs

In light of the uncertainty of the timing and receipt of regulatory approvals, the timing of progress on and results of clinical trial programs, and the timing and any receipt of product orders from the commercialization of our COVID-19 and other diagnostic test systems both within and outside the United States, during the second quarter of 2021 we engaged the services of an independent financial advisory firm. The financial advisory firm worked with management to develop a forecast model to assess the amount and timing of our liquidity needs, assuming various business cases, and together with legal counsel advised us regarding alternative approaches to enhancing our liquidity position, participating in discussions with the Lender, and related matters. During the three months ended September 30, 2021, we incurred $0.4 million related to these restructuring matters. The restructuring costs were concluded following the receipt of the July Purchase Orders as described under "—Recent Events—July Purchase Orders" above and raising funds through "at-the-market" offerings as described under "—Recent Events—At-the-Market Offerings of Common Stock" above, both of which were intended in part to improve our liquidity position.

Other Expense, Net

Other expense, net consists principally of interest expense, net of interest income earned on our deposits. Other expense, net for the three months ended September 30, 2021 was comparable to the corresponding period in 2020 and is associated with interest accruing on long-term debt, of which $20 million (carrying value of $18.6 million) was outstanding at September 30, 2021. For a description of this long-term debt, please see "—Liquidity and Capital Resources—Sources of Funds—Credit Agreement" below.

Nine Months Ended September 30, 2021 versus Nine Months Ended September 30, 2020

The results of operations for the nine months ended September 30, 2021 and 2020 were as follows (dollars in thousands):

	For the nine months ending September 30,			
	2021		2020	
TOTAL REVENUES	**$ 27,245**	**100%**	$ 22,243	100%
OPERATING COSTS AND EXPENSES:				
Cost of product sales	**15,491**	**57%**	17,513	79%
Research and development expenses	**9,102**	**33%**	6,233	28%
Selling, general and administrative expenses	**18,034**	**66%**	13,903	63%
Asset impairment, restructuring, severance and related costs	**2,441**	**9%**	1,122	5%
Acquisition	-	-	64	0%
	45,068		38,835	
LOSS FROM OPERATIONS	**(17,823)**		(16,592)	
OTHER EXPENSE, NET	**(2,175)**		(2,110)	
LOSS BEFORE INCOME TAXES	**(19,998)**	**(73)%**	(18,702)	(84)%
Income tax (expense) benefit	**68**		320	
NET LOSS	**$ (19,930)**		$ (18,382)	

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during the nine months ended September 30, 2021 were $27.2 million, an increase of $5.0 million, or 22.5%, compared to the nine months ended September 30, 2020. The increase in total revenues compared to the nine months ended September 30, 2020 reflected a $7.8 million increase in government grant income associated with the $12.7 million award from BARDA, offset by a decreases of $2.4 million in R&D revenue from non-governmental programs and $0.6 million in net product sales, the latter reflecting the net impact of lower sales in Latin America, United States and Asia, partially offset by increased sales in Africa, Europe and the Middle East, the former principally related to newer demand for SURE CHECK HIV Self-Tests.

Gross Product Margin

Cost of product sales is primarily composed of material, labor, manufacturing overhead, depreciation and amortization, and freight and distribution costs. 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 revenue.

Gross product margin during the nine months ended September 30, 2021 increased by $1.4 million or 356.7%.

The following schedule calculates gross product margin (dollars in thousands):

	For the nine months ended September 30,		Favorable/(unfavorable)	
	2021	2020	**$ Change**	**% Change**
Net product sales	**$ 17,327**	$ 17,915	$ (588)	(3.3)%
Less: Cost of product sales	**(15,491)**	(17,513)	2,022	(11.5)%
Gross product margin	**$ 1,836**	$ 402	$ 1,434	356.7%
Gross product margin percentage	**10.6%**	2.2%	8.4%	

The $1.4 million increase in gross product margin principally resulted from favorable product margins due to higher average selling prices.

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 September 30,		Favorable/(unfavorable)	
	2021	2020	**$ Change**	**% Change**
Clinical and regulatory affairs	**$ 3,156**	$ 758	$ 2,398	$ 316.4%
Other research and development	**5,946**	5,475	471	8.6%
Total research and development	**$ 9,102**	$ 6,233	$ 2,869	46.0%

The $2.9 million increase in research and development costs for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 was primarily associated with clinical and regulatory affairs costs related to pursuing an EUA and 510(k) from the FDA for the DPP SARS-CoV-2 Antigen test system and an EUA for the DPP Respiratory Panel, each pursuant to awards from BARDA.

Selling, General and Administrative Expense

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

The $4.1 million, or 29.7%, increase in selling, general and administrative expense for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 principally reflected increased costs associated with (a) fees for legal services, (b) compensation related to our expanded U.S. commercial team, (c) insurance; and (d) non-cash equity compensation, which was expanded to include all global employees.

