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 June 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)
N/A

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 July 31, 2021, the registrant had 28,622,803 shares outstanding of its common stock, $0.01 par value.

Quarterly Report on Form 10-Q
For The Quarterly Period Ended
June 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 AND STATISTICAL ESTIMATES

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

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

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

PART I

Item 1. FINANCIAL STATEMENTS

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	(Unaudited) June 30, 2021	December 31, 2020
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 5,564,349**	$ 23,066,301
Accounts receivable, net of allowance for doubtful accounts of $193,535 and $296,793 at June 30, 2021 and December 31, 2020, respectively	**2,977,082**	3,377,387
Inventories, net	**15,720,292**	12,516,402
Prepaid expenses and other current assets	**1,064,508**	778,683
TOTAL CURRENT ASSETS	**25,326,231**	39,738,773
FIXED ASSETS:		
Property, plant and equipment, net	**9,149,460**	8,688,403
Finance lease right-of-use asset, net	**225,947**	233,134
OTHER ASSETS:		
Operating lease right-of-use asset, net	**6,274,945**	6,112,632
Intangible assets, net	**2,329,859**	3,645,986
Goodwill	**5,899,531**	5,963,744
Deposits and other assets	**370,644**	509,342
TOTAL ASSETS	**$ 49,576,617**	$ 64,892,014
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 8,091,368**	$ 10,042,790
Deferred revenue	**404,486**	1,606,997
Operating lease liabilities	**867,154**	642,460
Finance lease liabilities	**65,435**	58,877
TOTAL CURRENT LIABILITIES	**9,428,443**	12,351,124
OTHER LIABILITIES:		
Long-term operating lease liabilities	**6,392,531**	6,327,143
Long-term finance lease liabilities	**174,466**	185,239
Long-term debt, net	**18,477,924**	18,182,158
Deferred tax liability	**-**	69,941
TOTAL LIABILITIES	**34,473,364**	37,115,605
COMMITMENTS AND CONTINGENCIES (Note 6)		
STOCKHOLDERS' EQUITY:		
Preferred stock - 10,000,000 shares authorized; none issued or outstanding	**-**	-
Common stock - $0.01 par value; 100,000,000 shares authorized; 20,337,372 shares and 20,223,498 shares issued at June 30, 2021 and December 31, 2020, respectively	**203,374**	202,235
Additional paid-in capital	**126,006,387**	124,961,514
Accumulated deficit	**(110,670,879)**	(97,106,331)
Treasury Stock, 41,141 shares at cost, at June 30, 2021 and December 31, 2020	**(190,093)**	(190,093)
Accumulated other comprehensive loss	**(245,536)**	(90,916)
TOTAL STOCKHOLDERS' EQUITY	**15,103,253**	27,776,409
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 49,576,617**	$ 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 six months ended	
	June 30, 2021	June 30, 2020	**June 30, 2021**	June 30, 2020
REVENUES:				
Net product sales	**$ 3,931,383**	$ 3,791,574	**$ 7,956,045**	$ 9,508,166
R&D revenue	**727**	1,193,973	**1,107,366**	2,101,660
Government grant income	**2,280,000**	-	**5,630,000**	-
License and royalty revenue	**250,000**	125,625	**493,058**	360,929
TOTAL REVENUES	**6,462,110**	5,111,172	**15,186,469**	11,970,755
COSTS AND EXPENSES:				
Cost of product sales	**4,039,696**	5,670,737	**7,588,137**	10,045,179
Research and development expenses	**2,796,981**	1,922,306	**5,660,319**	3,881,159
Selling, general and administrative expenses	**6,001,353**	4,397,593	**12,086,422**	8,554,234
Asset impairment, restructuring, severance and related costs	**1,961,156**	387,540	**2,044,243**	1,110,658
Acquisition costs	-	-	-	63,497
	14,799,186	12,378,176	**27,379,121**	23,654,727
LOSS FROM OPERATIONS	**(8,337,076)**	(7,267,004)	**(12,192,652)**	(11,683,972)
OTHER EXPENSE:				
Interest expense, net	**(727,374)**	(712,052)	**(1,439,851)**	(1,374,192)
LOSS BEFORE INCOME TAXES	**(9,064,450)**	(7,979,056)	**(13,632,503)**	(13,058,164)
Income tax benefit:	**65**	135,259	**67,955**	214,818
NET LOSS	**$ (9,064,385)**	$ (7,843,797)	**$ (13,564,548)**	$ (12,843,346)
Basic and diluted loss per share	**$ (0.45)**	$ (0.42)	**$ (0.67)**	$ (0.71)
Weighted average number of shares outstanding, basic and diluted	**20,219,617**	18,868,144	**20,191,657**	18,032,723

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 six months ended	
	June 30, 2021	June 30, 2020	**June 30, 2021**	June 30, 2020
Net loss	**$ (9,064,385)**	$ (7,843,797)	**$ (13,564,548)**	$ (12,843,346)
Other comprehensive loss:				
Foreign currency translation adjustments	**301,102**	(175,447)	**(154,620)**	(1,038,741)
Comprehensive loss	**$ (8,763,283)**	$ (8,019,244)	**$ (13,719,168)**	$ (13,882,087)

See accompanying notes to condensed consolidated financial statements

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

	For the six months ended June 30, 2021							
	Common Stock		Additional	Treasury Stock		Accumulated		
	Shares	Amount	Paid-in-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**

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

	For the six months ended June 30, 2020							
	Common Stock		Additional	Treasury Stock		Accumulated		
	Shares	Amount	Paid-in-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
Warrants Exercised:	253,161	2,532	(2,532)					-
Comprehensive loss	-	-	-	-	-		(175,447)	(175,447)
Net loss	-	-	-		-	(7,843,797)	-	(7,843,797)
Balance at June 30, 2020	**20,194,832**	**$ 201,948**	**$ 124,143,171**	**(33,290)**	**$ (150,919)**	**$ (84,428,349)**	**$ (1,028,897)**	**$ 38,736,954**

See accompanying notes to condensed consolidated financial statements

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

	June 30,2021	June 30, 2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	**$ 14,493,073**	$ 16,993,648
Cash paid to suppliers and employees	**(28,559,938)**	(22,751,210)
Cash paid for operating leases	**(696,188)**	(457,277)
Cash paid for finance leases	**(10,312)**	(9,367)
Interest and taxes, net	**(1,135,295)**	(1,106,778)
Net cash used in operating activities	**(15,908,660)**	(7,330,984)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Patent application costs	**(28,023)**	(98,186)
Acquisition of and deposits on fixed assets	**(1,270,989)**	(2,351,160)
Net cash used in investing activities	**(1,299,012)**	(2,449,346)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of stock, net	**-**	28,436,741
Stimulus package loan	**-**	2,978,315
Stimulus package loan payment	**-**	(2,978,315)
Payments on note payable	**-**	(104,542)
Payments of tax withholding on stock award	**(119,513)**	(343,080)
Payments on finance lease	**(29,820)**	(23,578)
Net cash (used in) provided by financing activities	**(149,333)**	27,965,541
Effect of exchange rate changes on cash	**(144,947)**	(29,095)
(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	**(17,501,952)**	18,156,116
Cash and cash equivalents - beginning of the period	**23,066,301**	18,271,352
Cash and cash equivalents - end of the period	**$ 5,564,349**	$ 36,427,468
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net loss	**$ (13,564,548)**	$ (12,843,346)
Adjustments:		
Depreciation and amortization	**1,390,897**	1,441,823
Share based compensation	**1,165,632**	347,141
Non-cash inventory adjustments	**863,612**	-
Benefit from deferred tax liability	**(69,941)**	(216,000)
Impairment of long-lived assets	**1,273,945**	-
Recovery of (provision of) doubtful accounts	**(103,258)**	94,262
Changes in assets and liabilities:		
Accounts receivable	**503,563**	1,050,738
Inventories	**(4,067,502)**	(4,533,511)
Prepaid expenses and other current assets	**(285,825)**	(49,894)
Deposits and other assets	**138,698**	113,655
Accounts payable and accrued liabilities	**(1,951,422)**	3,291,993
Deferred revenue	**(1,202,511)**	3,972,155
Net cash used in operating activities	**$ (15,908,660)**	$ (7,330,984)
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
June 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 rapid tests used for the detection and diagnosis of infectious diseases, including COVID-19, sexually transmitted disease, and fever and tropical disease. Coupled with the Company's extensive scientific expertise, its novel DPP technology offers broad market applications beyond infectious disease. Chembio's products are sold globally, directly and through distributors, to hospitals and clinics, physician offices, clinical laboratories, public health organizations, government agencies, and consumers under the Company's DPP, STAT-PAK, SURE CHECK and STAT-VIEW registered trademarks or under the private labels of the Company's marketing partners.

