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

FORM 10-Q

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

For the quarterly period ended March 31, 2021

OR

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

For the transition period from: _____ to _____

000-30379
(Commission File Number)

Chembio Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

Accelerated filer ☐
Smaller reporting company ☒

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

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

As of April 30, 2021, the registrant had 20,244,554 shares outstanding of its common stock, $0.01 par value.

Quarterly Report on Form 10-Q
For The Quarterly Period Ended
March 31, 2021

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Chembio Diagnostics, Inc.

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

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

FORWARD-LOOKING STATEMENTS AND STATISTICAL ESTIMATES

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

This report contains estimates, projections and other data concerning our industry, our business, and the markets for our products. Where expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by 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 II, Item 1A, “Risk Factors,” of this report. You should interpret many of the risks identified in these reports as being heightened as a result of the ongoing and numerous adverse impacts of the COVID-19 pandemic. Investors are cautioned not to place undue reliance on any forward-looking statements or statistical estimates, which speak only as of the date they are made. We undertake no obligation to update any forward-looking statement or statistical estimate, whether as a result of new information, future events or otherwise.

PART I

Item 1. FINANCIAL STATEMENTS

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	(Unaudited) March 31, 2021	December 31, 2020
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 14,350,953**	$ 23,066,301
Accounts receivable, net of allowance for doubtful accounts of $354,528 and $296,793 at March 31, 2021 and December 31, 2020, respectively	**2,413,552**	3,377,387
Inventories, net	**14,690,627**	12,516,402
Prepaid expenses and other current assets	**812,638**	778,683
TOTAL CURRENT ASSETS	**32,267,770**	39,738,773
FIXED ASSETS:		
Property, plant and equipment, net	**9,582,872**	8,688,403
Finance lease right-of-use asset, net	**217,376**	233,134
OTHER ASSETS:		
Operating lease right-of-use assets, net	**5,904,299**	6,112,632
Intangible assets, net	**3,377,003**	3,645,986
Goodwill	**5,689,315**	5,963,744
Deposits and other assets	**374,862**	509,342
TOTAL ASSETS	**$ 57,413,497**	$ 64,892,014
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 8,396,994**	$ 10,042,790
Deferred revenue	**404,486**	1,606,997
Operating lease liabilities	**572,478**	642,460
Finance lease liabilities	**60,064**	58,877
TOTAL CURRENT LIABILITIES	**9,434,022**	12,351,124
OTHER LIABILITIES:		
Long-term operating lease liabilities	**6,197,527**	6,327,143
Long-term finance lease liabilities	**169,765**	185,239
Long-term debt, net	**18,327,037**	18,182,158
Deferred tax liability	**-**	69,941
TOTAL LIABILITIES	**34,128,351**	37,115,605
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock - 10,000,000 shares authorized; none outstanding	-	-
Common stock - $0.01 par value; 100,000,000 shares authorized; 20,285,695 shares and 20,223,498 shares issued at March 31, 2021 and December 31, 2020, respectively	**202,857**	202,235
Additional paid-in capital	**125,425,514**	124,961,514
Accumulated deficit	**(101,606,494)**	(97,106,331)
Treasury Stock, 41,141 shares at cost, at March 31, 2021 and December 31, 2020	**(190,093)**	(190,093)
Accumulated other comprehensive (loss) income	**(546,638)**	(90,916)
TOTAL STOCKHOLDERS' EQUITY	**23,285,146**	27,776,409
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 57,413,497**	$ 64,892,014

See accompanying notes to condensed consolidated financial statements

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

	For the three months ended March 31,	
	2021	2020
REVENUES:		
Product revenue	**$ 4,024,662**	$ 5,716,593
R&D revenue	**1,106,639**	907,687
Government grant income	**3,350,000**	-
License and royalty revenue	**243,058**	235,304
TOTAL REVENUES	**8,724,359**	6,859,584
COSTS AND EXPENSES:		
Cost of product revenue	**3,548,441**	4,374,442
Research and development expenses	**2,863,338**	1,958,853
Selling, general and administrative expenses	**6,085,067**	4,156,641
Severance and other related costs	**83,087**	723,118
Acquisition costs	**-**	63,497
	12,579,933	11,276,551
LOSS FROM OPERATIONS	**(3,855,574)**	(4,416,967)
OTHER EXPENSE:		
Interest expense, net	**(712,477)**	(662,141)
LOSS BEFORE INCOME TAXES	**(4,568,051)**	(5,079,108)
Income tax benefit	**67,888**	79,559
NET LOSS	**$ (4,500,163)**	$ (4,999,549)
Basic and diluted loss per share	**$ (0.22)**	$ (0.29)
Weighted average number of shares outstanding, basic and diluted	**20,163,386**	17,197,301

See accompanying notes to condensed consolidated financial statements

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

	For the three months ended March 31,	
	2021	2020
Net loss	**$ (4,500,163)**	$ (4,999,549)
Other comprehensive loss:		
Foreign currency translation adjustments, net of tax	**(455,722)**	(863,294)
Comprehensive loss	**$ (4,955,885)**	$ (5,862,843)

