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

FORM 10-Q

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

For the quarterly period ended September 30, 2022

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from: _____ to _____

001-355669
(Commission File Number)

Chembio Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**88-0425691**
(State or other jurisdiction of incorporation)	*(IRS Employer Identification Number)*

555 Wireless Blvd.
Hauppauge, NY 11788
(Address of principal executive offices including zip code)

(631) 924-1135
(Registrant's telephone number, including area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐
Non-accelerated filer ☒
Emerging growth company ☐

Accelerated filer ☐
Smaller reporting company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.
Yes ☐ No ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes ☐ No ☒

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

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

As of October 24, 2022, the registrant had 36,708,474 shares outstanding of its common stock, $0.01 par value.

Quarterly Report on Form 10-Q
For The Quarterly Period Ended
September 30, 2022

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Chembio Diagnostics, Inc.

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

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

FORWARD-LOOKING STATEMENTS AND STATISTICAL ESTIMATES

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

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

Forward-looking statements and statistical estimates inherently involve risks and uncertainties that could cause actual results to differ materially from those predicted or expressed in this report. These risks and uncertainties include those described in Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, or our 2021 Form 10-K, as filed with the Securities and Exchange Commission or the SEC, on March 3, 2022, or Part II, Item 1A, “Risk Factors” in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022, as filed with the SEC on May 5, 2022 and August 5, 2022, respectively. 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) September 30, 2022	December 31, 2021
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 21,055,026**	$ 28,772,892
Accounts receivable, net of allowance for doubtful accounts of $242,354 and $243,042 at September 30, 2022 and December 31, 2021, respectively	**5,252,573**	11,441,107
Inventories, net	**8,465,210**	12,920,451
Prepaid expenses and other current assets	**12,509,604**	2,096,399
TOTAL CURRENT ASSETS	**47,282,413**	55,230,849
FIXED ASSETS:		
Property, plant and equipment, net	**8,813,699**	8,556,773
Finance lease right-of-use asset, net	**154,826**	191,870
OTHER ASSETS:		
Operating lease right-of-use assets, net	**5,639,763**	5,891,906
Goodwill	**-**	3,022,787
Deposits and other assets	**289,203**	358,010
TOTAL ASSETS	**$ 62,179,904**	$ 73,252,195
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 18,645,498**	$ 13,127,993
Current portion of long-term debt	**18,993,535**	1,200,000
Operating lease liabilities	**910,100**	886,294
Finance lease liabilities	**75,279**	68,176
TOTAL CURRENT LIABILITIES	**38,624,412**	15,282,463
OTHER LIABILITIES:		
Long-term operating lease liabilities	**5,655,468**	5,976,151
Long-term finance lease liabilities	**96,529**	139,678
Long-term debt, net	**-**	17,576,635
Other long-term liabilities	**10,684**	12,368
TOTAL LIABILITIES	**44,387,093**	38,987,295
STOCKHOLDERS' EQUITY:		
Preferred stock - 10,000,000 shares authorized; none outstanding	**-**	-
Common stock - $0.01 par value; 100,000,000 shares authorized; 35,440,553 shares and 30,104,986 shares issued at September 30, 2022 and December 31, 2021, respectively	**354,406**	301,050
Additional paid-in capital	**171,448,870**	165,772,636
Accumulated deficit	**(153,445,401)**	(131,009,860)
Treasury Stock, 48,057 shares at cost, at September 30, 2022 and December 31, 2021	**(206,554)**	(206,554)
Accumulated other comprehensive loss	**(358,510)**	(592,372)
TOTAL STOCKHOLDERS' EQUITY	**17,792,811**	34,264,900
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 62,179,904**	$ 73,252,195

See accompanying notes to condensed consolidated financial statements

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

	For the three months ended		For the nine months ended	
	September 30, 2022	September 30, 2021	**September 30, 2022**	September 30, 2021
REVENUES:				
Net product sales	**$ 10,844,003**	$ 9,371,160	**$ 38,229,605**	$ 17,327,204
R&D and grant revenue	**50,000**	441	**76,219**	1,107,808
Government grant income	**-**	2,400,000	**-**	8,030,000
License and royalty revenue	**306,145**	286,843	**872,365**	779,901
TOTAL REVENUES	**11,200,148**	12,058,444	**39,178,189**	27,244,913
COSTS AND EXPENSES:				
Cost of product sales	**9,658,678**	7,902,819	**32,969,388**	15,490,956
Research and development expenses	**1,871,113**	3,442,044	**5,567,169**	9,102,363
Selling, general and administrative expenses	**5,551,362**	5,947,327	**17,747,613**	18,033,748
Impairment, restructuring, severance and related costs	**110,250**	396,740	**3,153,429**	2,440,983
TOTAL COSTS AND EXPENSES	**17,191,403**	17,688,930	**59,437,599**	45,068,050
LOSS FROM OPERATIONS	**(5,991,255)**	(5,630,486)	**(20,259,410)**	(17,823,137)
OTHER EXPENSE:				
Interest (expense) income, net	**(707,549)**	(735,336)	**(2,169,525)**	(2,175,188)
LOSS BEFORE INCOME TAXES	**(6,698,804)**	(6,365,822)	**(22,428,935)**	(19,998,325)
Income tax (expense)/benefit	**-**	(28)	**(6,606)**	67,928
NET LOSS	**$ (6,698,804)**	$ (6,365,850)	**$ (22,435,541)**	$ (19,930,397)
Basic and diluted loss per share	**$ (0.21)**	$ (0.24)	**$ (0.73)**	$ (0.89)
Weighted average number of shares outstanding, basic and diluted	**32,274,664**	26,701,546	**30,862,982**	22,361,899

See accompanying notes to condensed consolidated financial statements

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

	For the three months ended		For the nine months ended	
	September 30, 2022	September 30, 2021	**September 30, 2022**	September 30, 2021
Net loss	**$ (6,698,804)**	$ (6,365,850)	**$ (22,435,541)**	$ (19,930,397)
Other comprehensive income/(loss):				
Foreign currency translation adjustments, net of tax	**127,457**	(352,918)	**233,862**	(507,538)
Comprehensive loss	**$ (6,571,347)**	$ (6,718,768)	**$ (22,201,679)**	$ (20,437,935)

See accompanying notes to condensed consolidated financial statements

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

	For the nine months ended September 30, 2022							
	Common Stock		Additional Paid-in-Capital	Treasury Stock		Accumulated Deficit	AOCI	Total
	Shares	Amount	Amount	Shares	Amount	Amount	Amount	Amount
Balance at December 31, 2021	**30,104,986**	**$ 301,050**	**$165,772,636**	**(48,057)**	**$ (206,554)**	**$(131,009,860)**	**$ (592,372)**	**$34,264,900**
Common Stock:								
Restricted stock issued	164,930	1,649	264,437	-	-	-	-	266,086
Restricted stock compensation	-	-	229,563	-	-	-	-	229,563
Shares tendered for withholding taxes	-	-	(38,514)	-	-	-	-	(38,514)
Options:								
Stock option compensation	-	-	255,254	-	-	-	-	255,254
Comprehensive income	-	-	-	-	-	-	348,151	348,151
Net loss	-	-	-	-	-	(8,790,294)	-	(8,790,294)
Balance at March 31, 2022	**30,269,916**	**$ 302,699**	**$166,483,376**	**(48,057)**	**$ (206,554)**	**$(139,800,154)**	**$ (244,221)**	**$26,535,146**
Common Stock:								
Restricted stock issued	2,747	28	(28)	-	-	-	-	-
Restricted stock compensation	-	-	276,024	-	-	-	-	276,024
Shares tendered for withholding taxes	-	-	(1,154)	-	-	-	-	(1,154)
Options:								
Stock option compensation	-	-	282,985	-	-	-	-	282,985
Comprehensive loss	-	-	-	-	-	-	(241,746)	(241,746)
Net loss	-	-	-	-	-	(6,946,443)	-	(6,946,443)
Balance at June 30, 2022	**30,272,663**	**$ 302,727**	**$167,041,203**	**(48,057)**	**$ (206,554)**	**$(146,746,597)**	**$ (485,967)**	**$19,904,812**
Common Stock:								
Restricted stock issued	17,623	176	(176)	-	-	-	-	-
Restricted stock compensation	-	-	268,751	-	-	-	-	268,751
Shares tendered for withholding taxes	-	-	(237)	-	-	-	-	(237)
Issuance of common stock under ATM agreement	5,150,267	51,503	3,871,754					3,923,257
Options:								
Stock option compensation	-	-	267,575	-	-	-	-	267,575
Comprehensive loss	-	-	-	-	-	-	127,457	127,457
Net loss	-	-	-	-	-	(6,698,804)	-	(6,698,804)
Balance at September 30, 2022	**35,440,553**	**$ 354,406**	**$171,448,870**	**(48,057)**	**$ (206,554)**	**$(153,445,401)**	**$ (358,510)**	**$17,792,811**

See accompanying notes to condensed consolidated financial statements

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

	For the nine months ended September 30, 2021							
	Common Stock		Additional Paid-in-Capital	Treasury Stock		Accumulated Deficit	AOCI	Total
	Shares	Amount	Amount	Shares	Amount	Amount	Amount	Amount
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)**	**$23,285,146**
Common Stock:								
Restricted stock issued	51,677	517	(517)	-	-	-	-	-
Restricted stock compensation, net	-	-	288,053	-	-	-	-	288,053
Shares tendered for withholding taxes	-	-	(4,454)	-	-	-	-	(4,454)
Options:								
Stock option compensation	-	-	297,791	-	-	-	-	297,791
Comprehensive income	-	-	-	-	-	-	301,102	301,102
Net loss	-	-	-	-	-	(9,064,385)	-	(9,064,385)
Balance at June 30, 2021	**20,337,372**	**$ 203,374**	**$126,006,387**	**(41,141)**	**$ (190,093)**	**$ (110,670,879)**	**$ (245,536)**	**$15,103,253**
Common Stock:								
Issuance of stock, net	9,709,328	97,093	38,714,867	-	-	-	-	38,811,960
Restricted stock issued	3,331	33	18,385	-	-	-	-	18,418
Restricted stock compensation, net	-	-	399,548	-	-	-	-	399,548
Options:								
Exercised	36,252	363	85,192	-	-	-	-	85,555
Stock option compensation	-	-	218,563	-	-	-	-	218,563
Comprehensive loss	-	-	-	-	-	-	(352,918)	(352,918)
Net loss	-	-	-	-	-	(6,365,850)	-	(6,365,850)
Balance at September 30, 2021	**30,086,283**	**$ 300,863**	**$165,442,942**	**(41,141)**	**$ (190,093)**	**$ (117,036,729)**	**$ (598,454)**	**$47,918,529**