The Company'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 U.S. manufacturing, and the timing of its investment in research and development as well as sales and marketing. If the Company is unable to increase its revenues and manage its expenses in accordance with its operating plan, it may need to reduce the level or slow the timing of the growth plans contemplated by its operating plan, which would likely curtail or delay the growth in its business contemplated by its operating plan and could impair or defer its ability to achieve profitability and generate cash flow, or to seek to raise additional funds through debt or equity financings, strategic relationships, or other arrangements (see Note 2(a)— Basis of Presentation and Note 12—Subsequent Events). 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 June 30, 2021 did not meet the Company's expectations, and the shortfall in revenues was a principal cause of the Company's limited cash and cash-equivalents position as of June 30, 2021. The decrease in cash and cash-equivalents over the first two quarters of 2021 reflected market, clinical trial and regulatory complications the Company 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. The decrease in cash and cash-equivalents also resulted in part from significant continuing expenses incurred 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 U.S. 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 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.

Following June 30, 2021, as discussed in Note 16 – Subsequent Events, the Company undertook measures to increase its total revenues and improve its liquidity position:

- The Company received significant purchase orders from two customers. The Company had pursued the purchase orders for an extended period of time, but did not receive them until July 2021 as follows:
    - 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 demands 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.
- The Company raised net proceeds of approximately $34.7 million from the issuance and sale of 8,323,242 shares of common stock pursuant to 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.

These measures and other plans and initiatives of the Company were 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 issued. Such plans and initiatives are dependent, however, on factors that are beyond the Company's control or that may not be available on terms acceptable to the Company, or at all. The Company considered how the uncertainties around the delivery of the full number of tests covered by the two purchase orders received in July 2021 and other customer orders may be affected by limitations of the Company's supply chain, staffing and liquidity, uncertainties regarding the achievement of milestones and related recognition of revenue under government grants, and other matters outside the Company's control. The Company further considered how such uncertainties could impact its ability to meet the obligations specified in the Credit Agreement (as defined in Note 7– Long-Term Debt) over the next twelve months, which include attaining Minimum Total Revenue (as defined) for the twelve-months preceding each quarter end. For the next year, the Minimum Total Revenue requirements range from approximately $37.4 million for the twelve months ending September 30, 2021 to approximately $43.8 million for the twelve months ending June 30, 2022 (see Note 7 – Long-Term Debt). 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, Chembio 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. Chembio'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 by the Company for its operations, could have a material adverse effect on the Company's business, prospects, results of operations, liquidity and financial condition. Accordingly, management determined the Company could not be certain that its plans and initiatives would be effectively implemented within one year after the date the accompanying unaudited condensed consolidated financial statements are issued.

Without giving effect to the prospect of raising additional capital pursuant to the ATM Agreement, 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 rent, 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 the accompanying unaudited condensed consolidated financial statements are 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 six months ended June 30, 2021, there has 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 expenses and other current liabilities approximate fair value due to the immediate or short-term maturity of these financial instruments. Included in cash and cash equivalents were $0.5 million and $14.8 million as of June 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 $18.5 million) and $20.0 million (carrying value of $18.2 million) as of June 30, 2021 and December 31, 2020, respectively, is a Level 2 fair value measurement under the hierarchy and the Company's debt face value approximates the recorded value, as the rate is based upon the current rates available to the Company for similar financial instruments.

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

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

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

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

(d) Cash and Cash Equivalents:

Cash and cash equivalents are defined as short-term, highly liquid investments with original maturities of three months or less at date of purchase, and include restricted cash of $0.4 million and $1.0 million as of June 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. The Company expects that the restriction will be released within the next three months.

(e) Loss Per Share:

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

There were 1,867,045 and 1,034,124 options outstanding as of June 30, 2021 and 2020, respectively, that were not included in the calculation of diluted per common share equivalents for the three and six months ended June 30, 2021 and 2020, respectively, because the effect would have been anti-dilutive.

There were 803,062 and 619,385 restricted stock outstanding, each corresponding to one share of common stock, as of June 30, 2021 and 2020, respectively, that were not included in the calculation of diluted per common share equivalents for the three and six months ended June 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 six months ended June 30, 2021 was (1.11)% and 0.51%, respectively, compared to the effective tax rate of 1.7% for both the three and six months ended June 30, 2020. 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 (the "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 has 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 has 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 has 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 by a board of directors. 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 has determined that the adoption did not have a material impact on the Company's consolidated financial statements.

Not Yet Adopted

ASU 2020-06 - Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity

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 U.S. GAAP. ASU 2020-06 simplifies the guidance in U.S. GAAP on the issuer's accounting for convertible debt instruments, requires entities to provide expanded disclosures about "the terms and features of convertible instruments" and how the instruments have been reported in the entity's financial statements. It also removes from ASC 815-40-25-10 certain conditions for equity classification and amends certain guidance in ASC 260 on the computation of 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 all potential impacts of the standard.

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

On May 3, 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 continues to assess the potential impact of the standard.

NOTE 3 — REVENUE:

Disaggregation of Revenue

The following table disaggregates Total Revenues:

	For the three months ended					
	June 30, 2021			June 30, 2020		
	Exchange Transactions	**Non-Exchange Transactions**	**Total**	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	**$ 3,931,383**	**$ -**	**$ 3,931,383**	$ 3,791,574	$ -	$ 3,791,574
R&D revenue	**727**	-	**727**	1,193,973	-	1,193,973
Government grant income	**-**	**2,280,000**	**2,280,000**	-	-	-
License and royalty revenue	**250,000**	-	**250,000**	125,625	-	125,625
	$ 4,182,110	**$ 2,280,000**	**$ 6,462,110**	$ 5,111,172	$ -	$ 5,111,172

	For the six months ended					
	June 30, 2021			June 30, 2020		
	Exchange Transactions	**Non-Exchange Transactions**	**Total**	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	**$ 7,956,045**	**$ -**	**$ 7,956,045**	$ 9,508,166	$ -	$ 9,508,166
R&D revenue	**1,107,366**	-	**1,107,366**	2,101,660	-	2,101,660
Government grant income	**-**	**5,630,000**	**5,630,000**	-	-	-
License and royalty revenue	**493,058**	-	**493,058**	360,929	-	360,929
	$ 9,556,469	**$ 5,630,000**	**$ 15,186,469**	$ 11,970,755	$ -	$ 11,970,755

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.

The following table disaggregates Total Revenues by geographic location:

	For the three months ended		For the six months ended	
	June 30, 2021	June 30, 2020	**June 30, 2021**	June 30, 2020
Africa	**$ 1,466,356**	$ 552,570	**$ 2,811,214**	$ 1,436,085
Asia	**53,592**	119,319	**270,547**	482,607
Europe & Middle East	**806,209**	1,635,017	**3,406,485**	3,811,172
Latin America	**487,517**	780,567	**745,536**	2,896,963
United States	**3,648,436**	2,023,699	**7,952,687**	3,343,928
	$ 6,462,110	$ 5,111,172	**$ 15,186,469**	$ 11,970,755

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 March 31, 2021, the Company reported $0.4 million in deferred revenue, none of which was earned and recognized during the three months ended June 30, 2021. At June 30, 2021, the Company reported $0.4 million in deferred revenue that is expected to be recognized in the three months ending September 30, 2021.

NOTE 4 — INVENTORY:

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

	June 30, 2021	December 31, 2020
Raw materials	**$ 6,611,511**	$ 5,955,215
Work in process	**6,921,768**	2,549,516
Finished goods	**2,187,013**	4,011,671
	$ 15,720,292	$ 12,516,402

During the three months ended June 30, 2021 the Company recognized a $0.9 million charge related to the write-down of inventory for products that were not salable, based on its periodic review of the current status and future benefits of inventory.

NOTE 5 — STOCKHOLDERS' EQUITY:

(a) Common Stock

During the three and six months ending June 30, 2021 and 2020, there were no options exercised.

(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, and Restricted Stock Units

The Board or its Compensation Committee may issue options, restricted stock, and restricted 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 six months ended**				**Accounts Receivable as of**	
	June 30, 2021		June 30, 2020		**June 30, 2021**		June 30, 2020		**June 30, 2021**	December. 31, 2020
	Sales	**% of Sales**	Sales	% of Sales	**Sales**	**% of Sales**	Sales	% of Sales		
Customer 1	**$1,014,638**	**25.8%**	$ *	*	**$1,151,615**	**14.5%**	$ *	*	**$ 376,075**	$ *
Customer 2	*****	*****	657,304	17.0%	*****	*****	2,297,376	24.0%	*****	806,196

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

There were no purchases the Company had from any vendor that totaled in excess of 10% of the Company's total net purchases for the three or six months ending in June, 30 2021.