See accompanying notes to condensed consolidated financial statements

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

	For the three months ended March 31, 2021							
	Common Stock		Additional Paid-in-	Treasury Stock		Accumulated		
	Shares	Amount	Capital	Shares	Amount	Deficit	AOCI	Total
Balance at December 31, 2020	20,223,498	$ 202,235	$ 124,961,514	(41,141)	$ (190,093)	$ (97,106,331)	$ (90,916)	$ 27,776,409
Common Stock:								
Restricted stock issued	62,197	622	58,909	-	-	-	-	59,531
Restricted stock compensation, net	-	-	309,010	-	-	-	-	309,010
Shares tendered for withholding taxes	-	-	(115,059)	-	-	-	-	(115,059)
Options:								
Stock option compensation	-	-	211,140	-	-	-	-	211,140
Comprehensive loss	-	-	-	-	-	-	(455,722)	(455,722)
Net loss	-	-	-	-	-	(4,500,163)	-	(4,500,163)
Balance at March 31, 2021	20,285,695	$ 202,857	$ 125,425,514	(41,141)	$ (190,093)	$ (101,606,494)	$ (546,638)	$ 23,285,146

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

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

See accompanying notes to condensed consolidated financial statements

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

	March 31,2021	March 31, 2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	**$ 8,485,683**	$ 6,061,411
Cash paid to suppliers and employees	**(14,830,243)**	(10,951,402)
Cash paid for operating leases	**(347,871)**	(165,218)
Cash paid for finance leases	**(4,944)**	(4,211)
Interest and Taxes, net	**(563,885)**	(592,540)
Net cash used in operating activities	**(7,261,260)**	(5,651,960)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Patent application costs	**(4,130)**	(45,057)
Acquisition of and deposits on fixed assets	**(1,235,038)**	(1,033,214)
Net cash used in investing activities	**(1,239,168)**	(1,078,271)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments of tax withholding on stock award	**(115,059)**	(145,056)
Payments on note payable	**-**	(67,321)
Payments on finance lease	**(14,282)**	(10,913)
Net cash used by financing activities	**(129,341)**	(223,290)
Effect of exchange rate changes on cash	**(85,579)**	(79,814)
DECREASE IN CASH AND CASH EQUIVALENTS	**(8,715,348)**	(7,033,335)
Cash and cash equivalents - beginning of the period	**23,066,301**	18,271,352
Cash and cash equivalents - end of the period	**$ 14,350,953**	$ 11,238,017
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net loss	**$ (4,500,163)**	$ (4,999,549)
Adjustments:		
Depreciation and amortization	**687,227**	733,804
Share based compensation	**579,789**	(37,083)
Benefit from deferred tax liability	**(69,941)**	(138,784)
Provision of (recovery of) doubtful accounts	**57,735**	-
Changes in assets and liabilities:		
Accounts receivable	**906,100**	(1,216,518)
Inventories	**(2,174,225)**	(1,332,129)
Prepaid expenses and other current assets	**(33,955)**	(105,215)
Deposits and other assets	**134,480**	15,278
Accounts payable and accrued liabilities	**(1,645,796)**	1,009,891
Deferred revenue	**(1,202,511)**	418,345
Net cash used in operating activities	**$ (7,261,260)**	$ (5,651,960)

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2021
(Unaudited)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. ("Chembio") and its subsidiaries (collectively with Chembio, the "Company") develop and commercialize point-of-care rapid tests used for the detection and diagnosis of infectious diseases, including COVID-19, sexually transmitted disease, and fever and tropical disease. Coupled with the Company's extensive scientific expertise, its novel DPP technology offers broad market applications beyond infectious disease. Chembio's products are sold globally, directly and through distributors, to hospitals and clinics, physician offices, clinical laboratories, public health organizations, government agencies, and consumers under the Company's DPP, STAT-PAK, STAT-VIEW and SURE CHECK registered trademarks or under the private labels of the Company's marketing partners.

The Company has been expanding its product portfolio based upon its proprietary DPP technology platform that provides high-quality, rapid diagnostic results in 15 to 20 minutes using a small drop of blood from the fingertip or alternative samples. Through advanced multiplexing, the DPP platform can detect up to eight, distinct test results from a single patient sample, which can deliver greater clinical value than other rapid tests. For certain applications, Chembio's easy-to-use, highly portable, battery-operated DPP Micro Reader optical analyzer then reports accurate results in approximately 15 seconds, making it well-suited for decentralized testing where real-time results enable patients to be clinically assessed while they are still onsite. Objective results produced by the DPP Micro Reader can reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many rapid tests.

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

During the first quarter of 2021, the Company continued to invest in automating its test manufacturing processes, all of which are now based in the United States, by, among other actions, validating and implementing automated lines to expand its manufacturing capabilities. The Company's transition from manual to automated assembly is intended to add capacity, reduce variable costs and improve product margins. In order to address challenging economic conditions and implement its business strategy, in the first quarter of 2021 the Company continued to execute a program to reduce operating expenses and better align its costs with revenues, including by eliminating positions that were no longer aligned with its strategy.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES:

(a) Basis of presentation:

The accompanying unaudited condensed consolidated financial statements include the accounts of Chembio and its subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X issued by the Securities and Exchange Commission (the "SEC"). Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in Chembio's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as filed with the SEC.