See accompanying notes to condensed consolidated financial statements

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

	September 30, 2022	September 30, 2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	**$ 45,366,035**	$ 22,355,958
Cash paid to suppliers and employees	**(52,481,928)**	(43,732,182)
Cash paid for operating leases	**(1,086,793)**	(1,049,198)
Cash paid for finance leases	**(13,278)**	(15,358)
Interest and taxes, net	**(1,645,952)**	(1,709,704)
Net cash used in operating activities	**(9,861,916)**	(24,150,484)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Patent application costs	**-**	(32,648)
Acquisition of and deposits on fixed assets	**(1,480,662)**	(1,387,601)
Net cash used in investing activities	**(1,480,662)**	(1,420,249)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of stock, net	**3,923,257**	38,811,960
Payments of tax withholding on stock award	**(39,906)**	(119,513)
Principal payments for finance leases	**(52,280)**	(45,680)
Principal payments on Note Payable	**(300,000)**	-
Net cash provided by financing activities	**3,531,071**	38,646,767
Effect of exchange rate changes on cash	**93,641**	(138,335)
DECREASE IN CASH AND CASH EQUIVALENTS	**(7,717,866)**	12,937,699
Cash and cash equivalents - beginning of the period	**28,772,892**	23,066,301
Cash and cash equivalents - end of the period	**$ 21,055,026**	$ 36,004,000
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net loss	**$ (22,435,541)**	$ (19,930,397)
Adjustments:		
Depreciation and amortization	**1,867,325**	2,186,684
Share based compensation	**1,846,238**	1,802,056
Non-cash inventory adjustment	**657,686**	926,499
Benefit from deferred tax liability	**-**	(69,941)
Provision of (recovery of) doubtful accounts	**(688)**	(103,258)
Impairment, restructuring and severance	**3,043,179**	1,273,945
Changes in assets and liabilities:		
Accounts receivable	**6,189,222**	(3,302,153)
Inventories	**3,797,556**	(5,215,766)
Prepaid expenses and other current assets	**(10,413,205)**	(412,995)
Deposits and other assets	**68,807**	141,946
Accounts payable and accrued liabilities	**5,517,505**	139,698
Deferred revenue	**-**	(1,586,802)
Net cash used in operating activities	**$ (9,861,916)**	$ (24,150,484)

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2022
(Unaudited)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. ("Chembio") and its subsidiaries (collectively with Chembio, the "Company") develop and commercialize point-of-care diagnostic tests used for the rapid detection and diagnosis of infectious diseases, including sexually transmitted disease, insect vector and tropical disease, COVID-19 and other viral and bacterial infections, enabling expedited treatment.

The Company's 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 such as sexually transmitted infections and HIV, Gastroenterology and Women's Health. Compared with traditional lateral flow technology, the DPP technology platform can provide:

- Enhanced sensitivity and specificity: This is achieved via the Company's proprietary approach to separating the sample path from the buffer path, together with patent and other proprietary strategies, which differ significantly from traditional lateral flow test.
- Advanced multiplexing capabilities: Through advanced multiplexing, the DPP platform can detect and differentiate up to eight distinct test results from a single patient sample, which can deliver greater clinical value than other rapid tests currently on the market.
- Objective results: For some diagnostic applications, the Company's easy-to-use, highly portable, battery-operated DPP Micro Reader optical analyzers can report accurate results in approximately 15 seconds, making it well-suited for decentralized testing where real-time results enable patients to be clinically assessed while they are still on site. Objective results produced by the DPP Micro Reader can reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many rapid tests.

The Company targets 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. The Company has 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 the Company began the process of shifting substantially all of its resources to seek to leverage the DPP technology platform to address the acute and escalating need for diagnostic testing for COVID-19. The Company is continuing to pursue:

- an emergency use authorization ("EUA"), from the U.S. Food and Drug Administration (the "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 Antigen Panel; and
- a Clinical Laboratory Improvement Amendment ("CLIA"), waiver from the FDA for the DPP HIV-Syphilis test system.

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. Certain reclassifications have been made to the unaudited condensed consolidated balance sheet of the prior year to conform to the current year presentation. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as filed with the SEC.

Going Concern Considerations

The Company continued to experience market, clinical trial and regulatory complications in seeking to develop and commercialize a portfolio of COVID-19 test systems during the continuing, but evolving, uncertainty resulting from COVID-19. For the three and nine months ended September 30, 2022, the Company also continued to incur significant expenses in connection with pending legal matters (see Note 6 – Commitments, Contingencies, and Concentrations: Litigation).

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

The Company achieved significant revenue growth in recent years while profitability has not been at levels as expected. It has taken steps including investments in automation to mitigate headwinds such as labor availability, volatile capacity planning and implementation of operational efficiency targets to proactively monitor production with the overarching goal of profitable growth. The Company undertook measures to increase its total revenues and improve its liquidity position by continuing to develop the Global Competitiveness Program. The main pillars of the Global Competitiveness Program include the following:

- Focus on higher margin business in growth markets
- Lower manufacturing costs
- Reduce infrastructure costs
- Strategic review of non-core businesses and assets

In addition, the Company will continue to focus on regulatory approvals for its DPP SARS-CoV-2 Antigen test system, DPP Respiratory Antigen Panel, and DPP HIV-Syphilis test system. These measures and other plans and initiatives have been designed to provide the Company with adequate liquidity to meet its obligations for at least the twelve-month period following the date the accompanying unaudited condensed consolidated financial statements are being issued. The Company's execution of its plans continue to depend, however, on factors and uncertainties that are beyond the Company's control, or that may not be addressable on terms acceptable to the Company or at all. The Company considered in particular how:

- The ongoing healthcare and economic impacts of COVID-19 on the global customer base for the Company's non-COVID-19 products continue to negatively affect the timing and rate of recovery of the Company's revenues from those products.
- Although the Company has entered into agreements to distribute third-party COVID-19 products in the United States, its ability to sell those products could be constrained because of staffing and supply chain limitations affecting the suppliers of those products.

The Company further considered how these factors and uncertainties could impact its ability over the next year to meet the obligations specified in the Credit Agreement with the Lender (as defined in Note 7 – Long-Term Debt). Those obligations include covenants requiring: i) minimum cash balance of $3.0 million and ii) minimum total revenue amounts for the twelve months preceding each quarter end. For the next three quarters, the minimum total revenue requirements range from $47.4 million for the twelve months ending December 31, 2022 to $50.1 million for the twelve months ending June 30, 2023. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. In such an event, there can be no assurance that the Company would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, the Company would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. The Company's inability to raise additional capital on acceptable terms in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for its operations, could have a material adverse effect on its business, prospects, results of operations, liquidity and financial condition.

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

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

(b) Significant Accounting Policies:

During the three and nine months ended September 30, 2022, there have been no significant changes to the Company's summary of significant accounting policies contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, 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 $ 17.2 million and $25.0 million as of September 30, 2022 and December 31, 2021, 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 $19.0 million) and $20.0 million (carrying value of $18.8 million) as of September 30, 2022 and December 31, 2021 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, such as money market funds, with original maturities of three months or less at date of purchase.

(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 net loss per share is computed using the treasury stock method if the additional shares are dilutive. For all periods presented, basic and diluted net loss per share are the same as any additional shares would be anti-dilutive.

There were 3,674,971 and 1,786,324 options outstanding as of September 30, 2022 and 2021, respectively, that were not included in the calculation of diluted per common share equivalents for the three and nine months ended September 30, 2022 and 2021, respectively, because the effect would have been anti-dilutive.

There were 1,723,384 and 811,038 shares of restricted stock outstanding as of September 30, 2022 and 2021, respectively, that were not included in the calculation of diluted per common share equivalents for the three and nine months ended September 30, 2022 and 2021, 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 months ended September 30, 2022 and 2021 was 0.0% and 0.0% respectively. For the nine months ended September 30, 2022 and 2021 the effective tax rate was (0.03)% and 0.34% respectively. The Company's effective tax rates for both periods were affected primarily by a full valuation allowance on domestic and foreign net deferred tax assets.

(g) Recently Issued Accounting Standards Affecting the Company:

Recently Adopted

ASU 2021-10 - Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance

In November 2021, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2021-10, Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance, which creates Accounting Standards Codification ("ASC") 832 and aims to provide increased transparency by requiring business entities to disclose information about certain types of government assistance they receive in the notes to the financial statements. The disclosure requirements in ASC 832 only apply to transactions with a government that are accounted for by analogizing to either a grant model (for example, in International Accounting Standard 20, Accounting for Government Grants and Disclosure of Government Assistance), or a contribution model (for example, in ASC 958-605, Not-for-Profit Entities – Revenue Recognition). The FASB broadly defined "government assistance" in ASC 832 to ensure that assistance received from most types of governmental entities or other related organizations would be disclosed. Entities are required to provide the new disclosures prospectively for all transactions with a government entity that are accounted for under either a grant or a contribution accounting model and are reflected in the financial statements at the date of initially applying the new amendments, and to new transactions entered into after that date. Retrospective application of the guidance is permitted. The Company adopted the standard effective January 1, 2022 and has determined that the adoption did not have an impact on the Company's consolidated financial statements.

Not Yet Adopted

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

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

ASU 2021-08—Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers

On October 28, 2021, the FASB issued ASU 2021-08,1 which amends ASC 805 to "require acquiring entities to apply Topic 606 to recognize and measure contract assets and contract liabilities in a business combination." Under current GAAP, an acquirer generally recognizes such items at fair value on the acquisition date. ASU 2021-08 amends ASC 805 to add contract assets and contract liabilities to the list of exceptions to the recognition and measurement principles that apply to business combinations and to "require that an entity (acquirer) recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with Topic 606." While primarily related to contract assets and contract liabilities that were accounted for by the acquiree in accordance with ASC 606, "the amendments also apply to contract assets and contract liabilities from other contracts to which the provisions of Topic 606 apply, such as contract liabilities from the sale of nonfinancial assets within the scope of Subtopic 610-20." The ASU's amendments are effective for public business entities for the fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The amendments should be applied prospectively to business combinations occurring on or after the effective date of the amendments. The Company continues to assess the potential impact of the standard and will disclose the nature and reason for any elections that the Company makes.

NOTE 3 — REVENUE:

Disaggregation of Revenue

The following table disaggregates Total Revenues by revenue type:

	Three Months Ended September 30, 2022			Three Months Ended September 30, 2021		
	Exchange Transactions	**Non-Exchange Transactions**	**Total**	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	**$ 10,844,003**	**$ -**	**$ 10,844,003**	$ 9,371,160	$ -	$ 9,371,160
R&D and grant revenue	**50,000**	**-**	**50,000**	441	-	441
Government grant income	**-**	**-**	**-**	-	2,400,000	2,400,000
License and royalty revenue	**306,145**	**-**	**306,145**	286,843	-	286,843
	$ 11,200,148	**$ -**	**$ 11,200,148**	$ 9,658,444	$ 2,400,000	$ 12,058,444

	Nine Months Ended September 30, 2022			Nine Months Ended September 30, 2021		
	Exchange Transactions	**Non-Exchange Transactions**	**Total**	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	**$ 38,229,605**	**$ -**	**$ 38,229,605**	$ 17,327,204	$ -	$ 17,327,204
R&D and grant revenue	**76,219**	**-**	**76,219**	1,107,808	-	1,107,808
Government grant income	**-**	**-**	**-**	-	8,030,000	8,030,000
License and royalty revenue	**872,365**	**-**	**872,365**	779,901	-	779,901
	$ 39,178,189	**$ -**	**$ 39,178,189**	$ 19,214,913	$ 8,030,000	$ 27,244,913

Exchange transactions are recognized in accordance with ASC 606, while non-exchange transactions are recognized in accordance with ASU No. 2018-08.

The following table disaggregates Total Revenues by geographic location:

	For the three months ended		For the nine months ended	
	September 30, 2022	September 30, 2021	**September 30, 2022**	September 30, 2021
Africa	**$ 2,730,311**	$ 1,293,405	**$ 6,642,263**	$ 4,104,619
Asia	**86,648**	208,750	**541,867**	479,297
Europe & Middle East	**1,263,050**	1,132,961	**3,556,778**	4,539,444
Latin America	**2,286,121**	5,698,920	**15,678,200**	6,444,456
United States	**4,834,018**	3,724,408	**12,759,081**	11,677,097
	$ 11,200,148	$ 12,058,444	**$ 39,178,189**	$ 27,244,913

NOTE 4 — INVENTORY:

Inventories are presented net of reserves and consist of the following at:

	September 30, 2022	December 31, 2021
Raw materials	**$ 5,633,735**	$ 7,306,095
Work in process	**915,590**	3,556,878
Finished goods	**1,915,885**	2,057,478
	$ 8,465,210	$ 12,920,451

During the nine months ended September 30, 2022 and 2021, the Company recognized a $0.7 million and $0.9 million charge, respectively, related to the write-down of inventory.