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 or the FDA, U.S. Department of Agriculture, certain U.S., 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 are scheduled to expire on December 2021, and the Company's minimum salary commitments under the agreements for the last six months of 2021 total $421,646. Under one of those contracts, however, the term of the contract will extend automatically until December 31, 2022 if neither party provides, by October 1, 2021, notice electing to have the contract terminate on December 31, 2021. If no such notice is timely delivered, the Company will have a minimum salary commitment under the contract of $460,000 for the year ending December 31, 2022.

(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 $29,933 and $35,456 for the three months ended June 30, 2021 and 2020, respectively. Matching contribution expenses totaled $65,388 and $49,407 for the six months ended June 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 June 2021, the Company permanently discontinued its operations in Malaysia. Impairment charges for the Malaysian facility right-of-use asset recorded during the three and six months ended June 30, 2021 was $0.1 million.

The components of lease expense were as follows:

	Three months ended June 30,		**Six months ended June 30,**	
	2021	2020	**2021**	2020
Operating lease expense	**$ 402,329**	$ 388,951	**$ 810,795**	$ 852,808
Finance lease cost				
Amortization of right-of-use assets	**$ 17,038**	$ 14,687	**$ 32,796**	$ 27,085
Interest on lease liabilities	**5,368**	5,156	**10,312**	9,367
Total finance lease expense	**$ 22,406**	$ 19,843	**$ 43,108**	$ 36,452

Supplemental cash flow information related to leases was as follows:

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	**2021**	2020
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows for operating leases	**$ 348,317**	$ 292,058	**$ 696,188**	$ 457,277
Operating cash flows for finance leases	**5,368**	5,156	**10,312**	9,367
Financing cash flows for finance leases	**15,538**	12,666	**29,820**	23,578
Right-of-use assets obtained in exchange for lease obligations:				
Operating leases	**$ 694,668**	$ -	**$ 694,668**	$ -
Finance leases	**25,609**	47,499	**25,609**	75,852

Supplemental balance sheet information related to leases was as follows:

	June 30, 2021	June 30, 2020
Finance Leases		
Finance lease right-of-use asset	**$ 340,762**	$ 309,574
Accumulated depreciation	**(114,815)**	(50,690)
Finance lease right-of-use asset, net	**$ 225,947**	$ 258,884
Weighted-Average Remaining Lease Term		
Operating leases	**7.9 Years**	9.0 Years
Finance leases	**3.4 Years**	4.0 Years
Weighted-Average Discount Rate		
Operating leases	**8.73%**	8.62%
Finance leases	**8.43%**	9.73%

Maturities of lease liabilities were as follows:

	June 30, 2021		June 30, 2020	
	Operating Leases	**Finance Leases**	Operating Leases	Finance Leases
2020 and 2021	**$ 708,344**	**$ 41,812**	$ 682,667	$ 37,720
2022	**1,447,249**	**83,624**	1,209,787	75,440
2023	**1,221,017**	**83,624**	1,057,757	75,440
2024	**1,018,875**	**55,856**	1,026,272	75,440
2025	**1,049,442**	**12,471**	1,018,875	47,672
Thereafter	**4,724,446**	**1,680**	5,773,887	4,775
Total lease payments	**$ 10,169,373**	**$ 279,067**	$ 10,769,245	$ 316,487
Less: imputed interest	**2,909,688**	**39,166**	3,427,535	50,366
Total	**$ 7,259,685**	**$ 239,901**	$ 7,341,710	$ 266,121

(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 J. 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 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 are alleged 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.

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 seeks 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 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 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 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 in 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 in the litigation, the Company is not able to predict the probability of a favorable or unfavorable outcome.

Commercial Litigation

Chembio's wholly owned subsidiary Chembio Diagnostic Systems Inc. ("Systems") and BioSure (UK) Ltd. ("BioSure") entered into the BioSure Sure Check HIV 1/2 Assay OTC Agreement dated April 2, 2014 and as subsequently amended (as so amended, the "Distribution Agreement"). Pursuant to the Distribution Agreement, BioSure acquired the right to sell bundled products in the United Kingdom containing the Company's Sure Check HIV 1/2 pouched tests. The Distribution Agreement terminated on April 1, 2019. On September 16, 2019, Systems initiated arbitration in the International Arbitration Tribunal of the International Centre for Dispute Resolution in New York, New York. Systems alleges that BioSure (a) breached various provisions of the Distribution Agreement, (b) misappropriated trade secrets of Systems, (c) engaged in deceptive business acts and practices, and (d) breached the implied covenant of good faith and fair dealing. On November 23, 2020, BioSure requested leave to file a counterclaim seeking recession of the Distribution Agreement based on alleged fraudulent concealment by Systems. Systems opposed BioSure's request for leave to file the counterclaim on procedural and substantive grounds, and on December 11, 2020 the Tribunal denied the request for leave to file the counterclaim. The Tribunal's denial was without prejudice to BioSure's ability to assert its claim in a separate proceeding. BioSure continues to deny the relief sought and alleges certain statements Systems made to third parties about the Distribution Agreement were in bad faith and are a defense to Systems' claims. BioSure also asserts that certain alleged misrepresentations entitle BioSure to "set off" any award Systems might receive from the Tribunal. The parties have completed discovery and submitted their first pre-hearing submissions. Systems intends to vigorously pursue its claims in the arbitration. The final merits hearing took place from April 20, 2021 to April 23, 2021. At this stage in 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. At this stage in 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, Chembio and certain of its subsidiaries, as guarantors, entered into a Credit Agreement and Guaranty (the "Credit Agreement") with Perceptive Credit Holdings II, LP (the "Lender"). The Credit Agreement provides for a $20,000,000 senior secured term loan credit facility, which was drawn in full on September 4, 2019. Under the terms of the Credit Agreement, Chembio may use the proceeds (i) for general working capital purposes and other permitted corporate purposes, (ii) to refinance certain of 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, Chembio's financial advisor for the financing.

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

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

The Credit Agreement contains financial covenants requiring that Chembio (i) maintain aggregate unrestricted cash of not less than $3,000,000 at all times and (ii) achieve specified minimum total revenue requirements for twelve months preceding each quarter end. 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 June 30, 2021, the loan balance, net of unamortized discounts and debt issuance costs, was $18.5 million, and Chembio was in compliance with its loan covenants. See Note 2(a)—Basis of Presentation.

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 June 30, 2021, there were 714,000 options expired, forfeited or exercised, and at June 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 June 30, 2021, there were 519,782 Equity Award Units expired, forfeited or exercised. At June 30, 2021, 259,157 Equity Award Units were outstanding, 21,061 shares were rolled over into the 2019 Plan, and 0 Equity Award Units remained 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 unit, or other stock-based award under the 2019 Plan (collectively, "2019 Equity Units"). The 2019 Equity Units become vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through June 30, 2021, 440,310 2019 Equity Units have been cancelled or forfeited. At June 30, 2021, 2,219,224 2019 Equity Units were outstanding, and 2,658,522 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 June 30		For the six months ended June 30	
	2021	2020	**2021**	2020
Cost of product sales	**$ 43,368**	$ -	**$ 72,136**	$ 6,300
Research and development expenses	**139,469**	90,924	**223,704**	154,737
Selling, general and administrative expenses	**403,007**	293,301	**869,792**	610,089
Severance and related costs	-	-	-	(423,985)
	$ 585,844	$ 384,225	**$ 1,165,632**	$ 347,141

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

	For the three months ended June 30, 2021	For the six months ended June 30, 2021
Expected term (in years)	**6.0**	**5.0**
Expected volatility	**76.42%**	**78.23%**
Expected dividend yield	**1.01%**	**0.81%**
Risk-free interest rate	**2.03%**	**2.93%**

The following table provides stock option activity for the six months ended June 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	925,949	4.73		-
Exercised	-	-		-
Forfeited	8,682	5.89		-
Expired	25,000	5.64		
Outstanding at June 30, 2021	**1,867,045**	**$ 4.40**	**7.08 years**	**$ 388,182**
Exercisable at June 30, 2021	**526,210**	**$ 4.79**	**4.28 years**	**$ 173,621**

The following table summarizes information about stock options outstanding at June 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	636,364	5.71	$ 2.36	$ 388,182	284,624	$ 2.36	$ 173,621
2.8 to 4.59999	27,502	9.92	3.11	-	-	-	-
4.6 to 6.39999	946,514	9.16	4.81	-	14,961	5.49	-
6.4 to 8.19999	209,790	2.62	7.30	-	198,500	7.27	-
8.2 to 12	46,875	2.10	11.45	-	28,125	11.45	-
Total	**1,867,045**	**7.08**	**$ 4.40**	**$ 388,182**	**526,210**	**$ 4.79**	**$ 173,621**

As of June 30, 2021, there was $2,907,843 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 2.89 years. The total fair value of options vested during the six months ended June 30, 2021 and 2020 were $335,579 and $112,311, respectively.