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

(b) Significant Accounting Policies:

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

(c) Fair Value of Financial Instruments:

The carrying values for cash and cash equivalents, accounts receivable, accounts payable and accrued expenses and other current liabilities approximate fair value due to the immediate or short-term maturity of these financial instruments. Included in cash and cash equivalents were $7.0 million and $14.80 million as of March 31, 2021 and December 31, 2020, respectively, of money market funds that are Level 1 fair value measurements under the hierarchy. The fair value of the Company's total debt of $20.0 million (carrying value of $18.3 million) and $20.0 million (carrying value of $18.2 million) as of March 31, 2021 and December 31, 2020, respectively, is a Level 2 fair value measurement under the hierarchy and the Company's debt face value approximates the fair value, as the rate is based upon the current rates available to the Company for similar financial instruments.

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

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

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

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

(d) Cash and Cash Equivalents:

Cash and cash equivalents are defined as short-term, highly liquid investments with original maturities of three months or less at date of purchase, and include restricted cash of $0.4 million and $1 million as of March 31, 2021 and December 31, 2020, respectively.

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

(e) Loss Per Share:

Basic loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding for the period excluding unvested restricted stock. Diluted loss per share is computed using the treasury stock method if the additional shares are dilutive. For all periods presented, basic and diluted loss per share are the same as any additional shares would be anti-dilutive.

There were 1,848,286 and 1,345,124 options outstanding as of March 31, 2021 and 2020, respectively, that were not included in the calculation of diluted loss per share because the effect would have been anti-dilutive.

There were 847,795 and 672,488 shares of restricted stock outstanding as of March 31, 2021 and 2020, respectively, that were not included in the calculation of diluted loss per share because the effect would have been anti-dilutive.

There were 0 and 550,000 shares of common stock issuable pursuant to warrants that were not included in the calculation of diluted loss per share 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 March 31, 2021 was 1.5%, compared to the effective tax rate of 1.6% for the three months ended March 31, 2020. The Company's effective tax rates for both periods were affected primarily by a full valuation allowance on domestic net deferred tax assets and a benefit from foreign net operating losses.

(g) Recently Issued Accounting Standards Affecting the Company:

Recently Adopted

ASU 2020-10, Codification Improvements

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

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

In March 2020, the FASB issued ASC Topic 848. ASC Topic 848 provides relief for impacted areas as it relates to impending reference rate reform. ASC Topic 848 contains optional expedients and exceptions for applying GAAP to debt arrangements, contracts, hedging relationships, and other areas or transactions that are impacted by reference rate reform. This guidance is effective upon issuance for all entities and elections of certain optional expedients are required to apply the provisions of the guidance. The Company adopted the standard effective January 1, 2021 and has determined that the adoption did not have a material impact on the Company's consolidated financial statements.

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

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

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

On January 7, 2021, the FASB issued ASU 2021-01, which refines the scope of ASC Topic 848 and clarifies some of its guidance as part of the monitoring of global reference rate reform activities. ASU 2021-01 permits entities to elect certain optional expedients and exceptions when accounting for derivative contracts and certain hedging relationships affected by changes in the interest rates used for discounting cash flows, for computing variation margin settlements, and for calculating price alignment interest in connection with reference rate reform activities under way in global financial markets (the "discounting transition"). ASU 2021-01 expands the scope of ASC Topic 848 to include all affected derivatives and give market participants the ability to apply certain aspects of the contract modification and hedge accounting expedients to derivative contracts affected by the discounting transition. In addition, ASU 2021-01 adds implementation guidance (codified in ASC Topic 848-10-55-1) to clarify which optional expedients in ASC Topic 848 may be applied to derivative instruments that do not reference London Interbank Offered Rate or a reference rate that is expected to be discontinued, but that are being modified as a result of the discounting transition. The Company adopted the standard effective January 1, 2021 and has determined that the adoption did not have a material impact on the Company's consolidated financial statements.

Not Yet Adopted

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

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. ASU 2020-06 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 entity'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 Topic 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 standard is effective for smaller public business entities' fiscal years beginning after December 15, 2023. The Company continues to assess all potential impacts of the standard.