NOTE 5 — STOCKHOLDERS' EQUITY:

(a) Common Stock

During the three and nine months ending September 30, 2022 and 2021, there were 0 and 36,252 options exercised for the purchase of common stock shares.

(b) Preferred Stock

Chembio has 10,000,000 shares of preferred stock authorized and none 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

Chembio has 48,057 shares of treasury stock acquired upon the vesting of restricted stock awards related to the tax withholding requirements paid on behalf of the employees.

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

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

NOTE 6 — COMMITMENTS, CONTINGENCIES, AND CONCENTRATIONS:

a) Concentrations:

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

	For the three months ended				For the nine months ended				Accounts Receivable as of	
	September 30, 2022		September 30, 2021		September 30, 2022		September 30, 2021		September 30, 2022	December 31, 2021
	Product Sales	% of Product Sales	Product Sales	% of Product Sales	Product Sales	% of Product Sales	Product Sales	% of Product Sales		
Customer 1	$ 2,163,414	20%	$ 5,434,186	58%	$ 14,503,058	38%	$ 5,724,171	33%	$ 1,424,614	$ 7,672,845
Customer 2	1,583,453	15%	1,196,217	13%	3,812,433	10%	2,347,832	14%	125,433	1,433,305
Customer 3	1,886,906	17%	*	*	5,318,816	14%	*	*	1,553,306	-
Customer 4	1,443,480	13%	*	*	*	*	*	*	195,011	-

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

The following table discloses purchases the Company had to each vendor in excess of 10% of the Company's net purchases for the periods indicated:

	For the three months ended				For the nine months ended				Accounts Payable as of	
	September 30, 2022		September 30, 2021		September 30, 2022		September 30, 2021		September 30, 2022	December 31, 2021
	Purchases	% of Purchases	Purchases	% of Purchases	Purchases	% of Purchases	Purchases	% of Purchases		
Vendor 1	$ *	*	$ 1,678,250	34%	$ *	$ *	$ 2,339,182	$ 19%	$ *	$ 1,107,530
Vendor 2	*	*	*	*	2,200,905	16%	*	*	148,255	103,443
Vendor 3	$ 944,460	14%	$ *	*	$ 4,585,298	$ 33%	$ *	$ *	$ -	$ 149,230

In the tables above, an asterisk (*) indicates that indicates that sales, accounts receivable, purchases or accounts payable, as applicable to the tabular column, did not exceed 10% for the period indicated.

The Company purchases materials pursuant to intellectual property rights agreements that 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 and a possible loss of sales, which could adversely affect operating results.

We have capital purchase obligations of $0.3 million related to additional automated manufacturing equipment with payments expected to come due during 2022 based on vendor performance milestones.

b) Employment Contracts:

The Company has multi-year contracts with three key employees. The contracts call for salaries presently aggregating $1,178,000 per year. The contracts expire in December 2022 and December 31, 2024. The following table is a schedule of future minimum salary commitments:

2022	$ 294,500
2023	383,000
2024	383,000

c) Benefit Plan:

Chembio has a 401(k) plan established for the Company's employees whereby it matches 40% of the first 5% of salary (or up to 2% of salary) that an employee contributes to the plan. Matching contribution expenses totaled approximately $44,103 and $35,533 for the three months ended September 30, 2022 and 2021, respectively. Matching contribution expenses totaled approximately $149,016 and $100,922 for the nine months ended September 30, 2022 and 2021, respectively.

d) Leases:

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

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

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

The components of lease expense were as follows:

	Three Months Ended September 30		Nine Months Ended September 30	
	2022	2021	**2022**	2021
Operating lease expense	**$ 390,204**	$ 398,089	**$ 1,180,953**	$ 1,208,885
Finance lease cost				
Amortization of right-of-use assets	**$ 17,850**	$ 17,038	**53,279**	49,834
Interest on lease liabilities	**4,112**	5,047	**13,278**	15,358
Total finance lease expense	**$ 21,962**	$ 22,085	**$ 66,557**	$ 65,192

Supplemental cash flow information related to leases was as follows.

	Three Months Ended September 30		Nine Months Ended September 30	
	2022	2021	**2022**	2021
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows for operating leases	**$ 364,590**	$ 353,009	**$ 1,086,793**	$ 1,049,198
Operating cash flows for finance leases	**4,112**	5,047	**13,278**	15,358
Financing cash flows for finance leases	**17,859**	15,859	**52,280**	45,680
Right-of-use assets obtained in exchange for lease obligations:				
Finance leases	**-**	-	**16,234**	25,609
Operating leases	**-**	-	**717,956**	616,100

Supplemental balance sheet information related to leases was as follows:

	September 30, 2022	September 30, 2021
Finance Leases		
Finance lease right of use asset	**$ 356,997**	$ 340,762
Accumulated depreciation	**(202,171)**	(131,854)
Finance lease right of use asset, net	**$ 154,826**	$ 208,908
Weighted Average Remaining Lease Term		
Operating leases	**6.8 years**	7.7 years
Finance leases	**2.0 years**	3.1 years
Weighted Average Discount Rate		
Operating leases	**8.38%**	8.41%
Finance leases	**9.11%**	8.74%

Maturities of lease liabilities were as follows.

	September 30, 2022		September 30, 2021	
	Operating Leases	**Finance Leases**	Operating Leases	Finance Leases
2022	**$ 366,985**	**$ 21,971**	$ 355,335	$ 20,906
2023	**1,428,821**	**87,884**	1,447,249	83,624
2024	**1,220,150**	**60,116**	1,221,017	83,624
2025	**1,049,442**	**16,731**	1,018,875	55,856
2026	**1,080,925**	**5,940**	1,049,442	12,471
Thereafter	**3,643,521**	**355**	4,724,446	1,679
Total lease payments	**$ 8,789,844**	**$ 192,997**	$ 9,816,364	$ 258,160
Less: imputed interest	**2,224,276**	**21,189**	2,751,749	34,119
Total	**$ 6,565,568**	**$ 171,808**	$ 7,064,615	$ 224,041

e) 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 former 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. One current employee, the Chief Executive Officer, also received a testimonial subpoena from the SEC. Chembio and the six individuals are cooperating fully in the SEC's investigation and expect to continue to do so.

The SEC's investigation is ongoing, and Chembio has recently engaged in discussions with the SEC regarding a potential resolution that would, among other things, involve the payment of a civil penalty. There can be no assurance that Chembio will be able to agree on a resolution with the SEC or that the terms of any such resolution will be favorable to Chembio. Chembio 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 purported 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 named as defendants Chembio, Richard L. Eberly, Gail S. Page, Neil A. Goldman, Javan Esfandiari, Katherine L. Davis, Mary Lake Polan, John Potthoff (together, the "Chembio Defendants") and the underwriters for the May 2020 Offering, Robert W. Baird & Co., Inc. and Dougherty & Company LLC (the "Underwriter Defendants").

The CAC purported to assert five counts under the Securities Act and the Exchange Act. Counts I through III were 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 purported to allege a claim for violation of Section 11 of the Securities Act against all defendants other than Messrs. Eberly and Esfandiari. Count II purported to allege a claim for violation of Section 12 of the Securities Act against all defendants other than Messrs. Eberly and Esfandiari. Count III purported 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 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 purported 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 purported to allege a claim under Section 20(a) of the Exchange Act against Mr. Eberly, Ms. Page, Mr. Goldman and Mr. Esfandiari.

In their CAC, the Lead Plaintiffs sought, 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 sought rescission "or a rescissory measure of damages" on behalf of the Securities Act Class as to Count II.

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

On March 5, 2021, the Court entered an order in which it advised the parties that it had determined a pre motion conference was not necessary and established a briefing schedule on the defendants' anticipated motions to dismiss. However, the defendants subsequently agreed with the Lead Plaintiffs' counsel to a modification of the schedule, which was then approved by the Court. Pursuant to that schedule, defendants' motions and supporting papers were filed on March 26, 2021, the Lead Plaintiffs' opposition papers were filed on April 16, 2021, and the defendants' reply papers were filed on April 30, 2021.

The Court issued its Opinion and Order (the "February 23 Order") on the defendants' motions to dismiss on February 23, 2022. In its February 23 Order, the Court: (i) dismissed Counts I and II without prejudice as to all defendants named in those Counts except the Underwriter Defendants as to which Counts I and II were not dismissed; (ii) dismissed Count III without prejudice as to all defendants named in that Count; and (iii) dismissed Counts IV and V with prejudice as to all defendants named in those Counts. The Court gave Lead Plaintiffs fourteen days within which to attempt to replead their claims under the Securities Act against Chembio, Ms. Page, Mr. Goldman, Ms. Davis, Dr. Polan and Dr. Potthoff.

On March 4, 2022, Lead Plaintiffs filed a letter motion in which they advised the Court that they intended to file an amended complaint, but that they wished to first seek reconsideration of the Court's February 23 Order. They accordingly requested, and the Court granted, an adjournment of the deadline for filing an amended complaint until three business days after the Court's ruling on Lead Plaintiffs' anticipated motion for reconsideration. The Court also granted a request by the Underwriter Defendants to extend the time for them to file their answer to the CAC, and set May 2, 2022 as the date for the filing of that answer.

On March 7, 2022, Magistrate Judge John Wicks entered an order requiring that the parties meet and confer regarding the scheduling of discovery in the case, requiring that the parties submit a Proposed Scheduling Order by March 23, and setting a hearing (via Zoom) on March 30. The Chembio Defendants filed a letter motion requesting that the Court adjourn the initial conference and suspend the other requirements in the March 7, 2022 order. Magistrate Judge Wicks granted the letter motion on March 14, and further ordered that the initial conference would be rescheduled "following the resolution of all preliminary dispositive issues."

On March 9, 2022, Lead Plaintiffs filed a motion for partial reconsideration of the Court's February 23 Order. In their motion, Lead Plaintiffs requested that the Court reconsider and reverse its dismissal of Counts IV and V with prejudice, and its dismissal of Counts I, II and III without prejudice. The Chembio Defendants filed their memorandum in opposition to this motion on March 23, 2022; Lead Plaintiffs filed their reply memorandum in support of the motion on March 30, 2022.

On April 26, 2022, the Court entered an order canceling the previously-set May 2 date by which the Underwriter Defendants were required to file their answer to the CAC, and providing that the Underwriter Defendants' answer to an amended complaint would be due within three weeks after such amended complaint had been served.

On April 28, 2022, Lead Plaintiffs expressed a willingness to participate in a mediation with the Chembio Defendants. Thereafter, on July 14, 2022, all parties in the In re Chembio Diagnostics, Inc. Securities Litigation action participated in a mediation. The mediation was adjourned without an agreement to resolve the action, but the parties continued to discuss a potential negotiated resolution with the mediator's assistance.