Asset Impairment, Restructuring, Severance and Related Costs

We incurred asset impairment, restructuring, severance and related costs of $2.4 million during the nine months ended September 30, 2021 as follows:

- We recorded an impairment loss of $1.3 million in June 2021 as the result of our write-off of the intangible assets, net, leasehold improvements, net and right-of-use assets for leases, net associated with our Malaysian operations, which underwent a retrenchment during the second quarter of 2020.
- In light of the uncertainty of the timing and receipt of regulatory approvals, the timing of progress on and results of clinical trial programs, and the timing and any receipt of product orders from the commercialization of our COVID-19 and other diagnostic test systems both within and outside the United States, during the second quarter of 2021 we engaged the services of an independent financial advisory firm. The financial advisory firm worked with management to develop a forecast model to assess the amount and timing of our liquidity needs, assuming various business cases, and together with legal counsel advised us regarding alternative approaches to enhancing our liquidity position, participating in discussions with the Lender, and related matters. During the nine months ended September 30, 2021, we incurred $1.1 million related to these restructuring matters. The restructuring costs were concluded following the receipt of the July Purchase Orders as described under "—Recent Events—July Purchase Orders" above and raising funds through "at-the-market" offerings as described under "—Recent Events—At-the-Market Offerings of Common Stock" above, both of which were intended in part to improve our liquidity position.

Other Expense, Net

Other expense, net consists principally of interest expense, net of interest income earned on our deposits, which increased in the nine months ended September 30, 2021 compared to the comparable period in 2020 due to interest accruing on long-term debt incurred in September 2019, of which $20 million (carrying value of $18.6 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, 2021, we recognized a tax benefit of $0.1 million related to losses generated by our foreign subsidiaries, which offsets the deferred tax liability balances recorded on acquisition date. As of September 30, 2021 and 2020, our U.S. deferred tax assets included a full valuation allowance.

Liquidity and Capital Resources

General

Our cash and cash equivalents totaled $36.0 million at September 30, 2021, an increase of $30.4 million from $5.6 million at June 30, 2021 and an increase of $12.9 million from $23.1 million at December 31, 2020. We are obligated to maintain aggregate unrestricted cash of not less than $3,000,000 at all times under a covenant in the Credit Agreement.

During the first nine months of 2021, we funded our business operations, including capital expenditures and working capital requirements, principally from cash and cash equivalents and issuance of common stock in at-the-market offerings. Our operations used $8.2 million of cash during the three months ended September 30, 2021 and $24.2 million of cash during the nine months ended September 30, 2021. Revenues during the three and nine months ended September 30, 2021 did not meet our expectations, and the shortfall in revenues was one of the principal reasons we issued common stock in the at-the-market offerings during the three months ended September 30, 2021, which provided us with net proceeds of $38.8 million. This increase in cash and cash equivalents was offset in part as the result of (a) market, clinical trial and regulatory complications we faced in seeking to develop and commercialize a portfolio of COVID-19 test systems during the continuing, but evolving, uncertainty of the COVID-19 pandemic and (b) significant continuing expenses incurred in connection with pending legal matters (see note 6(f) – Commitments, Contingencies, and Concentrations: Litigation in the Accompanying Financial Statements), delayed achievement of milestones associated with government grant income, investments in inventory, and, the continuing automation of U.S. manufacturing.

In light of the uncertainty of the timing and any receipt of regulatory approvals, the timing of progress on and results of clinical trial programs, and the timing and any receipt of product orders from the commercialization of our COVID-19 and other diagnostic test systems both within and outside the United States, during the three months ended June 30, 2021 we engaged the services of an independent financial advisory firm. The financial advisory firm worked with management to develop a forecast model to assess the amount and timing of our liquidity needs, assuming various business cases and, together with legal counsel, advised us regarding alternative approaches to enhancing our liquidity position, participating in discussions with the Lender under our credit facility and related matters. We incurred fees related to these restructuring matters totaling $0.7 million in the three months ended June 30, 2021 and $0.4 million in the three months ended September 30, 2021.

Factors and considerations with respect to our liquidity raised, as of September 30, 2021, substantial doubt as to our ability to continue as a going concern through one year after the date that the Accompanying Financial Statements are being issued. See “—Overview—Substantial Doubt as to Going Concern Status” above.

We have undertaken plans and initiatives, including fulfillment of the July Purchase Orders (see “—Recent Events—July Purchase Orders” above) and fundraising through “at-the-market” offerings (see “—Recent Events—At-the-Market Offerings of Common Stock” above), designed to provide us with adequate liquidity to meet our obligations for at least the twelve-month period following the filing date of this report, when the Accompanying Financial Statements are being issued. Our execution of those plans and initiatives is dependent, however, on a number of operational performance factors, such as the effectiveness of our automated manufacturing operations, as well as numerous other factors that are beyond our control or that may not be addressable on terms acceptable to us, or at all. We have considered how the uncertainties around the delivery of the full number of tests covered by the July Purchase Order from Bio-Manguinhos and other customer orders may be affected by limitations of our staffing, supply chain and liquidity, uncertainties regarding the achievement of milestones and related recognition of revenue under government grants from BARDA, and other matters outside our control. We further considered how those uncertainties could impact our ability to meet the obligations specified in the Credit Agreement over the next twelve months, which include (a) a covenant requiring minimum total revenues for the twelve months preceding each quarter end, which requirements range from $40.3 million for the twelve months ending December 31, 2021 to $45.6 million for the twelve months ending September 30, 2022 and (b) an obligation requiring the payment of principal installments, commencing with the payment of $300,000 on September 30, 2022. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. In such an event, there can be no assurance that we would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, we would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. Our inability to raise additional capital on acceptable terms in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for our operations, could have a material adverse effect on our business, prospects, results of operations, liquidity and financial condition.