NOTE 3 — REVENUE:

Disaggregation of Revenue

The following table disaggregates total revenues:

	March 31, 2021			March 31, 2020		
	Exchange Transactions	**Non-Exchange Transactions**	**Total**	Exchange Transactions	Non-Exchange Transactions	Total
Product revenue	$ 4,024,662	$ -	$ 4,024,662	$ 5,716,593	$ -	$ 5,716,593
R&D Revenue	1,106,639	-	1,106,639	907,687	-	907,687
Government grant income	–	3,350,000	3,350,000	–	–	–
License and royalty revenue	243,058	-	243,058	235,304	-	235,304
	$ 5,374,359	$ 3,350,000	$ 8,724,359	$ 6,859,584	$ -	$ 6,859,584

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

The following table disaggregates total revenues by geographic location:

	For the three months ended	
	March 31, 2021	March 31, 2020
Africa	**$ 1,344,858**	$ 883,515
Asia	**216,954**	363,288
Europe & Middle East	**2,600,274**	1,639,782
Latin America	**258,019**	2,116,395
United States	**4,304,254**	1,856,604
	$ 8,724,359	$ 6,859,584

Contract Liabilities

Deferred revenue relates to payments received in advance of performance under the contract. Deferred revenue is recognized as revenue as (or when) the Company performs under the contract. At December 31, 2020, the Company reported $1.6 million in deferred revenue, of which $1.2 million was earned and recognized during the three months ended March 31, 2021. At March 31, 2021, the Company reported $0.4 million in deferred revenue, which is expected to be recognized in the next six months.

NOTE 4 — INVENTORIES:

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

	March 31, 2021	December 31, 2020
Raw materials	**$ 6,747,142**	$ **5,955,215**
Work in process	**4,949,068**	2,549,516
Finished goods	**2,994,417**	4,011,671
	$ 14,690,627	$ **12,516,402**

NOTE 5 — STOCKHOLDERS' EQUITY:

(a) Common Stock

During the first three months of 2021 and 2020, there were no options exercised.

(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 41,141 shares of common stock held in treasury that were 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 issue 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				Accounts Receivable as of	
	March 31, 2021		March 31, 2020		March 31, 2021	December 31, 2020
	Sales	% of Sales	Sales	% of Sales		
Customer 1	$ *	*	$ 1,640,073	28.7%	$ *	$ 1,875,176

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 from each vendor that represented in excess of 10% of the Company's net purchases for the periods indicated:

	For the three months ended				Accounts Payable as of	
	March 31, 2021		March 31, 2020		March 31, 2021	December 31, 2020
	Purchases	% of Sales	Purchases	% of Sales		
Vendor 1	$ 609,000	13.8%	$ *	*	$ 253,853	$ *
Vendor 2	469,635	10.6%	*	*	336,868	*

In the tables above, an asterisk (*) 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 currently buys materials that are purchased under intellectual property rights agreements and are important components in its products. Management believes that other suppliers could provide similar materials on comparable terms. A change in suppliers, however, could cause a delay in manufacturing, either from the logistic and regulatory implications of changing suppliers or from product attributable changes to new components, any of which could result in a possible loss of sales and could adversely affect operating results.

b) Governmental Regulation:

All of the Company's existing and proposed diagnostic products are regulated by the U.S. Food and Drug Administration, U.S. Department of Agriculture, certain U.S., state and local agencies, and/or comparable regulatory bodies in other countries. Most aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and record keeping, are subject to regulatory review. After marketing approval has been granted, the Company must continue to comply with governmental regulations. Failure to comply with applicable requirements can lead to sanctions, including withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, civil money penalties, injunctions, and criminal prosecution.

c) Employment Contracts:

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

2021	$632,469
2022	460,000

d) Benefit Plan:

Chembio has a 401(k) plan established for its employees whereby it matches 40% of the first 5% of salary (or up to 2% of salary) that an employee contributes to the plan. Matching contribution expenses totaled approximately $35,456 and $28,120 for the three months ended March 31, 2021 and 2020, respectively.

e) Leases:

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

The Company's facility leases generally include optional renewal periods. Upon entering into a new facility lease, the Company evaluates the leasehold improvements and regulatory requirements related to its operations in that location. To the extent that the initial lease term of the related facility lease is less than the useful life of the leasehold improvements and potential regulatory costs associated with moving the facility, the Company concludes that it is reasonably certain that a renewal option will be exercised, and 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 nonlease components for all of the Company's facility leases.

The components of lease expense were as follows:

	Three months ended March 31,	
	2021	**2020**
Operating lease expense	**$ 408,466**	$ 463,857
Finance lease cost		
Amortization of right-of-use assets	**$ 15,758**	$ 12,398
Interest on lease liabilities	**4,944**	4,211
Total finance lease expense	**$ 20,702**	$ 16,609

Supplemental cash flow information related to leases was as follows.

	Three months ended March 31,	
	2021	**2020**
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	**$ 347,871**	$ 165,218
Operating cash flows for finance leases	**4,944**	4,211
Financing cash flows for finance leases	**14,282**	10,913
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	**$ -**	$ -
Finance leases	-	27,641

Supplemental balance sheet information related to leases was as follows:

	March 31, 2021	March 31, 2020
Finance Leases		
Finance lease right of use asset	$ 315,153	$ 262,075
Accumulated depreciation	(97,777)	(35,770)
Finance lease right of use asset, net	$ 217,376	$ 226,305
Weighted Average Remaining Lease Term		
Operating leases	8.6 years	9.0 years
Finance leases	3.5 years	4.0 years
Weighted Average Discount Rate		
Operating leases	9.30%	8.64%
Finance leases	8.18%	7.50%

Maturities of lease liabilities were as follows.