On July 21, 2022, the Court denied Lead Plaintiffs' motion for partial reconsideration. Lead Plaintiffs filed their Second Consolidated Amended Complaint (the "SCAC") on July 26, 2022. The SCAC purports to allege three counts under the Securities Act on behalf of the Securities Act Class. Count I purports to allege a claim for violation of Section 11 of the Securities Act against Chembio, Ms. Page, Mr. Goldman, Ms. Davis, Dr. Polan, Dr. Potthoff and the Underwriter Defendants. Count II purports to allege a claim for violation of Section 12 of the Securities Act against Chembio, Ms. Page, and the Underwriter Defendants. Count III purports to allege a claim under Section 15 of the Securities Act against Ms. Page, Mr. Goldman, Ms. Davis, Dr. Polan and Dr. Potthoff.

In their SCAC, Lead Plaintiffs seek, on behalf of the Securities Act Class, an award of damages in an amount to be proven at trial, as well as an award of reasonable costs and expenses, including counsel fees and expert fees, and such other relief as the Court deems just and proper. Lead Plaintiffs also seek rescission "or a rescissory measure of damages as to Count II."

In order to facilitate the parties' discussions concerning a potential settlement, the parties agreed that the defendants had until August 23, 2022 within which to respond to the SAC. The defendants submitted a letter to the Court requesting that the date by which they are required to respond to the SCAC be moved to August 23, 2022; the Court granted the defendants' request on August 1, 2022. Thereafter, the defendants requested that the date for their response be extended to September 6, 2022; the Court granted the request on August 19, 2022.

On August 26, 2022, the Company and the other parties to the litigation reached an agreement in principle on the financial terms of a proposed settlement of all claims that were asserted, or could have been asserted, on an individual and class-wide basis against all defendants in the case, including under both the Securities Act and the Securities Exchange Act. The agreement in principle to settle contemplates an $8.1 million payment on behalf of the defendants, approximately $209,000 of which is to be paid by us with the remainder being funded by certain of the Company's insurers.

Accordingly, on August 30, 2022, the Chembio Defendants filed a letter motion requesting that the Court stay all proceedings to allow the parties to focus their efforts on negotiating and preparing a stipulation of settlement and other settlement- documents. Lead Plaintiffs and the Underwriter Defendants consented to and joined in the request for relief sought in the letter motion. The Court granted the motion on August 31, 2022 and ordered the parties to file their stipulation of dismissal on or before October 17, 2022. Although the parties' negotiations on the form and content of documents necessary to effectuate a class-wide settlement of the claims asserted in the litigation have continued, the parties were unable to meet the October 17, 2022 date set by the Court for the submission of a stipulation of dismissal. Consequently, on October 12, 2022, the Company submitted a letter motion to the Court, on behalf of each of the parties, requesting a 30 day extension of time to submit the stipulation and agreement of settlement together with accompanying exhibits (including proposed forms of notice of the settlement to class members and proposed forms of orders granting preliminary and final approval to the settlement). The Court granted the motion on October 13, 2022, and directed the parties to file their proposed settlement papers for the Court's approval on or before November 14, 2022.

Negotiations between the parties concerning the form and substance of documents necessary to implement the proposed settlement continue. There can be no assurance that the parties will reach agreement on the terms of a stipulation of settlement and related documents, or if the parties reach agreement, that the stipulation of settlement will be granted preliminary and final approval by the Court.

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 Chembio, restitution, and an award of the plaintiff's costs and disbursements in the action, including reasonable attorneys' and experts' fees, costs and expenses, and improvements to Chembio's corporate governance and internal procedures 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 stipulation provides for a stay that lasts until all motions to dismiss the class action litigation have been finally resolved. Wong can, however, terminate the stipulation on 14 days' notice if a related derivative action is not stayed for a similar or longer duration. Further, if the defendants in the Wong action agree to engage in a mediation "or other similar formal process" with plaintiffs in any related class action or derivative action during the pendency of the stay or for a one-year period following its termination, they must promptly provide notice of the mediation to Wong, not object to Wong's participation in the mediation (subject to the consent of the other involved parties), and if consent to Wong's participation is not provided, they must separately engage in mediation or a similar formal process with Wong. The Court entered an order granting the requested stay on November 3, 2020.

On March 31, 2022, a second putative stockholder derivative action captioned Michelle Chen, 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 "Chen complaint") was filed purportedly on behalf of Chembio in the Supreme Court for the State of New York, County of Suffolk. The Chen complaint purports to assert a claim for breach of fiduciary duty against the defendants based on ostensibly false and misleading statements and omissions concerning the Company's rapid COVID-19 antibody test. The Chen complaint goes on to allege that the misconduct asserted in the complaint gave rise to the filing of the consolidated securities litigation described above.

The parties in the Chen action agreed to a stipulated stay of the action continuing until a motion to certify a class in the class action has been decided. Chen can, however, terminate the stay on seven days' notice if a related derivative action is not stayed for the same or a longer duration. The stipulation also provides that if the defendants agree to engage in a formal mediation with the class action plaintiffs or the plaintiff in any other related derivative action, they must notify Chen of the mediation and participate with Chen in a mediation "or other settlement talks," whether separately or in combination with a mediation involving other related actions.

The plaintiffs in the Wong and Chen actions took part in the July 14, 2022 mediation described above, and the parties subsequently reached an agreement in principle on the terms of a proposed settlement of both actions, other than with respect to the maximum amount of attorneys' fees which plaintiffs may request that the Court approve, and have executed a memorandum of understanding to that effect. The proposed settlement contemplates the adoption of certain corporate governance measures but does not entail any monetary compensation or payment other than the derivative plaintiffs' attorneys' fees not exceeding an amount to be negotiated, and subject to Court approval. On October 27, 2022, the parties reached agreement on the amount $595,000 of the derivative plaintiffs' attorneys' fees, which the Company believes will be funded by certain of its insurers.

There can be no assurance that the parties will reach agreement on the maximum amount of plaintiffs' attorneys' fees which plaintiffs may request that the court approve or on the terms of a formal stipulation or settlement, or that the court will approve the terms of a stipulation of settlement.

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 Chembio, 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 allegedly provided to Chembio 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 his initial disclosures served in discovery, Mr. Sperzel claims entitlement to recover damages in a total amount not less than $10 million, together with prejudgment interest at the rate of 9% per annum.

On May 20, 2021, Chembio filed its answer and affirmative defenses denying the material allegations of Mr. Sperzel's complaint. Chembio and Mr. Sperzel are presently engaged in discovery. All discovery in the case was completed on June 28, 2022. On July 6, 2022, pursuant to local court rules, Chembio filed a formal notice with the District Court stating its intention to file a motion for summary judgment on all of Mr. Sperzel's claims. Mr. Sperzel's responsive letter and factual statements were due on July 27, 2022 and were timely filed. On August 16, 2022, the Court held a pre-motion status conference, during which the Court directed the parties to confer regarding the renewal of settlement discussions. The parties subsequently agreed to engage in a formal mediation conference before a neutral, private mediator on October 25, 2022, and the parties must provide a status report to the Court on November 8, 2022. At this stage of the litigation, the Company is not able to predict the probability of a favorable or unfavorable outcome.

Other

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

Nasdaq Communications

On April 5, 2022, the Company received notification from the Listing Qualifications Department of The Nasdaq Stock Market, or Nasdaq, stating that the Company did not comply with the minimum $1.00 bid price requirement for continued listing set forth in Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement"). In accordance with Nasdaq listing rules, the Company was afforded 180 calendar days (until October 3, 2022) to regain compliance with the Bid Price Requirement. On October 4, 2022, the Company received written notice from Nasdaq stating that, although the Company had not regained compliance with the Bid Price Requirement by October 3, 2022, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company is eligible for an additional 180 calendar day period, or until April 3, 2023, to regain compliance with the Bid Price Requirement. To regain compliance, the closing bid price of the Company's common stock must meet or exceed $1.00 per share for a minimum of ten consecutive business days during this additional 180-day period, all as described in more detail in the Current Reports on Form 8-K filed with the SEC on April 7, 2022 and October 4, 2022. The closing price of Chembio's common stock was $0.42 on October 5, 2022. There can be no assurance that Chembio will be able to regain compliance with the Bid Price Requirement. The Company's inability to regain compliance with the Bid Price Requirement would, and the existence of the pending deficiency letter could, materially impair its ability to raise capital. Moreover, if Chembio were unable to regain compliance with the Bid Price Requirement, its common stock would likely then trade only in the over-the-counter market and the market liquidity of its common stock could be adversely affected and its market price could decrease. If our common stock were to trade on the over-the-counter market, selling its common stock could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and Chembio could face significant material adverse consequences, including: a limited availability of market quotations for its securities; reduced liquidity with respect to its securities; a determination that its shares are a "penny stock," which will require brokers trading in its securities to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for its securities; a reduced amount of news and analyst coverage; and a decreased ability to issue additional securities or obtain additional financing in the future. These factors could result in lower prices and larger spreads in the bid and ask prices for its common stock and would substantially impair its ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

NOTE 7 — LONG-TERM DEBT:

On September 3, 2019, Chembio entered into a Credit Agreement and Guaranty (the "Credit Agreement") with Perceptive Credit Holdings II, LP (the "Lender"). The Credit Agreement provides for a $20.0 million senior secured term loan credit facility, which was drawn in full on September 4, 2019. Under the terms of the Credit Agreement, Chembio may use the proceeds (i) for general working capital purposes and other permitted corporate purposes, (ii) to refinance certain of Chembio's existing indebtedness and (iii) to pay fees, costs and expenses incurred in connection with the Credit Agreement, including the Lender's closing cost amount of $550,000, which was netted from the proceeds, and a financing fee of $600,000 (3.0% of gross proceeds) payable to Craig-Hallum Capital Group LLC, 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 September 30, 2022 the interest rate was 11.32%.

No principal repayments were due under the Credit Agreement prior to September 30, 2022. Chembio did not elect to prepay principal and an event of default identified in the Credit Agreement did not occur that would have accelerated principal payments. 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. As of September 30, 2022, Chembio paid the first principal installment in accordance with the Credit Agreement.

Chembio's obligations under the Credit Agreement are secured by a first priority, perfected lien on substantially all of its property and assets, including its equity interests in subsidiaries.

As of September 30, 2022, the loan balance, net of unamortized discounts and debt issuance costs, was $19.0 million, and Chembio was in compliance with its loan covenants.

NOTE 8 — EQUITY INCENTIVE PLAN:

(a) Equity Plans:

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 March 31, 2022, there were 732,064 Equity Award Units expired, forfeited or exercised. At September 30, 2022, 46,875 Equity Award Units were outstanding and 21,061 shares were not issued. All shares that expired, forfeited or were not issued rolled over into the 2019 Plan. No Equity Award Units remain available to be issued under the 2014 Plan.

Effective June 18, 2019, Chembio's stockholders voted to approve the 2019 Omnibus Incentive Plan (the "2019 Plan"), with 2,400,000 shares of common stock available to be issued. At the Annual Stockholder Meeting on June 25, 2021, Chembio's stockholders voted to approve an increase to the shares of common stock issuable under the SIP by 2,400,000 to 4,800,000. In addition, shares of common stock underlying any outstanding award granted under the 2019 Plan that, following the effective date of the 2019 Plan, expire, or are terminated, surrendered or forfeited for any reason without issuance of such shares, shall be available for the grant of new awards under the 2019 Plan. Under the terms of the 2019 Plan, the Board or its Compensation Committee has the discretion to select the persons to whom awards are to be granted. Awards can be in the form of options, stock appreciation rights, restricted stock, restricted stock units, performance stock units or other stock-based awards under the 2019 Plan (collectively, "2019 Equity Units"). The 2019 Equity Units become vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through September 30, 2022, 1,168,331 2019 Equity Units have been cancelled or forfeited. At September 30, 2022, 4,812,903 2019 Equity Units were outstanding, and 87,672 2019 Equity Units were available to be awarded.