Accordingly, management determined we could not be certain that our plans and initiatives would be effectively implemented within one year after the filing date of this report, when the Accompanying Financial Statements are being issued. Without giving effect to the prospect of raising additional capital pursuant to our at-the-market offerings, increasing product revenue in the near future or executing other mitigating plans, many of which are beyond our control, it is unlikely that we will be able to generate sufficient cash flows to meet our required financial obligations, including our debt service and other obligations due to third parties. The existence of these conditions raises substantial doubt about our ability to continue as a going concern for the twelve-month period following the date of this report.

The Accompanying Financial Statements have been prepared assuming we will continue as a going concern, which contemplates continuity of operations, realization of assets and the satisfaction of liabilities in the normal course of business for the twelve-month period following the date of this report. As such, the Accompanying Financial Statements do not include any adjustments relating to the recoverability and classification of assets and their carrying amounts, or the amount and classification of liabilities that may result should we be unable to continue as a going concern.

Please see note 2(a) to the Accompanying Financial Statements for additional information regarding our going concern assessment in connection with the Accompanying Financial Statements. You are urged to read carefully the information provided in "Because of our liquidity limitations, we have concluded there is a substantial doubt about our ability to continue as a going concern and we may require additional capital to fund our operations, which capital may not be available to us on acceptable terms or at all," "Because of our liquidity and operational limitations, including the availability of staffing and supply chain resources that are necessary but outside of our control, we may not be able to timely fulfill some of the requirements of the July Purchase Orders without additional capital to fund our operations, which capital may not be available to us on acceptable terms, or at all," and "The failure to comply with the terms of the Credit Agreement could result in a default under its terms and, if uncured, could result in action against our pledged assets and dilution of our stockholders" under "Item 1A. Risk Factors" of Part II of this report.

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, accounts payable and inventory balances fluctuate from period to period, which affects our cash flow from operating activities. The amounts of these fluctuations vary depending on cash collections, client mix, raw material lead times, the mix of vendor terms, the timing of shipment of our products and the invoicing of our research and development activities.

We continually evaluate our liquidity requirements, capital needs and availability of capital resources based on our operating needs and our planned growth initiatives. Our future working capital needs will depend on many factors, including the rate of our business and revenue growth, the availability and cost of human, material and other resources required to build and deliver products in accordance with our existing or future product orders, the timing of our continuing automation of U.S. manufacturing, and the timing of our investment in 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. There can be no assurance that we would be able to complete any proposed financing on terms acceptable to us, or at all, or that we otherwise will be successful in any of our other endeavors to continue to be financially viable and continue as a going concern. Our inability to raise additional capital on acceptable terms could have a material adverse effect on our business, prospects, results of operations, liquidity and financial condition. If we were to raise additional funds through the issuance of equity or convertible securities, the issuance could result in substantial dilution to existing stockholders, and the holders of those new securities may have rights, preferences and privileges senior to those of the holders of common stock. Furthermore, any decline in the market price of our common stock could make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate.

Sources of Funds

Equity and Equity-Related Securities. On July 19, 2021, we entered into the ATM Agreement with Craig-Hallum, pursuant to which we may sell from time to time, at our option, up to an aggregate of $60,000,000 of shares of common stock through Craig-Hallum, as sales agent. Please see "¾Recent Events¾ At-the-Market Offerings of Common Stock." Any sales of shares made pursuant to the ATM Agreement will be made pursuant to our shelf registration statement on Form S-3 (File No. 333-254261) and the related prospectus previously declared effective by the SEC on May 5, 2021, as supplemented by a prospectus supplement dated July 19, 2021 that we filed with the SEC, pursuant to Rule 424(b)(5) under the Securities Act, on July 19, 2021, as such prospectus supplement may be amended or supplemented from time to time.

Prior to any sale of shares of common stock under the ATM Agreement, we may deliver a sales notice to Craig-Hallum that will set the parameters for such sale, including the number of shares to be issued and sold, the time period during which such sale is requested to be made, any limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Under the ATM Agreement, Craig-Hallum is required to use commercially reasonable efforts consistent with its normal trading and sales practices to sell shares in accordance with the terms of the ATM Agreement and any applicable sales notice.

Subject to the terms and conditions of the ATM Agreement, Craig-Hallum may sell any shares of common stock only by methods deemed to be an "at the market" offering as defined in Rule 415 under the Securities Act, including sales made directly through the Nasdaq Capital Market, by means of ordinary brokers' transactions, in negotiated transactions, to or through a market maker other than on an exchange or otherwise, at market prices prevailing at the time of sale, at prices related to such prevailing market prices, or at negotiated prices and/or any other method permitted by law. If any sale of shares pursuant to the ATM Agreement is not made directly on the Nasdaq Capital Market or any other existing trading market for common stock at market prices at the time of sale, including a sale to Craig-Hallum acting as principal or a sale in a privately negotiated transaction, we must file a prospectus supplement describing the terms of such sale, the number of shares sold, the price of the shares, the applicable compensation, and such other information as may be required pursuant to Rules 424 and 430B under the Securities Act, as applicable, within the time required by Rule 424 under the Securities Act.

Under the terms of the ATM Agreement, we are to pay Craig-Hallum a placement fee of 3.5% of the gross sales price of shares of common stock sold, unless Craig-Hallum acts as principal, in which case we may sell the shares to Craig-Hallum as principal at a price we agree upon with Craig-Hallum. We are obligated to reimburse Craig-Hallum for certain expenses incurred in connection with the ATM Agreement, and we have provided Craig-Hallum with customary indemnification and contribution rights with respect to certain liabilities, including liabilities under the Securities Act and the Securities Exchange Act of 1934.