	March 31, 2021		March 31, 2020	
	Operating Leases	Finance Leases	Operating Leases	Finance Leases
2019 and 2021	$ 861,916	$ 57,678	$ 1,039,942	$ 47,232
2022	1,057,757	76,904	1,209,787	62,976
2023	1,026,272	76,904	1,057,757	62,976
2024	1,018,875	49,136	1,026,272	62,976
2025	1,049,442	5,751	1,018,875	35,207
Thereafter	4,724,446	-	5,773,890	620
Total lease payments	$ 9,738,708	$ 266,373	$ 11,126,523	$ 271,987
Less: imputed interest	2,968,703	36,544	3,589,622	40,700
Total	$ 6,770,005	$ 229,829	$ 7,536,901	$ 231,287

f) Litigation:

Employee Litigation

John J. Sperzel III, our former chief executive officer, filed suit in the United States District Court in the Eastern District of New York asserting a right to exercise certain options to purchase, for an aggregate exercise price of $943,126, a total of 266,666 shares of common stock that were vested when he resigned on January 3, 2020. Under their terms, those options were exercisable for a period of thirty days after his service to our company ended. The compensation committee of the Board, acting in its discretion in accordance with the terms of the underlying equity incentive plans, has determined that Sperzel's attempt to exercise the options following the thirty day period was not valid. The United States District Court in Maine had previously dismissed Mr. Sperzel's lawsuit for lack of personal jurisdiction in Maine. Chembio intends to vigorously defend against any claim by Mr. Sperzel that he continues to have a right to exercise any options.

Stockholder Litigation

Putative Stockholder Securities Class Action Litigation

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

- Sergey Chernysh v. Chembio Diagnostics, Inc., Richard L. Eberly, and Gail S. Page, filed on June 18, 2020;
- 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. (together, 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 Chembio's May 2020 public offering.

Chembio and the plaintiffs entered into court-approved stipulations relieving the 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 ("MERS"). By Order entered December 29, 2020, Magistrate Judge Lindsay consolidated the cases and appointed the Special Situations Funds and MERS 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 Special Situations Funds and MERS (together "Lead Plaintiffs") filed their Consolidated Amended Complaint (the "CAC") on February 12, 2021. In summary, the CAC purports to allege claims based on assertedly false and misleading statements and omissions concerning the performance of the DPP COVID-19 IgM/IgG System, as well as an asserted failure to timely disclose that the Emergency Use Authorization that had been granted by the Food and Drug Administration with respect to the DPP COVID-19 IgM/IgG System "was -- or was at an increased risk of -- being revoked." The CAC names as defendants Chembio, Richard L. Eberly, Gail S. Page, Neil A. Goldman, Javan Esfandiari, Katherine L. Davis, Dr. Mary Lake Polan, Dr. John Potthoff, and the underwriters for the Company's May 2020 public offering, Robert W. Baird & Co., Inc. and Dougherty & Company LLC.

The CAC purports to assert five counts under the Securities Act and the Exchange Act. Counts I through III are brought under the Securities Act, allegedly on behalf of a purported class consisting of all persons who purchased Chembio common stock directly in or traceable to Chembio's May 2020 offering pursuant to the Company's Registration Statement on Form S-3 and its Prospectus and Prospectus Supplement dated May 7, 2020 (the "Securities Act Class"). Count I purports to allege a claim for violation of Section 11 of the Securities Act against all defendants other than Messrs. Eberly and Esfandiari. Count II purports to allege a claim for violation of Section 12 of the Securities Act against all defendants other than Messrs. Eberly and Esfandiari. Count III purports to allege a claim under Section 15 of the Securities Act against Ms. Davis, Dr. Polan, Dr. Potthoff, Ms. Page, and Mr. Goldman.

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

Lead Plaintiffs seek, on behalf of the Securities Act Class and the Exchange Act Class, among other things, an award of damages in an amount to be proven at trial, as well as an award of reasonable costs, including attorneys' fees and expenses, expert fees, pre-judgment and post-judgment interest, and such other relief as the court deems just and proper. The Lead Plaintiffs also seeks rescission "or a rescissory measure of damages" on behalf of the Securities Act Class as to Count II.

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

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

Putative Stockholder Derivative Litigation

On September 11, 2020, a putative stockholder derivative action was filed purportedly on Chembio's behalf in the United States District Court for the Eastern District of New York captioned Karen Wong, derivatively on behalf of Chembio Diagnostics, Inc., Plaintiff v. Richard L. Eberly, Gail S. Page, Neil A. Goldman, Javan Esfandiari, Katherine L. Davis, Mary Lake Polan, and John G. Potthoff, Defendants, and Chembio Diagnostics, Inc., Nominal Defendant (the "Wong complaint"). The Wong complaint purports to assert a claim for violation of Section 14(a) of the Exchange Act and Rule 14a-9 thereunder based on ostensibly false and misleading statements and omissions concerning our rapid COVID-19 antibody test in the proxy statement disseminated in advance of our 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 Court entered an order granting the requested stay on November 3, 2020.