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

	Number of Shares & Units	**Weighted Average Grant Date Fair Value**
Outstanding at December 31, 2020	603,531	$ 3.08
Granted	334,564	4.66
Vested	130,907	2.36
Forfeited	4,126	5.34
Outstanding at June 30, 2021	**803,062**	**$ 3.67**

As of June 30, 2021, there was $2,155,021 of net unrecognized compensation cost related to restricted stock and restricted stock units that had not vested, which is expected to be recognized over a weighted average period of approximately 2.51 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 June 30,		**For the six months ended June 30,**	
	2021	2020	**2021**	2020
Africa	**$ 1,466,356**	$ 552,570	**$ 2,811,215**	$ 1,436,085
Asia	**53,593**	119,319	**270,547**	482,607
Europe & Middle East	**805,482**	734,073	**2,299,216**	1,909,162
Latin America	**487,517**	780,567	**745,536**	2,896,963
United States	**1,118,435**	1,605,045	**1,829,531**	2,783,349
	$ 3,931,383	$ 3,791,574	**$ 7,956,045**	$ 9,508,166

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

	June 30, 2021	December 31, 2020
Asia	**$ 132,681**	$ 326,267
Europe & Middle East	**130,185**	147,692
Latin America	**34,014**	14,719
United States	**8,852,580**	8,199,725
	$ 9,149,460	$ 8,688,403

Effective June 2021, the Company permanently discontinued its operations in Malaysia. Impairment charges recorded for the Malaysian property, plant and equipment during the three months ended June 30, 2021 was $0.2 million.

NOTE 10 — ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:

Accounts payable and accrued liabilities consisted of:

	June 30, 2021	December 31, 2020
Accounts payable – suppliers	**$ 5,896,027**	$ 5,727,781
Accrued commissions and royalties	**586,341**	807,708
Accrued payroll	**223,111**	277,908
Accrued vacation	**525,137**	417,238
Accrued bonuses	**234,000**	1,193,985
Accrued severance	**-**	511,681
Accrued expenses – other	**626,752**	1,106,489
TOTAL	**$ 8,091,368**	$ 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	(64,213)
Balance at June 30, 2021	$ 5,899,531

Intangible assets consisted of the following at:

		June 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**	**$ 775,801**	**$ 166,366**	**$ 609,435**	$ 1,638,699	$ 472,190	$ 1,166,509
Developed technology	**5**	**2,036,368**	**709,538**	**1,326,830**	2,102,526	594,186	1,508,340
Customer contracts/relationships	**6**	**539,461**	**145,867**	**393,594**	1,323,424	423,093	900,331
Trade names	**7**	**4,231**	**4,231**	**-**	115,318	44,512	70,806
		$ 3,355,861	**$ 1,026,002**	**$ 2,329,859**	$ 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 six months ended June 30, 2021 and 2020 was $264,608 and $287,253. Amortization expense, subject to changes in currency exchange rates, is expected to average $389,023 per year from 2021 through 2025, and total $384,745 for all of the years thereafter.

Effective June 2021, the Company permanently discontinued its operations in Malaysia. Impairment charges relating to intangible assets recorded during the three months ended June 30, 2021 were as follows: Intellectual property ($0.5 million), Customer contracts/relationships ($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 for the three and six months ended June 30, 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 three months ended June 30, 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 our COVID-19 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 independent financial advisory firm 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 months ended June 30, 2021, the Company incurred $0.7 million 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 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 periods ending:

	For the three months ended June 30, 2021	For the six months ended June 30, 2021
Severance	**$ -**	**$ 83,087**
Restructuring costs	**687,211**	**687,211**
Asset impairment	**1,273,945**	**1,273,945**
	$ 1,961,156	**$ 2,044,243**

NOTE 13 — SUBSEQUENT EVENTS:

(a) At the Market Offering of Common Stock

On July 19, 2021, Chembio entered into the ATM Agreement with Craig-Hallum, pursuant to which Chembio can sell from time to time, at its option, up to an aggregate of $60,000,000 of shares of common stock (the "Shares") through Craig-Hallum, as sales agent. Any sales of Shares made pursuant to the ATM Agreement is to be made pursuant to Chembio's 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 Chembio 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 under the ATM Agreement, Chembio is to 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 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 Chembio's 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 transactions, Chembio 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, Chembio is to pay Craig-Hallum a placement fee of 3.5% of the gross sales price of Shares sold, unless Craig-Hallum acts as principal, in which case Chembio may sell the Shares to Craig-Hallum as principal at a price it agrees upon with Craig-Hallum. Chembio is obligated to reimburse Craig-Hallum for certain expenses incurred in connection with the ATM Agreement, and it has provided Craig-Hallum with customary indemnification and contribution rights with respect to certain liabilities, including liabilities under the Securities Act and the Exchange Act.

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

See Note 2(a)—Basis of Presentation.

(b) Issuance of Common Shares

As of the date of the issuance of these financial statements, Chembio had issued and sold pursuant to the ATM Agreement a total of 8,323,242 Shares at a volume-weighted average price of $4.4303 per Share for gross proceeds of approximately $36.9 million and net proceeds, after giving effect to placement fees and other estimated transaction costs, of approximately $34.7 million.

(c) Customer Purchase Orders

In July 2021 the Company received two customer purchase orders that the Company had been pursuing for an extended period of time. The delivery of the full number of tests covered by each of these purchase orders may be affected by limitations of the Company's supply chain, staffing and liquidity, including matters that are outside the Company's control. While the Company has established internal plans for delivery of the tests contemplated by the purchase orders, the number of uncertainties related to third parties — including the availability of required personnel and supplies — currently preclude the Company from accurately estimating the extent to which the Company will be able to fulfill the purchase orders on time and at an acceptable cost or at all.

- 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 needs of Brazil's Ministry of Health in addressing the COVID-19 pandemic.
- On July 22, 2021, the Company received a $4.0 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.

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

Overview

The following discussion and analysis should be read in conjunction with our unaudited consolidated financial statements and related notes included elsewhere in this report, which we refer to collectively as the Accompanying Financial Statements. In addition to historical information, the following discussion contains forward-looking statements that involves risks, uncertainties and assumptions. See "Forward-Looking Statements and Statistical Estimates" above. Please read "Item 1A. Risk Factors" of 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, manufacture and commercialize point-of-care tests for the detection and diagnosis of infectious diseases, including COVID 19, sexually transmitted disease, and fever and tropical disease.

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. As described our Current Report on Form 8-K filed with the SEC on July 19, 2021, 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, non-governmental organizations, medical professionals, and retail establishments. We continue to seek to expand our commercial distribution channels.

Substantial Doubt as to Going Concern Status

As we disclosed in our Current Report on Form 8-K filed with the SEC on July 19, 2021, or the July 19 Form 8-K, factors and considerations with respect to our liquidity raised, as of June 30, 2021, substantial doubt as to our ability to continue as a going concern through one year after the date that our financial statements with respect to the three and six months ended June 30, 2021 were expected to be issued. In July 2021 we received two significant customer purchase orders (see "—Recent Events—Customer Purchase Orders" below) and raised funds through an "at-the-market" offering (see "—Recent Events—At-the-Market Offering of Common Stock" below), which were intended to increase our total revenues and improve our liquidity position.

These measures and other plans and initiatives have been designed to provide us with adequate liquidity to meet its 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 are dependent, however, on factors that are beyond our control or that may not be available 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 two purchase orders received in July 2021 and other customer orders may be affected by limitations of our supply chain, staffing and liquidity, uncertainties regarding the achievement of milestones and related recognition of revenue under government grants, 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 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, over the next year. 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 $37.4 million for the twelve months ending September 30, 2021 to $43.8 million for the twelve months ending June 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 offering, 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 rent, 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 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," "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 fulfill all of the requirements of customer purchase orders received in July 2021 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.