(b) Stock Compensation Expense:

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

	For the three months ended September 30		**For the nine months ended September 30**	
	2022	2021	**2022**	2021
Cost of product sales	**$ 54,243**	$ 52,819	**$ 165,589**	$ 124,955
Research and development expenses	**113,874**	164,560	**317,381**	388,264
Selling, general and administrative expenses	**368,209**	419,152	**1,363,268**	1,288,837
	$ 536,326	$ 636,531	**$ 1,846,238**	$ 1,802,056

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

	For the nine months ended September 30, 2022
Expected term (in years)	**6.0**
Expected volatility	**91.62%**
Expected dividend yield	**N/A**
Risk-free interest rate	**1.97%**

The following table provides stock option activity for the nine months ended September 30, 2022:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contract Term	Aggregate Intrinsic Value
Outstanding at December 31, 2021	**1,600,372**	**$ 4.18**	**6.59 years**	**$ -**
Granted	2,481,968	1.24		-
Exercised	-	-		-
Forfeited	137,076	2.77		-
Expired	270,293	5.01		
Outstanding at September 30, 2022	**3,674,971**	**$ 2.20**	**8.30 years**	**$ -**
Exercisable at September 30, 2022	**553,360**	**$ 4.01**	**5.59 years**	**$ -**

The following table summarizes information about stock options outstanding at September 30, 2022:

	Stock Options Outstanding				Stock Options Exercisable		
Range of Exercise Prices	Number of Shares	Average Remaining Contract Term (Year)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
1 to 2.79999	2,838,509	8.52	$ 1.40	$ -	247,370	$ 2.36	$ -
2.8 to 4.59999	26,796	8.54	3.06	-	9,237	3.06	-
4.6 to 6.39999	762,791	7.93	4.81	-	249,878	4.90	-
6.4 to 8.19999	46,875	0.61	8.15	-	46,875	8.15	-
Total	3,674,971	8.30	$ 2.20	$ -	553,360	$ 4.01	$ -

As of September 30, 2022, there was $2,389,457 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 2.85 years. The total fair value of shares vested during the nine months ended September 30, 2022 and 2021 was $917,036 and $335,579, respectively.

The following table summarizes information about restricted stock, restricted stock units and performance stock units outstanding as of September 30, 2022:

	Number of Shares & Units	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2021	705,325	$ 3.34
Granted	1,308,547	-
Vested	190,064	-
Forfeited	100,424	-
Outstanding at September 30, 2022	**1,723,384**	**$ 1.39**

As of September 30, 2022, there was $1,530,896 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 2.03 years.

NOTE 9 — GEOGRAPHIC INFORMATION AND ECONOMIC DEPENDENCY:

The Company produces only one group of similar products known collectively as "rapid medical tests", and it operates in a single operating segment. Net product sales by geographic area were as follows:

	For the three months ended September 30		For the nine months ended September 30	
	2022	2021	**2022**	**2021**
Africa	**$ 2,730,311**	$ 1,293,405	**$ 6,642,263**	$ 4,104,619
Asia	**86,648**	208,750	**541,867**	479,297
Europe & Middle East	**956,905**	1,132,520	**2,670,529**	3,431,736
Latin America	**2,286,121**	5,698,920	**15,665,864**	6,444,456
United States	**4,784,018**	1,037,565	**12,709,082**	2,867,096
	$ 10,844,003	$ 9,371,160	**$ 38,229,605**	$ 17,327,204

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

	September 30, 2022	December 31, 2021
Asia	**$ 77,398**	$ 86,041
Europe & Middle East	**79,107**	113,883
Latin America	**80,255**	36,224
United States	**8,576,939**	8,320,625
	$ 8,813,699	$ 8,556,773

NOTE 10 — ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:

Accounts payable and accrued liabilities consisted of:

	September 30, 2022	December 31, 2021
Accounts payable – suppliers	**$ 3,066,133**	$ 7,745,592
Accrued commissions and royalties	**2,053,261**	1,359,691
Accrued payroll	**437,757**	494,258
Accrued vacation	**554,468**	421,416
Accrued bonuses	**1,523,979**	1,378,706
Accrued professional fees	**1,593,504**	522,935
Accrued expenses – other	**9,416,396**	1,205,395
TOTAL	**$ 18,645,498**	$ 13,127,993

NOTE 11 — GOODWILL AND INTANGIBLE ASSETS:

The following table reflects changes in goodwill:

Beginning balance at December 31, 2021	$ 3,022,787
Impairment	(3,033,565)
Change in foreign currency exchange rate	10,778
Balance at September 30, 2022	$ -

Goodwill represents the excess of the purchase price the Company paid over the fair value of the net tangible and identifiable intangible assets acquired in the Company's acquisition. Goodwill is not amortized but rather is tested annually as of the first day of the fiscal fourth quarter, or sooner if the Company believes that indicators of impairment exist. The Company makes a qualitative evaluation about the likelihood of goodwill impairment, which is based on a number of applicable factors. If the Company concludes that it is more likely than not that the carrying value of the applicable reporting unit is greater than its fair value, then it would recognize an impairment charge for the amount by which the carrying value exceeds the reporting unit's fair value, provided the impairment charge does not exceed the total amount of goodwill allocated to the reporting unit.

The quantitative goodwill impairment test is performed using a one-step process. The process is to compare the fair value of a reporting unit with its carrying amount. If the fair value of a reporting unit exceeds its carrying amount, goodwill of the reporting unit is not impaired. If the carrying amount of a reporting unit exceeds its fair value, goodwill of the reporting unit is impaired, and an impairment loss is recognized in an amount equal to that excess.

The Company operates as a single operating segment and has one reporting unit. The Company recognized an impairment loss of its goodwill totaling $3.0 million for the nine months ended September 30, 2022.

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

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

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

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

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

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

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

Our board of directors has initiated a review of strategic alternatives, including a potential sale or merger transaction, and of our financing strategy. We have retained Craig-Hallum Capital Group LLC as our financial advisor to assist with the strategic review. We have not set a timetable for completion of the strategic review process, and there can be no assurance that the process will result in a transaction at this time or at all. Even if a sale, merger or financing transaction is consummated, it may not return any value to holders of our common stock. Regardless of whether we execute a sale, merger or financing transaction, the adverse pressures that we have experienced may continue or intensify, and we will likely continue to face all of the risks we currently face, including the risk that we may not be able to continue as a going concern.

Going Concern Considerations

The Company continued to experience market, clinical trial and regulatory complications in seeking to develop and commercialize a portfolio of COVID-19 test systems during the continuing, but evolving, uncertainty resulting from COVID-19. For the three and nine months ended September 30, 2022, the Company also continued to incur significant expenses in connection with pending legal matters (see Note 6 – Commitments, Contingencies, and Concentrations: Litigation).

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

The Company achieved significant revenue growth in recent years while profitability has not been at levels as expected. It has taken steps including investments in automation to mitigate headwinds such as labor availability, volatile capacity planning and implementation of operational efficiency targets to proactively monitor production with the overarching goal of profitable growth. The Company undertook measures to increase its total revenues and improve its liquidity position by continuing to develop the Global Competitiveness Program. The main pillars of the Global Competitiveness Program include the following:

- Focus on higher margin business in growth markets
- Lower manufacturing costs
- Reduce infrastructure costs
- Strategic review of non-core businesses and assets

In addition, the Company will continue to focus on regulatory approvals for its DPP SARS-CoV-2 Antigen test system, DPP Respiratory Antigen Panel, and DPP HIV-Syphilis test system. These measures and other plans and initiatives have been designed to provide the Company with adequate liquidity to meet its obligations for at least the twelve-month period following the date the accompanying unaudited condensed consolidated financial statements are being issued. The Company's execution of its plans continue to depend, however, on factors and uncertainties that are beyond the Company's control, or that may not be addressable on terms acceptable to the Company or at all. The Company considered in particular how:

- The ongoing healthcare and economic impacts of COVID-19 on the global customer base for the Company's non-COVID-19 products continue to negatively affect the timing and rate of recovery of the Company's revenues from those products.

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

The Company further considered how these factors and uncertainties could impact its ability over the next year to meet the obligations specified in the Credit Agreement with the Lender (as defined in Note 7 – Long-Term Debt). Those obligations include covenants requiring: i) minimum cash balance of $3.0 million and ii) minimum total revenue amounts for the twelve months preceding each quarter end. For the next three quarters, the minimum total revenue requirements range from $47.4 million for the twelve months ending December 31, 2022 to $50.1 million for the twelve months ending June 30, 2023. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. In such an event, there can be no assurance that the Company would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, the Company would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. The Company's inability to raise additional capital on acceptable terms in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for its operations, could have a material adverse effect on its business, prospects, results of operations, liquidity and financial condition.

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

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

Consolidated Results of Operations

Three Months Ended September 30, 2022 versus Three Months Ended September 30, 2021

The results of operations for the three months ended were as follows (dollars in thousands):

	September 30, 2022		September 30, 2021	
TOTAL REVENUES	**$ 11,200**	**100%**	$ 12,058	100%
OPERATING COSTS AND EXPENSES:				
Cost of product sales	**9,659**	**86%**	7,903	66%
Research and development expenses	**1,871**	**17%**	3,442	29%
Selling, general and administrative expenses	**5,551**	**50%**	5,947	49%
Impairment, restructuring, severance and related costs	**110**	**1%**	397	3%
TOTAL OPERATING COSTS AND EXPENSES	**17,191**		17,689	
LOSS FROM OPERATIONS	**(5,991)**		(5,631)	
OTHER (EXPENSE) INCOME, NET	**(708)**		(735)	
LOSS BEFORE INCOME TAXES	**(6,699)**	**(60)%**	(6,366)	(53)%
Income tax (expense) benefit	**-**		-	
NET LOSS	**$ (6,699)**		$ (6,366)	

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during the quarter ended September 30, 2022 were $11.2 million, a decrease of $0.9 million, or 7%, compared to the quarter ended September 30, 2021. The decrease in total revenues is primarily due to lower sales in Latin America.

Gross Product Margin

Cost of product sales is primarily composed of material, labor, manufacturing overhead, depreciation, amortization, 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 sales.

Gross product margin decreased by $0.3 million, or 19% compared to the quarter ended September 30, 2021. The following schedule calculates gross product margin (dollars in thousands):

	For the three months ended September 30		Favorable/(unfavorable)	
	2022	2021	**$ Change**	**% Change**
Net product sales	**$ 10,844**	$ 9,371	$ 1,473	16%
Less: Cost of product sales	**(9,659)**	(7,903)	(1,756)	22%
Gross product margin	**$ 1,185**	$ 1,468	$ (283)	(19)%
Gross product margin percentage	11%	16%		

The $0.3 million decrease in gross product margin was comprised of (a) $0.5 million from unfavorable product margins and the impact of fixed manufacturing overhead, and (b) $0.2 million from favorable product sales volume.

Research and Development

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

	For the three months ended September 30		Favorable/(unfavorable)	
	2022	2021	**$ Change**	**% Change**
Clinical and regulatory affairs	**$ 391**	$ 1,520	$ (1,129)	$ (74)%
Other research and development	**1,480**	1,922	(442)	(23)%
Total research and development	**$ 1,871**	$ 3,442	$ (1,571)	(46)%

The decrease in total research and development costs for the three months ended September 30, 2022 compared to the three months ended September 30, 2021 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 the Biomedical Advanced Research and Development Authority, or BARDA (part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response). Total research and development cost incurred for the three months ended September 30, 2022 were primarily related to ongoing projects in our new product pipeline.