Commercial Litigation

Chembio's subsidiary Chembio Diagnostic Systems Inc. ("Systems") and BioSure (UK) Ltd ("BioSure") entered into the BioSure Sure Check HIV 1/2 Assay OTC Agreement dated April 2, 2014, and as subsequently amended (the "Distribution Agreement"). Pursuant to the Distribution Agreement, BioSure acquired the right to sell bundled products in the UK containing the Company's Sure Check HIV 1/2 pouched tests. The Distribution Agreement terminated on April 1, 2019. On September 16, 2019, Systems initiated arbitration in New York, USA. Systems alleges that BioSure (1) breached various provisions of the Distribution Agreement, (2) misappropriated trade secrets of Systems, (3) engaged in deceptive business acts and practices, and (4) breached the implied covenant of good faith and fair dealing. On November 23, 2020, BioSure requested leave to file a counterclaim seeking recession of the Distribution Agreement based on alleged fraudulent concealment by Systems. Systems opposed BioSure's request for leave to file the counterclaim on procedural and substantive grounds, and on December 11, 2020 the Tribunal denied the request for leave to file the counterclaim. The Tribunal's denial was without prejudice to BioSure's ability to assert its claim in a separate proceeding. BioSure continues to deny the relief sought and alleges certain statements Systems made to third parties about the Distribution Agreement were in bad faith and are a defense to Systems' claims. BioSure also asserts that certain alleged misrepresentations entitle BioSure to "set off" any award Systems might receive from the Tribunal. The parties have completed discovery, and submitted their first pre-hearing submissions. Systems intends to vigorously pursue its claims in the arbitration. The final merits hearing is scheduled for April 2021. At this stage in the litigation, the Company is not able to predict the probability of a favorable or unfavorable outcome.

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 $20,000,000 senior secured term loan credit facility, which was drawn in full on September 4, 2019. Under the terms of the Credit Agreement, Chembio may use the proceeds (i) for general working capital purposes and other permitted corporate purposes, (ii) to refinance certain of the Company's existing indebtedness and (iii) to pay fees, costs and expenses incurred in connection with the Credit Agreement, including the Lender's closing cost amount of $550,000, which was netted from the proceeds, and a financing fee of $600,000 (3.0% of gross proceeds) payable to Craig-Hallum 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 March 31, 2020 the interest rate was 11.25%.

No principal repayments are due under the Credit Agreement prior to September 30, 2022, unless Chembio elects to prepay principal or principal is accelerated pursuant to an event of default identified in the Credit Agreement. Principal installments in the amount of $300,000 are payable on the last day of each of the eleven months from September 2022 through July 2023, and all remaining principal is payable at maturity on September 3, 2023. Chembio may prepay outstanding principal from time to time, subject to payment of a premium on the prepaid principal amount equal to 10% through September 3, 2020, 8% from September 4, 2020 through September 3, 2021, and 4% from September 4, 2021 through September 3, 2022. No premium will be due with respect to any prepayment made on or after September 4, 2022.

As of March 31, 2021, the loan balance, net of unamortized discounts and debt issuance costs, was $18.3 million, and Chembio was in compliance with its loan covenants.

NOTE 8 — EQUITY INCENTIVE PLAN:

(a) Equity Plans:

Effective June 3, 2008, Chembio's stockholders voted to approve the 2008 Stock Incentive Plan (the "SIP08"), with 625,000 shares of common stock available to be issued. At the Annual Stockholder Meeting on September 22, 2011 Chembio's stockholders voted to approve an increase to the number of shares of common stock issuable under the SIP08 by 125,000 to 750,000. Under the terms of the SIP08, which expired during 2018, the Board or its Compensation Committee had the discretion to select the persons to whom awards were to be granted. Awards could be stock options, restricted stock and/or restricted stock units (collectively, "Equity Award Units"). The Equity Award Units became vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through March 31, 2021, there were 714,000 options expired, forfeited or exercised, and at March 31, 2021, 36,000 options were outstanding and no Equity Award Units were available to be issued under the SIP08.

Effective June 19, 2014, Chembio's stockholders voted to approve the 2014 Stock Incentive Plan (the "SIP14"), with 800,000 shares of common stock available to be issued. Under the terms of the SIP14, the Board or its Compensation Committee has the discretion to select the persons to whom Equity Award Units are to be granted. The Equity Award Units vest at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through March 31, 2021, there were 519,782 Equity Award Units expired, forfeited or exercised. At March 31, 2021, 259,157 Equity Award Units were outstanding and 0 Equity Award Units remained available to be issued under the SIP14.

Effective June 18, 2019, Chembio's stockholders voted to approve the 2019 Omnibus Incentive Plan (the "SIP19"), with 2,400,000 shares of common stock available to be issued. In addition, shares of common stock underlying any outstanding Equity Award Unit granted under the SIP19 that, following the effective date of the SIP19, expires, or is terminated, surrendered or forfeited for any reason without issuance of such shares, shall be available for the grant of new Equity Award Units under the SIP19. Under the terms of the SIP19, the Board or its Compensation Committee has the discretion to select the persons to whom Equity Award Units are to be granted. The Equity Award Units become vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through March 31, 2021, 429,724 Equity Award Units has been cancelled or forfeited. At March 31, 2021, 2,400,924 Equity Award Units were outstanding, and 129,865 Equity Award Units were available to be awarded.