Recent Events

Customer Purchase Orders

In July 2021 we received two customer purchase orders that we had been pursuing for an extended period of time. Our delivery of the full number of tests covered by each of these purchase orders may be affected by limitations of our supply chain, staffing and liquidity, including matters that are outside our control. While we have established internal plans for delivery of the tests contemplated by the purchase orders, the number of uncertainties related to third parties — including the availability of required personnel and supplies — currently preclude us from accurately estimating the extent to which we will be able to fulfill the purchase orders on time and at an acceptable cost or at all. 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 may not be able to fulfill all of the requirements of customer purchase orders received in July 2021 without additional capital to fund our operations, which capital may not be available to us on acceptable terms, or at all" under "Item 1A. Risk Factors" of Part II of this report.

- DPP SARS-CoV-2 Antigen Test System. As we described under "Item 8.01. Other Matters—Business—COVID-19 Antigen Test System—Commercialization" in the July 19 Form 8-K, throughout 2021 we have been actively pursuing sales opportunities for the DPP SARS-CoV-2 Antigen test system with governmental agencies, non-governmental organizations and distributors in countries where the test system is approved and registered. While we believed there continued to be opportunities for business awards in countries where the DPP SARS-CoV-2 Antigen test system is approved and registered, those business awards, including the issuance of purchase orders, had been repeatedly delayed for various reasons, including the impact of periodic COVID-19 lockdowns affecting product registrations and purchasing organization processes. 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. We have a long-standing relationship with Bio-Manguinhos, having supplied multiple products for point-of-care detection of COVID-19 antibodies, HIV and other infectious diseases. Bio-Manguinhos received regulatory approval from Agência Nacional de Vigilância Sanitária, or ANVISA, in March 2021, following ANVISA approval of the DPP SARS-CoV-2 Antigen test system for our Brazilian subsidiary in November 2020. We are taking advantage of investments we made earlier this year in inventory for DPP SARS-CoV-2 Antigen tests in order to provide an initial number of the tests deliverable under the Bio-Manguinhos purchase order.

- HIV 1/2 STAT-PAK Assay. 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.

At-the-Market Offering 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, 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 notes 13(a) and (b) to the Accompanying Financial Statements and the information set forth under "Item 1.01. Entry into a Material Definitive Agreement" in the July 19 Form 8-K.

To date, we have issued and sold pursuant to the ATM Agreement a total of 8,323,242 shares of common stock at a volume-weighted average price of $4.4303 per share for gross proceeds of approximately $36.9 million and net proceeds, after giving effect to placement fees and other estimated transaction costs, of approximately $34.7 million. Additional shares of common stock may be issued and sold pursuant to the ATM Agreement for gross proceeds of up to approximately $23.1 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.

We currently anticipate that the net proceeds from sales of shares under the ATM Agreement will be used for general corporate purposes, which may include, but are not limited to, working capital and capital expenditures. In particular, we expect to use a portion of the net proceeds to fund operations necessary or desirable in order to deliver products pursuant to the customer purchase orders described above under "—Customer Purchase Orders," including to fund the plan to incent and retain personnel described below under "—One-Time Incentive Plan."

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.

One-Time Incentive Plan

On August 8, 2021, the board of directors, upon the recommendation of its compensation committee, approved the adoption of a One-Time Incentive Plan, or the OTIP, under which up to $1.5 million, or the OTIP Pool, will be available for cash awards to our employees. The board intends that the OTIP help us:

- retain the employment of those employees in the light of our liquidity challenges and a highly competitive employment market stemming, in part, from the COVID-19 pandemic (see "—Substantial Doubt as to Going Concern Status" above, "—Liquidity and Capital Resources" below, and "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 "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 fulfill all of the requirements of customer purchase orders received in July 2021 without additional capital to fund our operations, which capital may not be available to us on acceptable terms, or at all" in "Item 1A. Risk Factors" of Part II of this report);

- optimize our potential to deliver tests in accordance with the two significant customer purchase orders received in July 2021, as described under "—Recent Events—Customer Purchase Orders"; and
- position our company on a solid path for the future.

Of the OTIP Pool, approximately $1.3 million will be available for awards to 37 identified "critical employees," who include our three executive officers, Richard Eberly, our Chief Executive Officer and President, Javan Esfandiari, our Executive Vice President and Chief Science Officer, and Neil Goldman, our Executive Vice President and Chief Financial Officer. The identified employees are assigned to two tiers, with the 19 members of Tier I having potential awards of up to 25% of their annual base salaries and the 18 members of Tier II having potential awards of up to 15% of their annual base salaries. Each of our executive officers is a member of Tier 1, and their maximum award amounts are as follows: Mr. Eberly, $115,000; Mr. Esfandiari, $95,750; and Mr. Goldman, $85,250. The remaining approximately $0.2 million available under the OTIP is reserved for future allocation to other employees, which allocations are to be based on a methodology similar to that used in allocating potential awards to the 37 identified employees (as described below) and are to be made to employees who are identified by management, subject to approval by the compensation committee.

Sixty percent, or up to $900,000, of the OTIP Pool would be available upon compliance with three performance milestones based on our receipt of payment for tests delivered under the two significant customer purchase orders, as follows:
- 20%, or up to $180,000, would be payable to OTIP participants following our receipt of payment for the initial delivery of tests under either order;
- 30%, or up to $270,000, would be payable to OTIP participants following our receipt of payments under the orders totaling approximately $16.2 million (one-half of the aggregate purchase prices of the two orders); and
- 50%, or up to $450,000, would be payable to OTIP participants upon our receipt of payment for the total purchase prices of the two orders.

In general, compliance with the performance milestones is to be completed by March 31, 2021.

The remaining forty percent, or $600,000, of the OTIP Pool is designed for employee retention, and will be available to OTIP participants who continue to be our employees in good standing as of August 31, 2022.

Non-Cash Write-Downs

Based on internal reviews conducted as part of our financial closing procedures for the three months ended June 30, 2021, we recorded two non-cash write-downs that affected our reported operating results for the period.

- We recorded an impairment loss of $1.3 million for the three months ended June 30, 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 that underwent a retrenchment during the three months ended June 30, 2020. During the three months ended June 30, 2021, we were informed that WHO had prioritized its review of prequalification of the manufacture of our HIV 1/2 STAT-PAK Assay on our U.S. automated manufacturing processes, which would reduce our reliance on manual labor that otherwise could have been performed at our Malaysian facilities had we re-started operations there. During July 2021, WHO approved the change notification. The products produced on our 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, including the timing and mix of products to be delivered pursuant to the customer purchase orders described above under "—Customer Purchase Orders." See note 12 to the Accompanying Financial Statements.

- We incurred a loss of $0.9 million for the three months ended June 30, 2021 related to the write-down of inventory for products that were not salable based on our periodic review of the current status and future benefits of inventory.

Consolidated Results of Operations

Three Months Ended June 30, 2021 Versus Three Months Ended June 30, 2020

The results of operations for the three months ended June 30, 2021 and 2020 were as follows (dollars in thousands). Percentages are percentages of total revenues.

	For the three months ended June 30,			
	2021		2020	
TOTAL REVENUES	**$ 6,462**	**100%**	$ 5,111	100%
OPERATING COSTS AND EXPENSES:				
Cost of product sales	**4,040**	**63%**	5,671	111%
Research and development expenses	**2,797**	**43%**	1,922	38%
Selling, general and administrative expenses	**6,001**	**93%**	4,397	86%
Asset impairment, restructuring, severance and related costs	**1,961**	**30%**	388	8%
	14,799		12,378	
LOSS FROM OPERATIONS	**(8,337)**		(7,267)	
OTHER EXPENSE, NET	**(727)**		(712)	
LOSS BEFORE INCOME TAXES	**(9,064)**	**(140)%**	(7,979)	(156)%
Income tax (expense) benefit	-		135	
NET LOSS	**$ (9,064)**		$ (7,844)	

Total Revenues

Total revenues during the three months ended June 30, 2021 were $6.5 million, an increase of $1.4 million, or 26.4%, compared to the three months ended June 30, 2020. In June 2020 the FDA revoked our EUA for the DPP COVID-19 System, which we refer to as the Revocation. The Revocation had a significant negative impact on our net product sales during the comparable period of 2020 by triggering the recall of unused tests from customers in the United States. In addition, given the uncertainty of the regulatory environment outside the United States, we did not recognize $2.7 million of net product sales revenue during the comparable period of 2020 for our shipments of the COVID-19 System outside the United States during that quarter due to the GAAP requirement that we have a high degree of confidence that it is probable that a significant reversal in revenue will not occur. Many factors can affect that consideration, including factors outside our influence, actions of third parties and evidence from similar situations. After considering all the information available to us at that time, we were not able to recognize the product sales revenue from those shipments in the second quarter due to our not having a high degree of confidence that it was probable that a significant reversal in revenue would not occur. The $2.7 million of revenue for such sales was recognized during the three months ended September 30, 2020.