The offering of shares of common stock pursuant to the ATM Agreement will terminate upon the earliest of (a) the sale of all of the shares registered for purposes of the offering pursuant to the ATM Agreement, (b) our mutual written agreement with Craig-Hallum, (c) written notice from Craig-Hallum, in its sole discretion, to us, and (d) five business days' prior written notice from us, in our sole discretion, to Craig-Hallum.

To date, we have issued and sold pursuant to the ATM Agreement a total of 9,709,328 shares of common stock at a volume-weighted average price of $4.2011 per share for gross proceeds of $40.8 million and net proceeds, after giving effect to placement fees and other transaction costs, of $38.8 million. Additional shares of common stock may be issued and sold pursuant to the ATM Agreement for gross proceeds of up to $19.2 million, but we cannot provide any assurance that will be able to issue any additional shares under the ATM Agreement at an acceptable price or at all.

Credit Agreement. The following description summarizes certain key provisions of the Credit Agreement:

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

- *Interest Rate.* Principal outstanding under the Credit Agreement bears interest at a rate per annum equal to the sum of (a) the greater of the one month London Interbank Offered Rate and 2.5% plus (b) 8.75%. At any time at which an event of default (as described under "—Default Provisions" below) has occurred and is continuing, the interest rate will increase by 4.0%. Accrued interest is payable on a monthly basis. On September 30, 2021 the interest rate was 11.25%.

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

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

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

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

- *Representations and Warranties; Financial and Other Covenants.* In the Credit Agreement we made customary representations and warranties as well as customary affirmative and negative covenants, including covenants limiting additional indebtedness, liens, guaranties, mergers and acquisitions, substantial asset sales, investments and loans, sale and leasebacks, transactions with affiliates, and fundamental changes. The Credit Agreement also contains financial covenants requiring that (a) we maintain aggregate unrestricted cash of not less than $3,000,000 at all times and (b) we achieve specified minimum total revenue requirements for the twelve months preceding each quarter end. The minimum total revenue amounts range from $32.0 million to $50.1 million and, for the next year, range from $40.3 million for the twelve months ending December 31, 2021 to $45.6 million for the twelve months ending September 30, 2022. The minimum total revenue requirements were developed for purposes of the Credit Agreement and do not reflect the internal estimates and plans used by our management and board of directors to understand and evaluate our operating performance, to establish budgets, and to establish operational goals for managing our business. We therefore do not believe that the covenant requirements provide useful information to investors or others in enhancing an understanding of our future prospects.

- *Default Provisions.* The Credit Agreement provides for customary events of default, including events of default based on non-payment of amounts due under the Credit Agreement, defaults on other debt, misrepresentations, covenant breaches, changes of control, insolvency, bankruptcy and the occurrence of a material adverse effect on our company. Upon an event of default resulting from a voluntary or involuntary proceeding for bankruptcy, insolvency or receivership, the amounts outstanding under the Credit Agreement will become immediately due and payable and the Lender's commitments will be automatically terminated. Upon the occurrence and continuation of any other event of default, the Lender may accelerate payment of all obligations and terminate its commitments under the Credit Agreement.

Research and Development Awards. Under a contract we entered into with BARDA on December 2, 2020, a total of up to $12.7 million of awards are available from BARDA to assist us in (a) developing, and pursuing an EUA from the FDA for, the DPP Respiratory Panel and (b) performing the clinical trials for and submitting the DPP SARS-CoV-2 Antigen test system to the FDA for 510(k) clearance. Of the total awards available under this contract, we recognized government grant income totaling $8.0 million during the nine months ended September 30, 2021 and have recognized additional government grant income totaling $0.9 million in the fourth quarter of 2021, as of the filing date of this report. Unless extended by BARDA in its discretion, all of the $2.2 million of awards remaining under the contract as of the date of filing this report will expire unless earned by December 2, 2021. The completion of milestones to earn a portion of the remaining awards are outside our control, and we cannot assure you that we will succeed in earning all or any significant portion of the remaining awards by December 2, 2021.

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

	September 30, 2021
	(in thousands)
Cash and cash equivalents	$ 36,004
Accounts receivable, net of allowance for doubtful amounts	6,783
Inventories, net	16,806
Prepaid expenses and other current assets	1,192
Total current assets	60,785
Less: Total current liabilities	11,426
Working capital	**$ 49,359**

Uses of Funds

Cash Flow Used in Operating Activities. Our operations used $24.2 million of cash during the nine months ended September 30, 2021, primarily due to: a net loss adjusted for non-cash items of $14.0 million; a $5.2 million increase in inventory related to materials and manufacturing costs for COVID-19 systems in anticipation of potential customer orders and regulatory approvals and production activities related to the July Purchase Orders; a $3.3 million increase in accounts receivable increased total revenues, principally from the July Purchase Orders and grant income under a contract with BARDA; a $1.6 million decrease in deferred revenue; and a $0.4 million increase in prepaid expenses and other current assets. Those uses of cash were offset in part by a $0.1 million decrease in deposits and other assets and a $0.1 million increase in accounts payable and other accrued liabilities.