(a) Stock Compensation Expense:

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

	For the three months ended March 31	
	2021	2020
Cost of product sales	**$ 28,768**	$ 6,300
Research and development expenses	**90,920**	63,813
Selling, general and administrative expenses	**460,101**	316,788
Severance and related costs	**-**	(423,984)
	$ 579,789	$ (37,083)

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

	For the three months ended March 31, 2021
Expected term (in years)	**5.0**
Expected volatility	**78.29%**
Expected dividend yield	**1%**
Risk-free interest rate	**2.95%**

The following table provides stock option activity for the three months ended March 31, 2021:

Stock Options	**Number of Shares**	**Weighted Average Exercise Price per Share**	**Weighted Average Remaining Contract Term**	**Aggregate Intrinsic Value**
Outstanding at December 31, 2020	**974,778**	**$ 4.12**	**2.87 years**	**$ 1,520,910**
Granted	899,550	4.72		-
Exercised	-	-		-
Forfeited	1,042	5.39		-
Expired	25,000	5.64		
Outstanding at March 31, 2021	**1,848,286**	**$ 4.40**	**5.98 years**	**$ 731,819**
Exercisable at March 31, 2021	**408,079**	**$ 5.36**	**4.21 years**	**$ 202,248**

The following table summarizes information about stock options outstanding at March 31, 2021:

	Stock Options Outstanding				Stock Options Exercisable		
Range of Exercise Prices	Number of Shares	Average Remaining Contract Term (Year)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
$1 to $2.79999	636,364	5.95	$ 2.36	$ 731,819	175,868	$ 2.36	$ 202,248
2.8 to 4.59999	1,103	9.97	4.10	-	-	-	-
4.6 to 6.39999	956,069	6.86	4.77	-	14,961	5.49	-
6.4 to 8.19999	161,000	2.80	7.31	-	161,000	7.22	-
8.2 to 12	93,750	2.35	11.45	-	56,250	11.45	-
Total	1,848,286	5.98	$ 4.40	$ 731,819	408,079	$ 5.36	$ 202,248

As of March 31, 2021, there was $3,176,611 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 3.44 years. The total fair value of shares vested during the three months ended March 31, 2021 and 2020 was $188,179 and $182,932, respectively.

The following table summarizes information about the number of shares of common stock underlying restricted stock, restricted stock units and performance stock units outstanding as of March 31, 2021:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2020	603,531	$ 3.08
Granted	323,243	4.71
Vested	77,863	2.36
Forfeited	1,116	5.39
Outstanding at March 31, 2021	847,795	$ 3.63

As of March 31, 2021, there was $2,423,435 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 2.57 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. Product revenue by geographic area was as follows:

	For the three months ended March 31	
	2021	2020
Africa	**$ 1,344,858**	$ 883,515
Asia	**216,954**	363,288
Europe & Middle East	**1,493,734**	1,175,089
Latin America	**258,019**	2,116,396
United States	**711,097**	1,178,305
	$ 4,024,662	$ 5,716,593

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

	March 31, 2021	December 31, 2020
Asia	**$ 291,919**	$ 326,267
Europe & Middle East	**136,161**	147,692
Latin America	**30,596**	14,719
United States	**9,124,196**	8,199,725
	$ 9,582,872	$ 8,688,403

NOTE 10 — ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:

Accounts payable and accrued liabilities consisted of:

	March 31, 2021	December 31, 2020
Accounts payable – suppliers	**$ 6,097,056**	$ 5,727,781
Accrued commissions and royalties	**541,853**	807,708
Accrued payroll	**317,364**	277,908
Accrued vacation	**427,317**	417,238
Accrued bonuses	**-**	1,193,985
Accrued severance	**-**	511,681
Accrued expenses – other	**1,013,404**	1,106,489
TOTAL	**$ 8,396,994**	$ 10,042,790

NOTE 11 — GOODWILL AND INTANGIBLE ASSETS:

The following table reflects changes in goodwill:

Beginning balance at December 31, 2020	$ 5,963,744
Change in foreign currency exchange rate	(274,429)
Balance at March 31, 2021	$ 5,689,315

Intangible assets consisted of the following at:

		March 31, 2021			December 31, 2020		
	Weighted Average Remaining Useful Life	**Cost**	**Accumulated Amortization**	**Net Book Value**	Cost	Accumulated Amortization	Net Book Value
Intellectual property	5	$1,616,097	$512,293	$1,103,804	$1,638,699	$472,190	$1,166,509
Developed technology	5	2,010,518	630,263	1,380,255	2,102,526	594,186	1,508,340
Customer contracts/relationships	6	1,269,543	442,909	826,634	1,323,424	423,093	900,331
Trade names	7	111,739	45,429	66,310	115,318	44,512	70,806
		$5,007,897	$1,630,894	$3,377,003	$5,179,967	$1,533,981	$3,645,986

Intellectual property, developed technology, customer contracts/relationships and trade names are amortized over 10, 7, 10 and 11 years, respectively. Amortization expense for the three months ended March 31, 2021 and 2020 was $153,840 and $144,661, respectively. Amortization expense, subject to changes in currency exchange rates, is expected to average $564,921 per year from 2021 through 2025 and to total $552,397 for all of the years thereafter.