The increase in total revenues compared to the comparable quarter of 2020 also reflected (a) the benefit of Government grant income totaling $2.3 million associated with our $12.7 million award from Biomedical Advanced Research and Development Authority, or BARDA, and an increase of $0.1 million in net product sales reflecting higher sales in Africa, Europe and the Middle East, predominantly offset by lower sales in the United States, Latin America and Asia, offset in part by (b) a $1.2 million decrease in research and development revenue.

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 June 30, 2021 increased by $1.8 million to $(0.1) million from $(1.9) million in the comparable period of 2020. The gross product margin during the three months ended June 30, 2021 was unfavorably impacted by a $0.9 million charge related to the write-down of inventory for products that were not salable based on our periodic review of the current status and future benefits of inventory. The gross product margin during the comparable period of 2020 was impacted by costs related to the Revocation during the second quarter, which triggered the return of COVID-19 Systems that were produced and sold to customers in the United States. It also resulted from cost of product sales including the cost of COVID-19 Systems that were produced and shipped outside the United States, but for which the corresponding $2.7 million of revenue was not recognized during the second quarter of 2020 as described under "—Total Revenues" above.

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

	For the three months ended June 30,		Favorable/(unfavorable)	
	2021	2020	**$ Change**	**% Change**
Net product sales	**$ 3,931**	$ 3,792	$ 139	3.7%
Less: Cost of product sales	**(4,040)**	(5,671)	1,631	28.8%
Gross product margin	**$ (109)**	$ (1,879)	$ 1,770	94.2%
Gross product margin percentage	**(2.8)%**	(49.6)%		

During the three months ended June 30, 2021, with the support of BARDA, we invested in developing and offering products to address the COVID-19 pandemic, which we expect to have average selling prices greater than those of our legacy products. The $1.8 million increase in gross product margin was comprised of (a) $1.7 million from relatively favorable product margins reflecting the relative impacts on the cost of product sales described above 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 June 30,		Favorable/(unfavorable)	
	2021	2020	**$ Change**	**% Change**
Clinical and regulatory affairs	**$ 871**	$ 178	$ (693)	$ (389.3)%
Other research and development	**1,926**	1,744	(182)	(10.4)%
Total research and development	**$ 2,797**	$ 1,922	$ (875)	(45.5)%

The increase in research and development costs for the three months ended June 30, 2021 compared to the three months ended June 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 $1.6 million, or 36.5%, increase in selling, general and administrative expense for the three months ended June 30, 2021 compared to the three months ended June 30, 2020 principally reflected increased costs associated with fees for legal services relating to shareholder litigation and compensation costs related to our expanded U.S. commercial team.

Asset Impairment, Restructuring, Severance and Related Costs

We incurred asset impairment, restructuring, severance and related costs of $2.0 million during the three months ended June 30, 2021 as follows:

- We recorded an impairment loss of $1.3 million for the three months ended June 30, 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. See "—Recent Events—Non-Cash Write-Downs."
- 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 June 30, 2021, we incurred $0.7 million related to these restructuring matters.

Other Expense, Net

Other expense, net consists principally of interest expense, net of interest income earned on our deposits, which increased in the three months ended June 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 $18.5 million) was outstanding at June 30, 2021. For a description of this long-term debt, please see "—Liquidity and Capital Resources —Sources of Funds—Credit Agreement" below.

Income Tax Benefit

During the three months ended June 30, 2021, we did not recognize a tax benefit related to losses generated by our foreign subsidiaries. As of June 30, 2021 and 2020, our U.S. and international deferred tax assets included a full valuation allowance.

Six Months Ended June 30, 2021 Versus Six Months Ended June 30, 2020

The results of operations for the six months ended June 30, 2021 and 2020 were as follows (dollars in thousands). Percentages are percentages of total revenues.

	For the six months ending June 30,			
	2021		2020	
TOTAL REVENUES	**$ 15,186**	**100%**	$ 11,971	100%
OPERATING COSTS AND EXPENSES:				
Cost of product sales	**7,588**	**50%**	10,045	84%
Research and development expenses	**5,660**	**37%**	3,881	32%
Selling, general and administrative expenses	**12,087**	**80%**	8,554	71%
Asset impairment, restructuring, severance and related costs	**2,044**	**13%**	1,111	9%
Acquisition	-	-	64	1%
	27,379		23,655	
LOSS FROM OPERATIONS	**(12,193)**		(11,684)	
OTHER EXPENSE, NET	**(1,440)**		(1,374)	
LOSS BEFORE INCOME TAXES	**(13,633)**	**(90)%**	(13,058)	(109)%
Income tax (expense) benefit	**68**		215	
NET LOSS	**$ (13,565)**		$ (12,843)	

Total Revenues

Total revenues during the six ended June 30, 2021 were $15.2 million, an increase of $3.2 million, or 26.9%, compared to the six months ended June 30, 2020. The Revocation in June 2020 had a significant negative impact on our net product sales during the comparable period of 2020 by triggering the recall of unused tests from customers in the United States. In addition, given the uncertainty of the regulatory environment outside the United States, we did not recognize $2.7 million of net product sales revenue during the comparable period of 2020 for our shipments of the COVID-19 System outside the United States during that period due to the GAAP requirement that we have a high degree of confidence that it is probable that a significant reversal in revenue will not occur. Many factors can affect that consideration, including factors outside our influence, actions of third parties and evidence from similar situations. After considering all the information available to us at that time, we were not able to recognize the product sales revenue from those shipments in the period due to our not having a high degree of confidence that it was probable that a significant reversal in revenue would not occur. The $2.7 million of revenue for such sales was recognized during the three months ended September 30, 2020.

The increase in total revenues compared to the six months ended June 30, 2020 also reflected the benefit of Government grant income totaling $5.6 million associated with tour $12.7 million award from BARDA, offset by a decrease of $1.0 million in R&D revenue from non-government contracts, and a $1.6 million reduction 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 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 six months ended June 30, 2021 increased by $0.9 million to $0.4 million from $(0.5) million in the comparable period of 2020. The gross product margin during the six months ended June 30, 2021 was unfavorably impacted by a $0.9 million charge related to the write-down of inventory for products that are not salable based on our periodic review of the current status and future benefits of inventory. The gross product margin during the comparable period of 2020 was impacted by costs related to the Revocation during the second quarter, which triggered the return of COVID-19 Systems that were produced and sold to customers in the U.S. It also resulted from cost of product sales including the cost of COVID-19 Systems that were produced and shipped outside the U.S., but for which the corresponding $2.7 million of revenue was not recognized during that quarter as described under "—Total Revenues" above.

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

	For the six months ended June 30,		**Favorable/(unfavorable)**	
	2021	2020	**$ Change**	**% Change**
Net product sales	**$ 7,956**	$ 9,508	$ (1,552)	(16.3)%
Less: Cost of product sales	**(7,588)**	(10,045)	2,457	24.5%
Gross product margin	**$ 368**	$ (537)	$ 905	168.5%
Gross product margin percentage	**4.6%**	(5.6)%		

During the six months ended on June 30, 2021 we invested in developing and offering products to address the COVID-19 pandemic, which we expect to have average selling prices greater than those of our legacy products. We also continued to implement automation in order to reduce our reliance on manual labor and improve our product margins. The $0.9 million increase in gross product margin was comprised of (a) $1.0 million from favorable product margins reflecting the relative impacts on the cost of product sales described above, offset in part by (b) $0.1 million of lower 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 six months ended June 30,		**Favorable/(unfavorable)**	
	2021	2020	**$ Change**	**% Change**
Clinical and regulatory affairs	**$ 1,636**	$ 500	$ (1,136)	$ (227.2)%
Other research and development	**4,024**	3,381	(643)	(19.0)%
Total research and development	**$ 5,660**	$ 3,881	$ (1,779)	(45.8)%

The increase in research and development costs for the six months ended June 30, 2021 compared to the six months ended June 30, 2020 was primarily associated with work 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 $3.5 million, or 41.3%, increase in selling, general and administrative expense for the six months ended June 30, 2021 compared to the six months ended June 30, 2020 principally reflected increased costs associated with (a) fees for legal services relating to stockholder litigation, (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 $2.0 million during the six months ended June 30, 2021 as follows:

- We recorded an impairment loss of $1.3 million for the six months ended June 30, 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. See "—Recent Events—Non-Cash Writedowns."
- 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 six months ended June 30, 2021, we incurred $0.7 million related to these restructuring matters.
- In order to address challenging economic conditions and implement its business strategy, in the first quarter of 2021 we continued to execute a program to reduce operating expenses and better align costs with revenues, including by eliminating positions that were no longer aligned with its strategy, and recognized severance charges of $0.1 million during the six months ended June 30, 2021.