Credit Agreement. Principal installments in the amount of $300,000 are payable under the Credit Agreement on the last day of each of the eleven months from September 2022 through July 2023, and all remaining principal is payable at maturity on September 3, 2023. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable, as further described "—Sources of Funds—Credit Agreement—Default Provisions" above. In addition, we could determine to prepay from time to time outstanding principal under the Credit Agreement (see "—Sources of Funds—Credit Agreement—Optional Prepayment" above) or to make other payments under the Credit Agreement that may not be then due or otherwise required under the Credit Agreement, although, as of the date of the filing of this report, we do not intend to make any such prepayments or other payments.

Capital Expenditures. Our capital expenditures totaled $1.4 million in the nine months ended September 30, 2021, all of which related to investments in automated manufacturing equipment, facilities, and other fixed assets. As of September 30, 2021, we had capital purchase obligations of $1.5 million related to additional automated manufacturing equipment, with payments expected to come due during 2022 based on vendor performance milestones.

Effects of Inflation

In addition to the impact of increases in minimum wage levels in New York, we have encountered inflation and changing prices that have had a material effect on our business, and we expect that they will continue to materially affect our business in the foreseeable future. Our delivery of the full number of tests covered by the July Purchase Orders, and in particular the July Purchase Order from Bio-Manguinhos, has been adversely affected to date by limitations of our staffing and supply chain that are largely outside of our control. Upon receiving the July Purchase Orders, we launched a broad campaign to recruit and retain manufacturing personnel and, more recently, we temporarily increased pay for manufacturing personnel. Our recruiting efforts have not, however, proven sufficient to overcome the tight labor market that has been impacting many U.S. companies, including employers on Long Island, New York, where our manufacturing operations are located. Because of the number of tests deliverable under the July Purchase Orders and the required timing of the deliveries, we have had to identify sources of supplies on a short timeframe and in a markedly increased quantity. As the result, we have been required to seek to identify new sources of materials to replace or augment our past sources. Moreover, scarcity has caused increases in the cost of some supplies. Any impact of inflation on cost of revenue and operating expenses, especially employee compensation costs (including any effects of future increases in minimum wages levels in New York), may not be readily recoverable in the price of our product offerings.

Off-Balance Sheet Arrangements

As of September 30, 2021, 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.

Significant Accounting Policies and Critical Accounting Estimates

There were no significant changes in our critical accounting estimates during the nine months ended September 30, 2021 to augment the critical accounting estimates disclosed under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, other than those described in the notes to the Accompanying Financial Statements.

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, 2020 and is updated in note 2 to the Accompanying Financial Statements.

ITEM 4. CONTROLS AND PROCEDURES

(a) **Disclosure Controls and Procedures.** Under the supervision and with the participation of our senior management, consisting of our principal executive officer and our principal financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of the end of the period covered by this report. Based on this evaluation, our management, including our principal executive officer and principal financial officer, concluded that as of September 30, 2021 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, 2021, 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

This information is set forth under – Commitments, Contingencies and Concentrations – Litigation – Legal Proceedings" to the Accompanying Financial Statements and is incorporated herein by reference.

ITEM 1A. RISK FACTORS

Except as set forth below, there have been no material changes to the risk factors described in the section captioned "Item 1A. Risk Factors" in Part 1 of our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021, as filed with the SEC on May 5, 2021, as amended and supplemented by the information in the section captioned "Item 8.01. Other Events—Risk Factors" in our Current Report on Form 8-K filed with the SEC on July 19, 2021. In addition to the other information set forth in this report, you should carefully consider the factors discussed in the sections captioned "Item 1A. Risk Factors" in Part 1 of our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021 and "Item 8.01. Other Events—Risk Factors" in our Current Report on Form 8-K filed with the SEC on July 19, 2021, which factors could materially affect our business, financial condition or future results. Moreover, you should interpret many of the risks identified in those sections as being heightened as a result of the ongoing and numerous adverse impacts of the COVID-19 pandemic. The risks described in those sections 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.

Because of our liquidity limitations, we have concluded there is a substantial doubt about our ability to continue as a going concern and we may require additional capital to fund our operations, which capital may not be available to us on acceptable terms or at all.

As described under "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Substantial Doubt as to Going Concern Status" and "—Liquidity and Capital Resources—General" and in note 2(a) to the Accompanying Financial Statements, management has determined we could not be certain that our plans and initiatives to increase our total revenues and improve our liquidity position would be effectively implemented within one year after the filing date of this report, when the Accompanying Financial Statements are being issued. Without giving effect to the prospect of raising additional capital pursuant to our at-the-market offerings under the ATM Agreement, increasing product revenue in the near future or executing other mitigating plans, many of which are beyond our control, it is unlikely that we will be able to generate sufficient cash flows to meet our required financial obligations, including our debt service and other obligations due to third parties. The existence of these conditions raises substantial doubt about our ability to continue as a going concern for the twelve-month period following the filing date of this report, when the Accompanying Financial Statements are being issued.

Our diagnostic test products require ongoing funding to continue our current development and operational plans, and we have a history of net losses. We intend to continue to expend substantial resources in the short term in connection with the July Purchase Orders (see "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Events—July Purchase Orders"), but we may encounter challenges in fulfilling our obligations, and therefore receiving revenue, under those purchase orders. See "—Because of our liquidity and operational limitations, including the availability of staffing and supply chain resources that are necessary but outside of our control, we will not be able to timely fulfill all of the requirements of the July Purchase Order from Bio-Manguinhos and it is difficult to reliably estimate the extent to which we will be able to timely meet those requirements" below. We will also incur costs associated with research and development activity, corporate administration, business development, debt service, marketing and selling of our products, and litigation. In addition, other unanticipated costs may arise.