Selling, General and Administrative Expense

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

The $0.4 million, or 7%, decrease in selling, general and administrative expense for the three months ended September 30, 2022 compared to the three months ended September 30, 2021 is principally due to lower compensation costs and professional fees.

Impairment, restructuring, severance and related costs

During the three months ended September 30, 2022, $0.1million in impairment, restructuring, severance and related costs were recorded. For the three months ended September 30, 2021, $0.4 million was incurred, which was related to restructuring matters.

Other Income (Expense), net

Other income (expense), net, consists principally of interest expense on our long-term debt under the Credit Agreement on September 3, 2019, of which $20 million (carrying value of $19.0 million) was outstanding at September 30, 2022. For a description of Credit Agreement, please see "Liquidity and Capital Resources—Sources of Funds—Credit Agreement" below.

Nine Months Ended September 30, 2022 versus Nine Months Ended September 30, 2021

The results of operations for the nine months ended September 30, 2022 and 2021 were as follows (dollars in thousands):

	September 30, 2022		September 30, 2021	
TOTAL REVENUES	**$ 39,178**	**100%**	$ 27,245	100%
OPERATING COSTS AND EXPENSES:				
Cost of product sales	**32,969**	**84%**	15,491	57%
Research and development expenses	**5,567**	**14%**	9,102	33%
Selling, general and administrative expenses	**17,748**	**45%**	18,034	66%
Impairment, restructuring, severance and related costs	**3,153**	**8%**	2,441	9%
TOTAL OPERATING COSTS AND EXPENSES	**59,437**		45,068	
LOSS FROM OPERATIONS	**(20,259)**		(17,823)	
OTHER (EXPENSE) INCOME, NET	**(2,170)**		(2,175)	
LOSS BEFORE INCOME TAXES	**(22,429)**	**(57)%**	(19,998)	(73)%
Income tax benefit	**(7)**		68	
NET LOSS	**$ (22,436)**		$ (19,930)	

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during the nine months ended September 30, 2022 were $39.2 million, an increase of $11.9 million, or 44% compared to the nine months ended September 30, 2021. The increase in total net revenues was composed of the following:

- $20.9 million net increase in product sales, reflecting gains in the U.S., Latin America, and Africa, offset by lower sales in Europe and the Middle East. Higher sales in Latin America were primarily due to Bio-Manguinhos for DPP SARS-CoV 2 Antigen tests.

- $9.0 million, or 99%, decrease in R&D, grant and license and royalty revenues were primarily associated with the completion of 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.

Gross Product Margin

Cost of product sales is primarily composed of material, labor, manufacturing overhead, depreciation, amortization, 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 sales.

Gross product margin increased by $3.4 million, or 187%, compared to the first nine months ended of 2022. The following schedule calculates gross product margin (dollars in thousands):

	For the nine months ended		**Favorable/(unfavorable)**	
	September 30, 2022	**September 30, 2021**	**$ Change**	**% Change**
Net product sales	**$ 38,230**	**$ 17,327**	$ 20,903	121%
Less: Cost of product sales	**(32,969)**	**(15,491)**	(17,478)	113%
Gross product margin	**$ 5,261**	**$ 1,836**	$ 3,425	187%
Gross product margin percentage	14%	11%		

The $3.4 million increase in gross product margin was composed of the following:

- $2.2 million favorable product sales volume as described above, together with

- $1.2 million from favorable product margins related to the impact of geographic mix on average selling price.

Research and Development

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

	For the nine months ended		**Favorable/(unfavorable)**	
	September 30, 2022	September 30, 2021	**$ Change**	**% Change**
Clinical and regulatory affairs	**$ 1,229**	$ 3,156	$ (1,927)	(61)%
Other research and development	**4,338**	5,946	(1,608)	(27)%
Total Research and Development	**$ 5,567**	$ 9,102	$ (3,535)	(39)%

The decrease in total research and development costs for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 was primarily associated with the end of the BARDA contract in late 2021. Total research and development cost incurred for the nine months ended September 30, 2022 were primarily related to ongoing projects in our new product pipeline.

Selling, General and Administrative Expense

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

The $0.3 million, or 2%, decrease in selling, general and administrative expenses for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 is principally due to lower professional fees.

Impairment, restructuring, severance and related costs

Impairment, restructuring, severance and related costs include an impairment loss of $3.0 million during the first quarter of 2022 as a result of an impairment of goodwill due to the substantial decrease in our share price at March 31, 2022. The low price per share value at March 31, 2022 caused our book value to exceed our fair value. During the third quarter of 2022, $0.1 million of severance cost was recorded. For the nine months ended September 30, 2021, $2.4 million was incurred, of which $1.3 million was related to the write-off of intangible assets, net leasehold improvements, and net right-of-use assets for leases associated with our Malaysian operations, and $1.1 million was related to restructuring matters.

Other (Expense) Income, net

Other income (expense), net consists principally of interest expense on our long-term debt under the Credit Agreement on September 3, 2019, of which $20 million (carrying value of $19.0 million) was outstanding at September 30, 2022. For a description of Credit Agreement, please see “Liquidity and Capital Resources—Sources of Funds—Credit Agreement” below

Liquidity and Capital Resources

Our cash and cash equivalents totaled $21.1 million at September 30, 2022. We are obligated to maintain aggregate unrestricted cash of not less than $3.0 million at all times under a covenant in the Credit Agreement.

During the nine months ended September 30, 2022, we funded our business operations, including capital expenditures and working capital requirements, principally from cash and cash equivalents, using $7.7 million of cash.

Factors and considerations with respect to our liquidity raised substantial doubt as to our ability to continue as a going concern through one year after the date that the accompanying financial statements are being issued. See “Going Concern Considerations” above.

We have considered how the uncertainties around the delivery of the full number of tests covered by customer orders may be affected by limitations of our staffing, supply chain and liquidity and other matters outside our control. We further considered how those uncertainties could impact our ability to meet the obligations specified in the Credit Agreement over the next twelve months, which include (a) a covenant requiring minimum total revenues for the twelve months preceding each quarter end, which requirements range from $47.4 million for the twelve months ending December 31, 2022 to $50.1 million for the twelve months ending June 30, 2023 and (b) an obligation requiring the payment of principal installments, commencing with the payment of $300,000 on September 30, 2022. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. In such an event, there can be no assurance that we would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, we would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. Our inability to raise additional capital on acceptable terms or to otherwise generate cash 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.

We cannot 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 or likewise, increasing product revenue in the near future or executing other mitigating plans, many of which are beyond our control, it is unlikely that we will be able to generate sufficient cash flows to meet our required financial obligations, including our debt service and other obligations due to third parties. The existence of these conditions raises substantial doubt about our ability to continue as a going concern for the twelve-month period following the filing date of this report, when the accompanying financial statements are being issued.

Please see note 2 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" under Part II, Item 1A, "Risk Factors" of this report 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 Part I, Item 1A, "Risk Factors" of our 2021 Form 10-K.

On April 5, 2022, we received notification from the Listing Qualifications Department of The Nasdaq Stock Market, or Nasdaq, stating that the Company did not comply with the minimum $1.00 bid price requirement for continued listing set forth in Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement"). In accordance with Nasdaq listing rules, the Company was afforded 180 calendar days (until October 3, 2022) to regain compliance with the Bid Price Requirement. On October 4, 2022, the Company received written notice from Nasdaq stating that, although the Company had not regained compliance with the Bid Price Requirement by October 3, 2022, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company is eligible for an additional 180 calendar day period, or until April 3, 2023, to regain compliance with the Bid Price Requirement. To regain compliance, the closing bid price of the Company's common stock must meet or exceed $1.00 per share for a minimum of ten consecutive business days during this additional 180-day period, all as described in more detail in the Current Reports on Form 8-K filed with the SEC on April 7, 2022 and October 4, 2022. The closing price of our common stock was $0.42 on October 5, 2022. There can be no assurance that we will be able to regain compliance with the Bid Price Requirement. Our inability to regain compliance with the Bid Price Requirement would, and the existence of the pending deficiency letter could, materially impair our ability to raise capital. Moreover, if we were unable to regain compliance with the Bid Price Requirement, our common stock would likely then trade only in the over-the-counter market and the market liquidity of our common stock could be adversely affected and its market price could decrease. If our common stock were to trade on the over-the-counter market, selling our common stock could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and we could face significant material adverse consequences, including: a limited availability of market quotations for our securities; reduced liquidity with respect to our securities; a determination that our shares are a "penny stock," which will require brokers trading in our securities to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our securities; a reduced amount of news and analyst coverage; and a decreased ability to issue additional securities or obtain additional financing in the future. These factors could result in lower prices and larger spreads in the bid and ask prices for our common stock and would substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends. We have not entered into, and do not expect to enter into, investments for trading or speculative purposes. Our accounts receivable, accounts payable and inventory balances fluctuate from period to period, which affects our cash flow from operating activities. The amounts of these fluctuations vary depending on cash collections, client mix, raw material lead times, the mix of vendor terms, the timing of shipment of our products and the invoicing of our research and development activities. As of September 30, 2022, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K under the Securities Exchange Act of 1934.

We continually evaluate our liquidity requirements, capital needs and availability of capital resources based on our operating needs and our planned growth initiatives. Our future working capital needs will depend on many factors, including the rate of our business and revenue growth, the availability and cost of human, material and other resources required to build and deliver products in accordance with our existing or future product orders, the timing of our continuing automation of U.S. manufacturing, and the timing of our investment in research and development as well as sales and marketing. If we are unable to increase our revenues and manage our expenses in accordance with our operating plan, we may need to reduce the level or slow the timing of the growth plans contemplated by our operating plan, which would likely curtail or delay the growth in our business contemplated by our operating plan and could impair or defer our ability to achieve profitability and generate cash flow, or to seek to raise additional funds through debt or equity financing, 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

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 (i) for general working capital purposes and other permitted corporate purposes, (ii) to refinance certain of our existing indebtedness and (iii) to pay fees, costs and expenses incurred in connection with the Credit Agreement, including the Lender's closing cost amount of $550,000, which was netted from the proceeds, and a financing fee of $600,000 (3.0% of gross proceeds) payable to Craig-Hallum Capital Group LLC, our financial advisor for the financing.

- Interest Rate. Principal outstanding under the Credit Agreement bears interest at a rate per annum equal to the sum of (a) the greater of the one-month London Interbank Offered Rate and 2.5% plus (b) 8.75%. At any time at which an event of default (as described under "—Default Provisions" below) has occurred and is continuing, the interest rate will increase by 4.0%. Accrued interest is payable on a monthly basis. On September 30, 2022, the interest rate was 11.32%.

- Scheduled Repayment. No principal repayments were due prior to September 30, 2022. Chembio did not elect to prepay principal as described under "—Optional Prepayment" below and an event of default as described under "—Default Provisions" below did not occur. Principal installments in the amount of $300,000 are payable on the last day of each of the eleven months from September 2022 through July 2023, and all remaining principal is payable at maturity on September 3, 2023.