Other Expense, Net

Other expense, net consists principally of interest expense, net of interest income earned on our deposits, which increased in the six months ended June 30, 2021 compared to comparable period in 2020 due to interest accruing on long-term debt incurred in September 2019, of which $20 million (carrying value of $18.5 million) was outstanding at June 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 six months ended June 30, 2021, we recognized a tax benefit of $0.1 million related to losses generated by our foreign subsidiaries, which offset the deferred tax liability balances recorded on the acquisition date. As of June 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 $5.6 million at June 30, 2021 (which included a restricted amount of $0.4 million), a decrease of $8.8 million from $14.4 million at March 31, 2021 and a decrease of $17.5 million from $23.1 million at December 31, 2020. During the first half of 2021, we funded our business operations, including capital expenditures and working capital requirements, principally from cash and cash equivalents. Our operations used $8.7 million of cash during the three months ended June 30, 2021 and $15.9 million of cash during the six months ended June 30, 2021. Revenues during the three and six months ended June 30, 2021 did not meet our expectations, and the shortfall in revenues was a principal cause of our limited cash and cash-equivalents position at June 30, 2021. Our decrease in cash and cash-equivalents over the first two quarters of 2021 reflected 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. The decrease in cash and cash-equivalents also resulted in part from significant continuing expenses incurred 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 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. For additional information regarding our consultation with the financial advisory firm, see "Item 2.02. Results of Operations and Financial Condition —Estimated Cash Position and Related Actions" in the July 19 Form 8-K. During the three months ended June 30, 2021, we incurred $0.7 million related to these restructuring matters.

As we disclosed in the July 19 Form 8-K, factors and considerations with respect to our liquidity raised, as of June 30, 2021, substantial doubt as to our ability to continue as a going concern through one year after the date that our financial statements with respect to the three and six months ended June 30, 2021 were expected to be issued. Subsequent to the July 19 Form 8-K, in July 2021 we received two significant customer purchase orders (see "—Recent Events—Customer Purchase Orders" above and raised funds through an "at-the-market" offering (see "—Recent Events—At-the-Market Offering of Common Stock" above), which were intended to increase our total revenues and improve our liquidity position.

These measures and other plans and initiatives have been designed to provide us with adequate liquidity to meet its 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 are dependent, however, on factors that are beyond our control or that may not be available 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 two purchase orders received in July 2021 and other customer orders may be affected by limitations of our supply chain, staffing and liquidity, uncertainties regarding the achievement of milestones and related recognition of revenue under government grants, and other matters outside our control. We further considered how those uncertainties could impact our ability to meet the obligations specified in the our existing Credit Agreement over the next twelve months, which include a covenant requiring minimum total revenues for the twelve months preceding each quarter end. Those requirements range from $37.4 million for the twelve months ending September 30, 2021 to $43.8 million for the twelve months ending June 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 offering, 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 rent, 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 fulfill all of the requirements of customer purchase orders received in July 2021 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.

Our cash and cash equivalents totaled $37.8 million at July 31, 2021, an increase of $32.2 million from June 30, 2021, reflecting funds raised through the offering pursuant to the ATM Agreement. Our cash and cash equivalents at July 31, 2021, which included a restricted amount of $0.4 million, were held for working capital and other general corporate purposes. We are obligated to maintain aggregate unrestricted cash of not less than $3,000,000 at all times under a covenant in our credit facility.

We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends. We have not entered into, and do not expect to enter into, investments for trading or speculative purposes. Our accounts receivable and inventory balances fluctuate from period to period, which affects our cash flow from operating activities. Fluctuations vary depending on cash collections, client mix, raw material lead times, the mix of vendor terms, and 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, it 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. In July 2021 we issued and sold pursuant to the ATM Agreement a total of 8,323,242 shares of common stock at a volume-weighted average price of $4.4303 per share for gross proceeds of approximately $36.9 million and net proceeds, after giving effect to placement fees and other estimated transaction costs, of approximately $34.7 million. Additional shares of common stock may be issued and sold pursuant to the ATM Agreement for gross proceeds of up to approximately $23.1 million, but we cannot provide any assurance that we will be able to issue any additional shares under the ATM Agreement at an acceptable price or at all. For more information about the ATM Agreement, please see "—Recent Events—At-the-Market Offering of Common Stock" above.

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 June 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 8% through September 3, 2021 and 4% from September 4, 2021 through September 3, 2022. No premium will be due with respect to any prepayment made on or after September 4, 2022.

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

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

- *Representations and Warranties; Financial and Other Covenants.* In the Credit Agreement we made customary representations and warranties as well as customary affirmative and negative covenants, including covenants limiting additional indebtedness, liens, guaranties, mergers and acquisitions, substantial asset sales, investments and loans, sale and leasebacks, transactions with affiliates, and fundamental changes. The Credit Agreement also contains financial covenants requiring that (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, which range from $32.0 million to $50.1 million, were developed for purposes of the Credit Agreement and do not reflect the internal estimates and plans used by our management and board of directors to understand and evaluate our operating performance, to establish budgets, and to establish operational goals for managing our business. We therefore do not believe that the covenant requirements provide useful information to investors or others in enhancing an understanding of our future prospects. the Credit Agreement for the next twelve months, which include attaining Minimum Total Revenue (as such term is defined in the Credit Agreement) requirements for the twelve months preceding each quarter end. For the next year, the minimum total revenue requirements range from $37.4 million for the twelve months ending September 30, 2021 to $43.8 million for the twelve months ending June 30, 2022 (see Note 7 – Long-Term Debt).

- *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. Upon an acceleration of payment following an event of default occurring prior to September 4, 2021, the amounts due and payable by us will include a prepayment premium on accelerated principal in the amount described under "—Optional Prepayment" above.

Research and Development Awards. We routinely seek research and development programs that may be awarded by government, non-governmental organizations, and non-profit entities, including private foundations. Since 2015 we have received over $19.8 million of funding from some of the world's leading health organizations, which has helped us accelerate the expansion of our pipeline of infectious disease tests. Our collaborators have included Bill & Melinda Gates Foundation, The Paul G. Allen Family Foundation, Fiocruz and FIND, as well as U.S. government agencies such as Centers for Disease Control and Prevention, BARDA, and the U.S. Department of Agriculture. See "Item 1. Business—Products" above.

During the six months ended June 30, 2021 we recognized government grant income totaling $5.6 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.

Working Capital. The following table sets forth selected working capital information (dollars in thousands):

	June 30, 2021
Cash and cash equivalents	$ 5,564
Accounts receivable, net of allowance for doubtful amounts	2,977
Inventories, net	15,720
Prepaid expenses and other current assets	1,065
Total current assets	25,326
Less: Total current liabilities	9,428
Working capital	**$ 15,898**

Uses of Funds

Cash Flow Used in Operating Activities. Our operations used $15.9 million of cash during the six months ended June 30, 2021, primarily due to: a net loss adjusted for non-cash items of $9.0 million; a $4.0 million increase in inventory related to materials and manufacturing costs for COVID-19 systems in anticipation of potential customer orders and regulatory approvals; a $2.0 million decrease in accounts payable and other accrued liabilities; and a $1.2 million decrease in deferred revenue. Those uses of cash were offset in part by a $0.5 million decrease in accounts receivable and a $0.1 million decrease in deposits and other assets.

Capital Expenditures. Our capital expenditures totaled $1.3 million in the six months ended June 30, 2021, all of which related to investments in automated manufacturing equipment, facilities, and other fixed assets. As of June 30, 2021, we had capital purchase obligations of $1.1 million related to additional automated manufacturing equipment, with payments expected to come due during 2021 based on vendor performance milestones.

Effects of Inflation

Other than the impact of increases in minimum wage levels in New York, inflation and changing prices have not had a material effect on our business, and we do not expect that they will materially affect our business in the foreseeable future. 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 June 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 Exchange Act.

Significant Accounting Policies and Critical Accounting Estimates

There were no significant changes in our critical accounting estimates during the three and six months ended June 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 Exchange Act, as of June 30, 2021. Based on this evaluation, our management, including our principal executive officer and principal financial officer, concluded that as of June 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 June 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 "Note 6(f) – 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 II 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 July 19 Form 8-K. 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 II 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 July 19 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 offering 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 rent, 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.