As of September 30, 2021, we had outstanding indebtedness of $20.0 million under the Credit Agreement. We may face further liquidity challenges if we are unable to meet obligations set forth in the Credit Agreement, including a financial covenant requiring that we achieve specified minimum total revenue amounts measured as of the end of each quarter. A breach of the minimum total revenue covenant or any other covenant in the Credit Agreement would result in a default under the Credit Agreement, which could enable the Lender to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. We cannot assure you that, in such an event, we would have sufficient assets to pay amounts due under the Credit Agreement. See "—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" below.

As a result, we may need to raise capital in one or more debt and/or equity offerings to fund our operations and obligations. There can be no assurance, however, that we will be successful in raising the necessary capital or that any such offering will be available to us on terms acceptable to us, or at all. If we are unable to raise additional capital that may be needed on terms in sufficient amounts or on terms acceptable to us, it could have a material adverse effect on our company. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our deliveries under our outstanding customer purchase orders or the development or commercialization of one or more of our products or one or more of our other research and development initiatives. The outbreak of the COVID-19 pandemic has significantly disrupted world financial markets, negatively impacted U.S. market conditions and may reduce opportunities for us to seek out additional funding. A decline in the market price of our common stock, whether or not coupled with the suspension of trading of our common stock on the Nasdaq Capital Market, could make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate, or at all.

Continuing doubt about our ability to continue as a going concern may materially and adversely affect the price of our common stock, and it may be more difficult for us to obtain financing. Any uncertainty about our ability to continue as a going concern may also adversely affect our relationships with current and future employees, suppliers, vendors, customers, grantors, creditors, regulators and investors, who may become concerned about our ability to meet our ongoing financial obligations. There is risk that, among other things:

- third parties lose confidence in our ability to continue to operate in the ordinary course, which could impact our ability to execute on our business strategy;
- it may become more difficult for us to attract, retain or replace employees;
- employees could be distracted from performance of their duties;
- we could lose some or a significant portion of our liquidity, either due to stricter credit terms from vendors, or, in the event we undertake a Chapter 11 proceeding and conclude that we need to procure debtor-in-possession financing, an inability to obtain any needed debtor-in-possession financing or to provide adequate protection to certain secured lenders to permit us to access some or all of our cash; and
- our vendors and service providers could seek to renegotiate the terms of our arrangements, terminate their relationships with us or require financial assurances from us.

The Accompanying Financial Statements have been prepared assuming we will continue as a going concern, which contemplates continuity of operations, realization of assets and the satisfaction of liabilities in the normal course of business for the twelve-month period following the date of this report. As such, the Accompanying Financial Statements do not include any adjustments relating to the recoverability and classification of assets and their carrying amounts, or the amount and classification of liabilities that may result should we be unable to continue as a going concern.

Because of our liquidity and operational limitations, including the availability of staffing and supply chain resources that are necessary but outside of our control, we will not be able to timely fulfill all of the requirements of the July Purchase Order from Bio-Manguinhos and it is difficult to reliably estimate the extent to which we will be able to timely meet those requirements.

In July 2021 we received the July Purchase Orders, which we had been pursuing for an extended period of time. See “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Recent Events—July Purchase Orders” above. Our delivery of the full number of tests covered by each of the July Purchase Orders may be affected by limitations of our supply chain, staffing and liquidity, including matters that are outside our control. We have established internal plans designed to maximize the number of tests we can deliver timely, or at all, pursuant to the July Purchase Orders, and we expect to continue to revise those plans as we obtain new information. The number of uncertainties related to third parties — including the availability of required personnel, raw materials and other resources — currently preclude us, however, from reliably estimating the extent to which we will be able to fulfill the July Purchase Orders on time and at an acceptable cost, or at all. Our ability to generate revenue from the July Purchase Orders, and the margins we can realize from that revenue, will depend on the availability and cost of human, material and other resources required to build and deliver tests in accordance with the July Purchase Orders.

In anticipation of receipt of significant purchase orders in 2021, during the first half of 2021 we continued to invest in automating our test manufacturing processes, all of which are now based in the United States, by, among other actions, validating and implementing automated lines to expand our manufacturing capabilities. We did not know, however, the number or mix of tests for which purchase orders might be received, and we now need to configure our automated manufacturing lines for the most efficient use feasible, subject to numerous staffing and other constraints, in producing DPP SARS-CoV-2 Antigen tests and HIV 1/2 STAT-PAK Assays contemplated by the July Purchase Orders. The number of tests to be delivered pursuant to the July Purchase Orders significantly exceeds the capacity of our automated manufacturing lines. We have neither the time nor the resources to increase our automated manufacturing capacity meaningfully during the delivery periods contemplated by the July Purchase Orders.

We therefore are relying upon manual assembly processes to produce a significant portion of the tests deliverable under the July Purchase Orders and other customer orders, which require that we successfully recruit, hire and train a significant number of personnel for employment at our Long Island, New York facilities. Identifying, hiring and retaining assembly line, formulations, production, warehouse, quality control and other personnel for our Long Island facilities at acceptable compensation levels has been challenging in the past, and those circumstances have been exacerbated by the continuing effects of the COVID-19 pandemic, which may discourage potential employees from returning to a physical worksite at compensation levels that are acceptable to us, or at all. Upon receiving the July Purchase Orders, we launched a broad campaign to recruit and retain manufacturing and other personnel and, more recently, we temporarily increased pay for manufacturing personnel. Our recruiting efforts have not, however, proven sufficient to overcome the tight labor market that has been impacting many U.S. companies, including employers on Long Island, and we have not been able to hire the number of manufacturing personnel required to meet our internal plans for delivery of all of the tests contemplated by the July Purchase Orders. Our continued inability to identify and hire sufficient numbers of manufacturing personnel, and to manage turnover of currently existing and newly hired personnel, would continue to materially limit our ability to deliver tests under the July Purchase Orders.