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

- Guarantees. 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, guarantees, mergers and acquisitions, substantial asset sales, investments and loans, sale and leasebacks, transactions with affiliates, and fundamental changes. The Credit Agreement also contains financial covenants requiring that (i) we maintain aggregate unrestricted cash of not less than $3,000,000 at all times and (ii) we achieve specified minimum rolling four-quarter ("last twelve month") total revenue amounts as of September 30, 2019 and the last day of each calendar quarter thereafter. For the next year, the minimum total revenue requirements range from $47.4 million for the twelve months ending December 31, 2022, and $50.1 million for the twelve months ending June 30, 2023. The minimum total revenue amounts were developed for purposes of the Credit Agreement and do not reflect the internal estimates and plans used by our management and board of directors to understand and evaluate our operating performance, to establish budgets, and to establish operational goals for managing our business. We therefore do not believe that the covenant requirements provide useful information to investors or others in enhancing an understanding of our future prospects.

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

Equity and Equity-Related Securities. On July 19, 2021, we and Craig-Hallum Capital Group LLC, or Craig-Hallum, 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. Any sales of shares made pursuant to the ATM Agreement will be made pursuant to our shelf registration statement on Form S-3 (File No. 333-254261) and the related prospectus previously declared effective by the SEC on May 5, 2021, as supplemented by a prospectus supplement dated July 19, 2021 that we filed with the SEC, pursuant to Rule 424(b)(5) under the Securities Act, on July 19, 2021, as such prospectus supplement may be amended or supplemented from time to time.

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

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

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

We are currently subject to General Instruction I.B.6 to Form S-3, or the Baby Shelf Rule, and the amount of funds we can raise through primary public offerings of securities in any twelve-month period using our existing registration statement on Form S-3 is limited to one-third of the aggregate market value of the voting and non-voting common equity held by non-affiliates.

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

As of the filing date of this report, we have issued and sold pursuant to the ATM Agreement a total of 14,859,595 shares of common stock at a volume-weighted average price of $3.03 per share for gross proceeds of $45.0 million and net proceeds, after giving effect to placement fees and other transaction costs, of $42.7 million. Additional shares of common stock may be issued and sold pursuant to the ATM Agreement, 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. Furthermore, any such sales shall be subject to the Baby Shelf Rule.

Research and Development Awards. Under a contract we entered into with BARDA on December 2, 2020, a total of up to $12.7 million of awards were available from BARDA to assist us in (a) developing, and pursuing an EUA from the FDA for, the DPP Respiratory Antigen Panel and (b) performing the clinical trials for and submitting the DPP SARS-CoV-2 Antigen test system to the FDA for 510(k) clearance. Of the total awards available under this contract, $12.5 million was recognized in prior periods and no government grant income was recognized during the nine months ended September 30, 2022. The completion of milestones to earn the remaining awards are outside our control, and contingent to the EUA approval by the FDA.

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

	September 30, 2022
	(in thousands)
Cash and cash equivalents	$ 21,055
Accounts receivable, net of allowance for doubtful amounts	5,253
Inventories, net	8,465
Prepaid expenses and other current assets	12,510
Total current assets	47,283
Less: Total current liabilities	(38,624)
Working capital	$ 8,659

Our cash and cash equivalents at September 30, 2022, were held for working capital purposes. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends. We have not entered into, and do not expect to enter into, investments for trading or speculative purposes. Our accounts receivable and inventory balances fluctuate from period to period, which affects our cash flow from operating activities. Fluctuations vary depending on cash collections, 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.

Uses of Funds

Cash Flow Used in Operating Activities. Our operations used $9.9 million of cash during the nine months ended September 30, 2022, primarily due to the net loss which was offset by changes in the principal working capital accounts and impairment.

Capital Expenditures. Our capital expenditures totaled $1.5 million in the nine months ended September 30, 2022 compared to $1.4 million in prior year period, which were primarily attributable to investments in automated manufacturing equipment, facilities, and other fixed assets.

As of September 30, 2022 we have capital purchase obligations of $0.3 million related to additional automated manufacturing equipment with payments expected to come due during 2022 based on vendor performance milestones.

Significant Accounting Policies and Critical Accounting Estimates

There were no significant changes in our accounting policies or critical accounting estimates during the three months ended September 30, 2022 to augment the significant accounting policies or critical accounting estimates disclosed under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our 2021 Form 10-K, other than those described in the notes to the condensed consolidated financial statements included elsewhere in this report.

Recently Issued Accounting Pronouncements

A discussion of recent accounting pronouncements was included in our 2021 Form 10-K and is updated in Note 2 to the condensed consolidated financial statements included elsewhere in this report.

ITEM 3. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures. Under the supervision and with the participation of our senior management, consisting of our principal executive officer and our principal financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of the end of the period covered by this report. Based on this evaluation, our management, including our principal executive officer and principal financial officer, concluded that as of September 30, 2022 our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our Exchange Act reports is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

(b) Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 under the Exchange Act that occurred during the three months ended September 30, 2022, 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 – Commitments, Contingencies And Concentrations – Litigation" to the Consolidated Financial Statements of this report 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 sections captioned "Risk Factors," in our 2021 Form 10-K and updated in our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2022 and June 30, 2022, as filed with the SEC on May 5, 2022 and August 5, 2022, respectively. In addition to the other information set forth in this report, you should carefully consider the factors discussed in the sections "Risk Factors" in our 2021 Form 10-K and Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022, which could materially affect our business, financial condition, or future results. The risks described in our 2021 Form 10-K, our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022 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.

Risks Related to Our Business and Our Industry

Our near term success is highly dependent on the success of the our DPP platform, and we cannot be certain that we will succeed in developing one or more of those systems or that, if we do, they will attain market acceptance or be successfully commercialized in the United States or elsewhere.

We do not currently have an Emergency Use Authorization, or EUA, from the U.S. Food and Drug Administration, or FDA, for any of the COVID-19 Diagnostic Test Systems or for our DPP Respiratory Panel. We also do not have a CLIA waiver from the FDA for our DPP HIV-Syphilis test system. Market and regulatory requirements continue to change at a rapid pace. There can be no assurance that, if we make a submission of any future EUA or CLIA waiver application, we will meet the requirements of the prioritization guidance in effect at the time of the submission or otherwise be successful in obtaining either (1) an EUA that would permit us to offer and sell the DPP SARS-CoV-2 Antigen test system or DPP Respiratory Panel in the United States or (2) a CLIA waiver for our DPP HIV-Syphilis test.

Even if we are able to obtain any such EUA or CLIA waiver, our product may not gain broad market acceptance among physicians, healthcare payers, patients, and the medical community. We cannot guarantee market acceptance of our product, and have somewhat limited information on which to estimate our anticipated level of sales. Our products will require healthcare providers and doctors to accept and adopt our technology. Our industry is susceptible to rapid technological developments and there can be no assurance that we will be able to match any new technological advances. Acceptance and use of any products we market will depend upon a number of factors including:

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

In addition, with respect to any EUA we obtain, the FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, even if we obtain an EUA, we cannot predict how long such EUA would remain in place. Such revocation could materially adversely impact our business in a variety of ways, including if the relevant product is not yet approved by the FDA under a traditional approval pathway and if we have invested in the supply chain to provide any of our products under an EUA, and would require us to obtain a 510(k) or other marketing authorization from the FDA. If the FDA revokes a previously issued EUA prior to us having received regulatory approval to commercialize our DPP SARS-CoV-2 Antigen test system or DPP Respiratory Panel through a traditional approval pathway, we would be required to cease our commercialization efforts in the United States, which would substantially and negatively impact our business.

The failure of these products to find market acceptance would substantially harm our business and would adversely affect our revenue. If the DPP SARS-CoV-2 Antigen test system, DPP Respiratory Panel or DPP HIV-Syphilis test are not as successfully commercialized as expected, we may not be able to generate sufficient revenue to become profitable. Any failure of one of these products to be successfully commercialized in the United States may have a material adverse effect on our business, operating result financial condition and cash flows, and could result in a substantial decline in the price of our common stock. In addition, the production and widely administered use of efficacious vaccines for COVID-19 may reduce the demand for diagnostic tests and, as a result, the COVID-19 diagnostic testing market may not develop or substantially grow. Our future success is substantially dependent on the manner in which the market for diagnostic testing develops and grows. If the market develops in a manner that does not facilitate demand for our products, or fails to develop or grow in the manner in which we expect or at all, our business, financial condition, results of operations and cash flows may be negatively affected.

Clinical trials necessary to support a future test kit submission will be expensive and may require the enrollment of large numbers of subjects, and suitable subjects may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new test kits and will adversely affect our business, operating results and prospects.

Some of our programs are supported by government grant awards, and our inability to obtain additional grant awards in the future or to derive all of the funding potentially available under those awards could delay our development and introduction of products.

We have received funding under grant award programs funded by governmental agencies such as BARDA. To fund a portion of our future research and development programs, we may apply for additional grant funding from these or similar governmental agencies. Funding by these governmental agencies may, however, be significantly reduced or eliminated in the future for a number of reasons. For example, some programs are subject to a yearly appropriations process in Congress. We may not receive full funding under current or future grants because of budgeting constraints of the agency administering the program or unsatisfactory progress on the study being funded.

In addition, some or all of the funding available under grant awards, including our $3.2 million contract from the CDC for development and clinical validation of a DPP Syphilis Screen & Confirm Assay, may be conditioned upon our successfully meeting specified milestones or other conditions, and there can be no assurance that those milestones or conditions will be met. For example, in December 2020 we were awarded the Second Grant pursuant to a contract from BARDA that included funding milestones related to our development and pursuit of an EUA for a DPP Respiratory Antigen Panel and our submission for 510(k) clearance from the FDA for the DPP SARS CoV 2 Antigen System.

There can be no assurance that we will receive any future grant awards from any government agencies or that, if a grant award is obtained, we will receive the full amount potentially available under the grant award. Our inability to obtain future grant awards, or to earn the full amount available under those awards, could delay the development of our product candidates and the introduction of new products.

Our U.S. government contracts require compliance with numerous laws and increase our risk and liability.

We are currently receiving funding from the U.S. government related to the DPP SARS-CoV-2 Antigen System, the DPP Respiratory Antigen Panel and DPP Syphilis Screen & Confirm Assay, and our growth strategy may target sales to U.S. government entities. As a condition to our U.S. government funding and potential product sales to the U.S. government, we must comply with laws and regulations relating to the award, administration and performance of U.S. government contracts. A violation of these specific laws and regulations, as well as others, could result in the imposition of fines and penalties or the termination of our U.S. government contracts and could harm our reputation and cause our business to suffer.

U.S. government contracts typically contain a number of extraordinary provisions that would not typically be found in commercial contracts and which may create a disadvantage and additional risks to us as compared to competitors that do not rely on government contracts. As a U.S. government contractor, we are subject to increased risks of investigation, criminal prosecution and other legal actions and liabilities to which purely private sector companies are not. The results of any such actions could adversely impact our business and have an adverse effect on our consolidated financial performance.

Stockholder litigation could negatively impact our business, operating results and financial condition.

We may incur additional costs in connection with the defense or settlement of existing and any future stockholder litigation, including the securities class-action and stockholder derivative lawsuits that have been brought against us. See "Part II, Item 1. Legal Proceedings" above and the information set forth under "Note 6 - Commitments, Contingencies And Concentrations - Litigation" to the consolidated financial statements included in this Quarterly Report on Form 10-Q for additional information regarding certain existing lawsuits. These lawsuits or other future litigation may adversely affect the ability of our technical and management personnel, and our directors, to perform their normal responsibilities. We could incur significant costs in connection with any such litigation, including costs associated with the indemnification of obligations to our directors, officers and other employees, as well as to third parties such as underwriters of our public offerings. We have engaged in settlement discussions with respect to our putative stockholder securities class action litigation and putative stockholder derivative litigation. (See "Note 6 - Commitments, Contingencies And Concentrations - Litigation" above). We expect to continue working toward resolving these matters, but there can be no assurance that we will be able to do so, or that we will be able to do so on the terms currently being discussed.