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 for the foreseeable future in connection with the two significant customer purchase orders we received in July 2021 (see "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Events—Customer 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 may not be able to fulfill all of the requirements of customer purchase orders received in July 2021 without additional capital to fund our operations, which capital may not be available to us on acceptable terms, or at all" 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 June 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 may not be able to fulfill all of the requirements of customer purchase orders received in July 2021 without additional capital to fund our operations, which capital may not be available to us on acceptable terms, or at all.

In July 2021 we received two customer purchase orders, or the July Orders, that 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—Customer Purchase Orders" above. Our delivery of the full number of tests covered by each of the July 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 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 accurately estimating the extent to which we will be able to fulfill the July Orders on time and at an acceptable cost, or at all. Our ability to generate revenue from the July 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 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 personnel and other constraints, in producing the combination of DPP SARS-CoV-2 Antigen tests and HIV 1/2 STAT-PAK Assays contemplated by the July Orders. Our inability to quickly and successfully configure our automated manufacturing lines to produce high quality tests could delay the rate at which we can produce and deliver tests pursuant to the July Orders and could adversely affect the profitability of those tests.

The number of tests to be delivered pursuant to the July 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 schedules contemplated by the July Orders. We therefore will need to rely upon manual assembly processes to produce a significant portion of the tests deliverable under the July Orders and other orders, which will 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. Our inability to identify and hire assembly line personnel, and to manage turnover of currently existing and newly hired personnel, could materially limit our ability to deliver tests under the July Orders, or at all.

We must obtain additional raw materials in order to manufacture tests to meet the requirements of the July Orders. Some raw materials require significant ordering lead time, and some are currently obtained from a sole supplier or a limited group of suppliers. It is possible that one or more of our suppliers may become unwilling or unable to deliver materials to us. It may be difficult to find an alternate supply source in a reasonable time period or on commercially reasonable terms, if at all. With some of these suppliers, we do not have long term agreements and instead purchase components and materials through a purchase order process. 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. Our reliance on a limited number of suppliers could also result in delivery problems, reduced control over product pricing and quality, and our inability to identify and qualify another supplier in a timely manner.

We currently are seeking to schedule deliveries of raw materials required in connection with the July Orders, but we are early in that process given that we could not begin arranging for supply deliveries until we received the order commitments reflected by the July Orders. Any shortfall in the supply of raw materials, or our inability to quickly and cost effectively obtain alternative sources for this supply, could have a material adverse effect on our ability to produce tests for delivery under the July Orders. Even if we succeed in arranging to obtain needed raw materials, our receipt of those raw materials may be significantly delayed by the suppliers' production schedules. For example, we have been advised by one of our sole source suppliers based in Europe that the supplier will not be able to begin forecasting a delivery schedule for our purposes until the latter half of August, due to the supplier being closed for a scheduled shutdown during the first half of August and that, in any event, due to existing orders the supplier might not be able to begin deliveries to us for a number of weeks thereafter. Any supply chain deficiencies could materially and adversely affect our ability to fulfill the July Orders. The availability of critical raw materials from sole or limited source suppliers could reduce our control over pricing, quality and timely delivery, increase our costs, and disrupt, or even preclude, our ability to manufacture and sell tests pursuant to the July Orders. Our inability to obtain required raw materials, or a significant delay in receiving those raw materials, could have a material adverse effect on our total revenues, cost of sales and related margin as well as our cash flow.

Because of the foregoing factors and considerations, we may be unable to timely deliver a significant number of the tests required by the July Orders, which would impair our ability to achieve desired profit margins and generate cash flow from the Purchase Orders. If we are unable to timely meet the requirements of the July Orders, it 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. Moreover, in the event we do not timely deliver tests under the July Orders, the customers, including Bio-Manguinhos, could choose to purchase products from our competitors with whom our customers already have existing business relationships, which competitors may have greater technical, financial and other resources than we have. Under the July Order with Bio-Manguinhos, the initial tranche of tests were due to be delivered in July 2021, and our inability to timely deliver those or future tests due to delays in converting automated manufacturing assembly, hiring additional personnel or obtaining need raw materials could impair our ability to meet the minimum total revenue covenant under the Credit Agreement for the twelve months ended September 30, 2021 or thereafter.

As a result of the foregoing, we may need to raise additional funds pursuant to the ATM Agreement or through other 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.

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 $37.4 million for the twelve months ending September 30, 2021 to $43.8 million for the twelve months ending June 30, 2022 (see note 7 to the condensed consolidated financial statements included elsewhere herein). 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 September 30, 2021 do not, for example, take into account the challenges we are facing during the three months ending September 30, 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 may not be able to fulfill all of the requirements of customer purchase orders received in July 2021 without additional capital to fund our operations, which capital may not be available to us on acceptable terms, or at all."

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 Chembio and its 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. If an event of default under our Credit Agreements occurs, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. If we were unable to pay such amounts, the Lender could proceed against the collateral pledged to them. We have pledged substantially all of our assets, including our inventory, accounts receivable, cash, securities, other general intangibles and the capital stock of certain subsidiaries, to the Lender. We cannot assure you that, in such an event, we would have sufficient assets to pay amounts due under the Credit Agreement.

You may experience future dilution as a result of future equity offerings, exercises of outstanding options and vesting of restricted 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. To date, we have issued and sold pursuant to the ATM Agreement a total of 8,323,242 shares of common stock at a volume-weighted average price of $4.4303 per share for gross proceeds of approximately $36.9 million and net proceeds, after giving effect to placement fees and other estimated transaction costs, of approximately $35.6 million. For additional information about the at-the-market offering 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 Offering 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 approximately $23.1 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 the at-the-market offering 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 August 3, 2021, our market capitalization was approximately $61 million, and as a result existing stockholders may experience significant dilution in connection with our issuance and sale of up to $23.1 million of additional shares of common stock pursuant to the ATM Agreement. In addition, as of June 30, 2021, 2,502,911 shares of common stock were reserved for future issuance under our 2019 Omnibus Incentive Plan, 1,867,045 shares were subject to outstanding options, and 802,947 shares were subject to outstanding restricted stock units. Stockholders will incur dilution upon vesting of restricted 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
3.1	Amendment No. 1 to Amended and Restated Bylaws of Chembio Diagnostics, Inc.
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	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Definition Linkbase Document
101.LAB	XBRL Taxonomy Label Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document
104	Cover page interactive date file (embedded within the 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: August 9, 2021

By: /s/ Richard Eberly

Richard Eberly
Chief Executive Officer and President

Date: August 9, 2021

By: /s / Neil A. Goldman

Neil A. Goldman
Chief Financial Officer and Executive Vice President

Exhibit 3.1

AMENDMENT NO. 1
TO
AMENDED AND RESTATED BYLAWS
OF
CHEMBIO DIAGNOSTICS, INC.

THIS FIRST AMENDMENT (this "**First Amendment**") to the Amended and Restated Bylaws (the "**Bylaws**") of Chembio Diagnostics, Inc., a Nevada corporation (the "**Corporation**"), was approved by the Board of Directors of the Corporation (the "**Board**") on June 10, 2021. In accordance with Article IX of the Bylaws, this First Amendment is effective as of June 10, 2021.

WHEREAS, the Board adopted the Bylaws as of September 17, 2018;

WHEREAS, pursuant to Article IX of the Bylaws, the Board currently has the exclusive power to amend or repeal the Bylaws or to adopt new bylaws; and

WHEREAS, the Board wishes to permit the amendment of the Bylaws not only by action of the Board, but also by action of the holders of at least two-thirds of the outstanding shares of capital stock;

NOW, THEREFORE, the Bylaws are hereby amended as follows:

1. Amendment. Article IX of the Bylaws is hereby amended and restated as follows:

"***ARTICLE IX***

AMENDMENT OF BYLAWS

Section 1. ***By Board.*** These Bylaws may be altered, amended or repealed, or new Bylaws may be adopted, by the affirmative vote of a majority of the directors present at any regular or special meeting of the Board at which a quorum is present.

Section 2. ***By Stockholders.*** These Bylaws may be altered, amended or repealed, or new Bylaws may be adopted, by the affirmative vote of the holders of at least two-thirds of the shares of capital stock of the Corporation issued, outstanding and entitled to vote at any Annual Meeting or Special Meeting, provided notice of such alteration, amendment or repeal, or of such adoption of new Bylaws, shall have been stated in the notice of such Annual Meeting or Special Meeting."

2. Miscellaneous. Except as expressly amended hereby, the Bylaws shall remain in full force and effect and are hereby ratified and confirmed in all respects.

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: August 9, 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: August 9, 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 June 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: August 9, 2021

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

Date: August 9, 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.