Our delivery of tests covered by the July Purchase Orders has also been negatively affected by limitations on raw materials, components and other supplies. We must obtain additional supplies in order to manufacture tests to meet the requirements of the July Purchase Orders. Some supplies require significant ordering lead time, and some are currently obtained from a sole supplier or a limited group of suppliers. With some of these suppliers, we do not have long term agreements and instead purchase materials, components and other supplies through a purchase order process. The COVID-19 pandemic has disrupted nearly every aspect of the global supply chain, including the manufacturing or delivery of some of the key supplies used in our tests. Many suppliers are experiencing shortages of required personnel as the result of the tight labor market and underlying raw material commodities. Some suppliers have been unable to deliver supplies in the quantity we need or at all. As a result, these suppliers may stop supplying us components and materials, limit the allocation of supply and equipment to us due to increased industry demand, or significantly increase their prices at any time with little or no advance notice. Because of the foregoing limitations, as exacerbated by the quantities and timing of supplies required to timely fulfill the July Purchase Orders, we have been required to seek to identify new sources of supplies to replace or augment our past sources, which has proven difficult to do in a reasonable time period and on commercially reasonable terms, if at all. Moreover, scarcity has caused increases in the cost of some supplies. Our inability to timely obtain required supplies has had an adverse effect on our ability to timely fulfill the July Purchase Orders as well as on our total revenues, cost of sales, related margin and cash flow.

Because of the foregoing factors and considerations, we expect our ability to manufacture tests covered by the July Purchase Order from Bio-Manguinhos will continue to be limited through at least the end of 2021, which is the existing schedule for delivering tests under the order. We therefore will be unable to timely deliver a significant number of the tests required by the July Purchase Order from Bio-Manguinhos, which will impair our ability to achieve desired profit margins and generate cash flow from the order. We currently anticipate that at least $11.5 million of the July Purchase Order from Bio-Manguinhos will not be fulfilled by December 31, 2021, the end of the shipment schedule under the order. Our inability to timely meet the requirements of the July Purchase Order from Bio-Manguinhos could harm our relationship with Bio-Manguinhos and impair our reputation with other customers within the industry, which, in turn, could have a material adverse effect on our business. Moreover, in the event we do not timely deliver tests under such July Purchase Order, Bio-Manguinhos could choose to purchase products from our competitors with whom Bio-Manguinhos already has existing business relationships, which competitors may have greater technical, financial and other resources than we have.

Because of our liquidity and operational limitations, we may be required to prioritize fulfillment of customer orders, including the July Purchase Orders, which could harm our relationships with customers and our reputation and thereby negatively impact our business and operating results.

Our liquidity and operational limitations described under "—Because of our liquidity and operational limitations, including the availability of staffing and supply chain resources that are necessary but outside of our control, we will not be able to timely fulfill all of the requirements of the July Purchase Order from Bio-Manguinhos and it is difficult to reliably estimate the extent to which we will be able to timely meet those requirements" above are limiting our ability to timely fulfill not only the July Purchase Orders but also other purchase orders for a range of our products. Our inability to timely meet the requirements of the July Purchase Orders or any other purchase orders could harm our relationships with our customers and impair our reputation within the industry, which, in turn, could have a material adverse effect on our business. To the extent we therefore are required to prioritize purchase orders, or are perceived by customers as prioritizing purchase orders, could further damage our customer relationships and our reputation. As a result, customers, including Bio-Manguinhos and Partnership for Supply Chain Management, could become dissatisfied and cease purchasing our products and instead choose to purchase products from our competitors, which may have greater technical, financial and other resources than we have, which would adversely affect our business, financial condition, results of operations and prospects.

Our ability to receive the amount of grants remaining under our existing contracts with BARDA is limited by operational factors as well as regulatory and other factors outside our control, and we cannot assure you that we will be able to receive all, or a significant portion, of those remaining amounts before the contracts expire.

Through the date of filing of this report, we had recognized government grant income totaling $10.7 million, which was awarded under a contract we entered into with BARDA on December 2, 2020. A total of up to $12.7 million of awards are available from BARDA under that contract to assist us in (a) developing, and requesting an EUA from the FDA for, the DPP Respiratory Panel and (b) performing the clinical trials for and submitting the DPP SARS-CoV-2 Antigen test system to the FDA for 510(k) clearance. Unless extended by BARDA in its sole discretion, all of the remaining $2.2 million of awards remaining under the contract as of the date of this report will expire unless earned by December 2, 2021. The completion of milestones to earn a portion of the remaining awards are outside our control, and we cannot assure you that we will succeed in earning all or any significant portion of the remaining awards by December 2, 2021. Any such inability to earn a significant portion of potential grant receipts would adversely affect our business, financial condition, results of operations and prospects.