We face risks related to an ongoing SEC investigation.

The SEC is conducting a non-public, fact-finding investigation relating to the May 2020 Offering and to the FDA's revocation in June 2020 of an EUA for the DPP COVID-19 IgM/IgG system that was issued in April 2020. We 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 our employees (including our three executive officers, who consist of our Chief Executive Officer and President, our Executive Vice President and Chief Financial Officer, and our Executive Vice President and Chief Scientific and Technology Officer). An additional subpoena was issued in June 2021 to our 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 we received. One current employee, our Chief Executive Officer, also received a testimonial subpoena from the SEC. We and the six individuals are cooperating fully in the SEC's investigation and expect to continue to do so. The SEC's investigation is ongoing, and there can be no assurance that we will be able to agree on a resolution with the SEC or that the terms of any such resolution will be favorable to us. We are unable to predict what the timing or outcome of the SEC investigation will be or what, if any, consequences the SEC investigation may have with respect to our company or the six individuals mentioned above. The SEC investigation could result in considerable legal expenses, divert management's attention from other business concerns and harm our business. If the SEC were to determine that legal violations occurred, we could be required to pay significant civil penalties or other amounts, and remedies or conditions could be imposed as part of any resolution. We can provide no assurances as to the outcome of the SEC investigation.

Risks Related to Our Products

Industry adoption of alternative technology to our COVID-19 Diagnostic Test Systems could negatively impact our ability to compete successfully.

As of August 30, 2022, the FDA has authorized 439 COVID-19 Diagnostic tests and sample collection devices, 85 were for serology tests, 302 were for molecular tests and sample collection devices, 51 were for antigen tests and one diagnostic breath test. Customers or the industry as a whole could adopt alternative technologies for testing, including molecular point of care testing, which could result in lower demand for our antigen test. Various advances in the treatment and monitoring of patients could cause lower demand for the COVID-19 Diagnostic Test Systems, including our revised DPP SARS CoV 2 Antigen System or for antigen testing for COVID-19 as a whole.

Risks Related to Regulations

Our inability to respond to changes in regulatory requirements could adversely affect our business.

We believe that our existing products and procedures are in material compliance with all applicable FDA regulations, ISO requirements, and other applicable regulatory requirements, but the regulations regarding the manufacture and sale of our products and QSR, ISO and other requirements may be unclear and are subject to change. Newly promulgated regulations could require changes to our products, necessitate additional clinical trials or procedures, or make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all. The FDA and other regulatory authorities also have the ability to change the requirements for obtaining product approval and/or impose new or additional requirements as part of the approval process. These changes or new or additional requirements may occur after the completion of substantial clinical work and other costly development activities. The implementation of such changes or new or additional requirements may result in additional clinical trials and substantial additional costs and could delay or make it more difficult or complicated to obtain approvals and sell our products. In addition, the FDA may revoke an Emergency Use Authorization under which our products are sold, where it is determined that the underlying health emergency no longer exists or warrants such authorization. Such revocation would preclude the sale of our affected products unless and until a further regulatory approval or authorization is obtained. For example, For example, on June 16, 2020, the FDA revoked the EUA it had granted for the DPP COVID-19 IgM/IgG System based in part on performance criteria identified after the Emergency Use Authorization was granted on April 14, 2020, and since that time we expended resources to design the new COVID-19 Diagnostic Test Systems, including the DPP Respiratory Antigen Panel. We cannot anticipate or predict the effect, if any, that these types of changes might have on our business, financial condition or results of operations.

Financial, Economic and Financing Risks

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─Going Concern Considerations” and “─Liquidity and Capital Resources,” management has determined we could not be certain that our plans and initiatives to increase our total revenues and improve our liquidity position would be effectively implemented within one year after the filing date of this report, when the accompanying financial statements are being issued. Without giving effect to the prospect of raising additional capital pursuant to our at-the-market offerings under the ATM Agreement, increasing product revenue in the near future or executing other mitigating plans, many of which are beyond our control, it is unlikely that we will be able to generate sufficient cash flows to meet our required financial obligations, including our debt service and other obligations due to third parties. The existence of these conditions raises substantial doubt about our ability to continue as a going concern for the twelve-month period following the filing date of this report, when the accompanying financial statements are being issued.

Our diagnostic test products require ongoing funding to continue our current development and operational plans, and we have a history of net losses. We may encounter challenges in fulfilling our obligations, and therefore receiving revenue, under those purchase orders. We will also incur costs associated with research and development activity, corporate administration, business development, debt service, marketing and selling of our products, and litigation. In addition, other unanticipated costs may arise.

As of September 30, 2022, our loan balance, net of unamortized discounts and debt issuance costs, of $19.0 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.

As a result, we may need to raise capital in one or more debt or equity offerings to fund our operations and obligations, including under the ATM Agreement. 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 effects of COVID-19 have significantly disrupted world financial markets and negatively impacted U.S. market conditions, and they 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. Moreover, on April 5, 2022, we received a deficiency letter from the Listing Qualifications Department of The Nasdaq Stock Market notifying us that, because the bid price for shares of our common stock had closed below the $1.00 per share minimum Bid Price Requirement for thirty consecutive business days, our common stock may be subject to delisting by as early as October 3, 2022 if we have been unable to regain compliance with the Bid Price Requirements or to qualify for an additional period to regain compliance by such date, all as described in more detail in the Current Report on Form 8-K we filed with the SEC on April 7, 2022. On October 4, 2022, we received written notice from Nasdaq stating that, although we had not regained compliance with the Bid Price Requirement by October 3, 2022, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), we are eligible for an additional 180 calendar day period, or until April 3, 2023, to regain compliance with the Bid Price Requirement. There can be no assurance that we will be able to regain compliance with the Bid Price Requirement. Our inability to regain compliance with the Bid Price Requirement would, and the existence of the pending deficiency letter could, materially impair our ability to raise capital.

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.

Additionally, we are currently subject to the Baby Shelf Rule and the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the voting and non-voting common equity held by non-affiliates. We will be limited by the Baby Shelf Rule until such time, if any, as our public float exceeds $75 million.

Our failure to meet the minimum bid price for continued listing on the Nasdaq Capital Market could adversely affect our ability to publicly or privately sell equity securities and the liquidity of our common stock

On April 5, 2022, we received notification from the Listing Qualifications Department of The Nasdaq Stock Market, or Nasdaq, stating that the Company did not comply with the minimum $1.00 bid price requirement for continued listing set forth in Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement"). In accordance with Nasdaq listing rules, the Company was afforded 180 calendar days (until October 3, 2022) to regain compliance with the Bid Price Requirement. On October 4, 2022, the Company received written notice from Nasdaq stating that, although the Company had not regained compliance with the Bid Price Requirement by October 3, 2022, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company is eligible for an additional 180 calendar day period, or until April 3, 2023, to regain compliance with the Bid Price Requirement. To regain compliance, the closing bid price of the Company's common stock must meet or exceed $1.00 per share for a minimum of ten consecutive business days during this additional 180-day period, all as described in more detail in the Current Reports on Form 8-K filed with the SEC on April 7, 2022 and October 4, 2022. The closing price of our common stock was $0.42 on October 5, 2022. There can be no assurance that we will be able to regain compliance with the Bid Price Requirement. Our inability to regain compliance with the Bid Price Requirement would, and the existence of the pending deficiency letter could, materially impair our ability to raise capital. Moreover, if we were unable to regain compliance with the Bid Price Requirement, our common stock would likely then trade only in the over-the-counter market and the market liquidity of our common stock could be adversely affected and its market price could decrease. If our common stock were to trade on the over-the-counter market, selling our common stock could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and we could face significant material adverse consequences, including: a limited availability of market quotations for our securities; reduced liquidity with respect to our securities; a determination that our shares are a "penny stock," which will require brokers trading in our securities to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our securities; a reduced amount of news and analyst coverage; and a decreased ability to issue additional securities or obtain additional financing in the future. These factors could result in lower prices and larger spreads in the bid and ask prices for our common stock and would substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

There can be no assurance that our review of strategic alternatives and our financing strategy will result in a transaction satisfactory to holders of our common stock or any change at all.

Our board of directors has initiated a review of strategic alternatives, including a potential sale or merger transaction, and of our financing strategy. We have retained Craig-Hallum Capital Group LLC as our financial advisor to assist with the strategic review. We have not set a timetable for completion of the strategic review process, and there can be no assurance that the process will result in a transaction at this time or at all. Even if a sale, merger or financing transaction is consummated, it may not return any value to holders of our common stock. Regardless of whether we execute a sale, merger or financing transaction, the adverse pressures that we have experienced may continue or intensify, and we will likely continue to face all of the risks we currently face, including the risk that we may not be able to continue as a going concern. See "—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."

The pursuit of strategic alternatives or financing transactions may consume a substantial portion of the time and attention of our You may experience future dilution as a result of future equity offerings, exercises of outstanding options and vesting of options and restricted and performance stock units.

On July 19, 2021, we entered into the ATM Agreement, pursuant to which we may sell from time to time, at our option, up to an aggregate of $60,000,000 of shares of common stock through Craig-Hallum, as sales agent. As of the filing date of this report, we have issued and sold pursuant to the ATM Agreement a total of 14,859,595 shares of common stock at a volume-weighted average price of $3.03 per share for gross proceeds of $45.0 million and net proceeds, after giving effect to placement fees and other transaction costs, of $42.7 million. For additional information about the at-the-market offerings pursuant to the ATM Agreement, see “Part I, Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations”.

In order to raise additional capital, we may seek to offer pursuant to the ATM Agreement additional shares of common stock for up to $15.0 million in gross proceeds and we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock. There can be no assurance that we will be able to sell additional shares in at-the-market offerings made pursuant to the ATM Agreement, or in any other offering, at a price per share that is equal to or greater than the price per share paid by existing stockholders. Investors purchasing securities in other offerings in the future could have rights superior to existing stockholders.

As of the close of business on September 30, 2022, our market capitalization was approximately $12.6 million. Existing stockholders may experience significant dilution in connection with our issuance and sale of up to $15.0 million of additional shares of common stock pursuant to the ATM Agreement. In addition, as of September 30, 2022, 87,672 shares of common stock were reserved for future issuance under our 2019 Omnibus Incentive Plan, 3,674,971 shares were subject to outstanding options, and 1,723,384 shares were subject to outstanding restricted and performance stock units. Stockholders will incur dilution upon vesting of restricted and performance stock units, and they may incur dilution upon exercises of stock options.

ITEM 6. EXHIBITS

Number	Description
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	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 data file (embedded within the XBRL document)

SIGNATURES

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

Chembio Diagnostics, Inc.

Date: November 3, 2022

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

Date: November 3, 2022

By: /s / Lawrence J. Steenvoorden
Lawrence J. Steenvoorden
Chief Financial Officer and Executive Vice President

Exhibit 31.1

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

I, Richard L. Eberly, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 3, 2022

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

Exhibit 31.2

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

I, Lawrence J. Steenvoorden, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 3, 2022

/s/ Lawrence J. Steenvoorden
Lawrence J. Steenvoorden
Chief Financial Officer and Executive Vice President

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Chembio Diagnostics, Inc. for the quarterly period ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge on the date hereof:

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

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

Date: November 3, 2022

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

Date: November 3, 2022

/s/ Lawrence J. Steenvoorden
Lawrence J. Steenvoorden
Chief Financial Officer and Executive Vice President

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.