The failure to comply with the terms of the Credit Agreement 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 and certain of our subsidiaries, as guarantors, entered into the Credit Agreement, under which we received a $20,000,000 senior secured term loan credit facility that 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. See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Sources of Funds—Credit Agreement."

The Credit Agreement also contains financial covenants requiring that we (a) maintain aggregate unrestricted cash of not less than $3,000,000 at all times, which must be held in one or more accounts subject to the first priority perfected security interests of the Lender under the Credit Agreement, and (b) achieve specified minimum total revenue requirements for the twelve months preceding each quarter end. The minimum total revenue amounts over the next year increase from $40.3 million for the twelve months ending December 31, 2021 to $45.6 million for the twelve months ending September 30, 2022 (see note 7 to the Accompanying Financial Statements). These minimum revenue requirements were developed for purposes of the Credit Agreement and do not reflect the internal estimates and plans used by our management and board of directors to establish operational goals for managing our business. The minimum revenue requirements for the twelve months ending December 31, 2021 do not, for example, take into account the challenges we are facing during the last five months of 2021 in ramping up production, including hiring personnel and obtaining commitments from our supply chain as described above in "—Because of our liquidity and operational limitations, including the availability of staffing and supply chain resources that are necessary but outside of our control, we will not be able to timely fulfill all of the requirements of the July Purchase Orders and it is difficult to reliably estimate the extent to which we will be able to timely meet those requirements."

In addition, 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 the ability of our company and the restricted subsidiaries to:

- incur, assume or guarantee additional Indebtedness (as defined in the Credit Agreement);
- repurchase capital stock;
- make other restricted payments, including 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.

A breach of the minimum total revenue covenant or any other covenant in the Credit Agreement would result in a default under the Credit Agreement. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. In such an event, there can be no assurance that we would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, we would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. Our inability to raise additional capital on acceptable terms in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for our operations, could have a material adverse effect on our business, prospects, results of operations, liquidity and financial condition.

You may experience future dilution as a result of future equity offerings, exercises of outstanding options and vesting of options and restricted and performance stock units.

On July 19, 2021, we entered into the ATM Agreement, pursuant to which we may sell from time to time, at our option, up to an aggregate of $60,000,000 of shares of common stock through Craig-Hallum, as sales agent. As of the filing date of this report, we have issued and sold pursuant to the ATM Agreement a total of 9,709,328 shares of common stock at a volume-weighted average price of $4.2011 per share for gross proceeds of $40.8 million and net proceeds, after giving effect to placement fees and other transaction costs, of $38.8 million. For additional information about the at-the-market offerings pursuant to the ATM Agreement, see "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Events—At-the-Market Offerings of Common Stock" in Part I of this report.

In order to raise additional capital, we may seek to offer pursuant to the ATM Agreement additional shares of common stock for up to $19.2 million in gross proceeds and we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock. There can be no assurance that we will be able to sell additional shares in at-the-market offerings made pursuant to the ATM Agreement, or in any other offering, at a price per share that is equal to or greater than the price per share paid by existing stockholders. Investors purchasing securities in other offerings in the future could have rights superior to existing stockholders.

As of the close of business on November 1, 2021, our market capitalization was approximately $70.3 million. Existing stockholders may experience significant dilution in connection with our issuance and sale of up to $19.2 million of additional shares of common stock pursuant to the ATM Agreement. In addition, as of September 30, 2021, 3,051,405 shares of common stock were reserved for future issuance under our 2019 Omnibus Incentive Plan, 1,786,324 shares were subject to outstanding options, and 811,038 shares were subject to outstanding restricted and performance stock units. Stockholders will incur dilution upon vesting of restricted and performance stock units, and they may incur dilution upon exercises of stock options.

The volatility of our common stock and stockholder base may hinder or prevent us from engaging in beneficial corporate initiatives.

Our stockholder base is comprised of a large number of retail, or non-institutional, investors, which creates more volatility because our common stock may change hands more frequently. In accordance with our governing documents and applicable laws, there are a number of initiatives that require the approval of stockholders at an annual or special meeting. To hold a valid meeting, a quorum comprised of stockholders representing a majority of the voting power of our outstanding shares of capital stock is necessary. A record date is established to determine which stockholders are eligible to vote at the meeting, which record date must be not more than sixty days or less than ten days prior to the meeting. Since our stock changes hands frequently, there can be a significant turnover of stockholders between the record date and the meeting date, which makes it harder to get stockholders to vote. While we make every effort to engage retail investors, such efforts can be expensive and the resulting frequent turnover can create logistical issues. Further, retail investors tend to be less likely to vote in comparison to institutional investors. Failure to secure sufficient votes or to achieve the minimum quorum needed for a meeting to happen may impede our ability to move forward with initiatives that are intended to grow the business and create stockholder value or prevent us from engaging in such initiatives at all. If we find it necessary to delay or adjourn meetings or to seek approval again, it will be time consuming and we will incur additional costs.

ITEM 6. EXHIBITS

Number	Description
10.1	At the Market Offering Agreement, dated July 19, 2021, between Chembio Diagnostics, Inc. and Craig-Hallum Capital Group LLC *(incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on July 19, 2021)*
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	XBRL Taxonomy Presentation Linkbase Document
104	Cover page interactive data file (embedded within the Inline XBRL document)

† The certifications attached as Exhibit 32.1 accompany this 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, 2021

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

Date: November 5, 2021

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 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.

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, 2021

/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.

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, 2021

/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, 2021, 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, 2021

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

Date: November 5, 2021

/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.