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 condensed consolidated financial statements and related notes included elsewhere in this report. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. See "Forward-Looking Statements and Statistical Estimates" 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.

Overview

We develop, manufacture and commercialize point-of-care tests for the detection and diagnosis of infectious diseases, including COVID 19, sexually transmitted disease, and fever and tropical disease.

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

We target the market for rapid diagnostic test solutions for infectious diseases, which is driven by the high prevalence of infectious diseases globally, an increase in the geriatric population, growing demand for rapid test results, and advancements in multiplexing. We have a broad portfolio of infectious disease products, which prior to 2020 were focused principally on sexually transmitted disease and fever and tropical disease. In February 2020 we began the process of shifting substantially all of our resources to seek to leverage the DPP technology platform to address the acute and escalating need for diagnostic testing for COVID-19. On April 1, 2021, we announced that we had entered into a distribution agreement with respect to our offering of an in-licensed third-party point-of-care test that is sourced from a third party for use in decentralized and traditional testing settings to detect COVID-19, Flu A and B antigens from a single patient sample in approximately 15 minutes.

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

During the first quarter of 2021, we continued to invest in automating our test manufacturing processes, all of which are now based in the United States, by, among other actions, validating and implementing automated lines to expand our manufacturing capabilities. Our transition from manual to automated assembly is intended to add capacity, reduce variable costs and improve product margins. In order to address challenging economic conditions and implement our business strategy, in the first quarter of 2021 we continued to execute a program to reduce operating expenses and better align our costs with revenues, including by eliminating positions that were no longer aligned with our strategy.

Consolidated Results of Operations
Three Months Ended March 31, 2021 versus Three Months Ended March 31, 2020

The results of operations for the three months ended March 31, 2021 and 2020 were as follows (dollars in thousands):

	March 31, 2021		March 31, 2020	
TOTAL REVENUES	**$ 8,724**	**100%**	$ 6,860	100%
OPERATING COSTS AND EXPENSES:				
Cost of product sales	**3,548**	**41%**	4,374	64%
Research and development expenses	**2,863**	**33%**	1,959	29%
Selling, general and administrative expenses	**6,086**	**70%**	4,157	61%
Severance and other related costs	**83**	**1%**	723	11%
Acquisition Costs	**0**	**0%**	64	1%
	12,580		11,277	
LOSS FROM OPERATIONS	**(3,856)**		(4,417)	
OTHER (EXPENSE) INCOME, NET	**(712)**		(662)	
LOSS BEFORE INCOME TAXES	**(4,568)**	**(52)%**	(5,079)	(74)%
Income tax (expense) benefit	**68**		79	
NET LOSS	**$ (4,500)**		$ (5,000)	

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during the quarter ended March 31, 2021 were $8.7 million, an increase of $1.9 million, or 27%, compared to the quarter ended March 31, 2020. The increase in total revenues reflected the benefit of Government grant income totaling $3.4 million associated with our $12.7 million award from Biomedical Advanced Research and Development Authority, or BARDA, offset by a $1.7 million reduction in product revenue, the reduction in product revenue reflects the net impact of gains in Europe associated with our long term agreement with UNICEF for our DPP Zika IgM/IgG and DPP ZCD IgM/IgG multiplex tests and Micro Readers sales to Europe and sales of HIV tests to Africa, offset by lower sales in Latin America and the United States.

Gross Product Margin

Cost of product sales is primarily composed of material, labor, manufacturing overhead, depreciation and amortization, and freight and distribution costs. Gross product margin is net product revenue less cost of product revenue, and gross product margin percentage is gross product margin as a percentage of net product revenue.

Gross product margin decreased by $0.9 million, or 64.5%, compared to the quarter ended March 31, 2020. The following schedule calculates gross product margin:

	For the three months ended March 31		Favorable/(unfavorable)	
	2021	2020	**$ Change**	**% Change**
Net product sales	**$ 4,025**	$ 5,717	$ (1,692)	29.6%
Less: Cost of product sales	**(3,548)**	(4,375)	827	18.9%
Gross product margin	**$ 477**	$ 1,342	$ (865)	64.5%
Gross product margin percentage	**11.9%**	23.5%		

During the first quarter of 2021 we continued to invest in developing and offering products to address the COVID-19 pandemic, which we expect would have average selling prices greater than those of our legacy products. We also continued to implement manufacturing automation in order to reduce our reliance on manual labor and improve our product margins (see "—2021 Plan" below). The $0.9 million decrease in gross product margin was comprised of (a) $0.5 million from unfavorable product margins due to the impact of geographic product mix and the impact of fixed manufacturing overhead, and (b) $0.4 million from unfavorable product sales volume as described under "—Total Revenues" above.

Research and Development

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

	For the three months ended March 31		Favorable/(unfavorable)	
	2021	2020	**$ Change**	**% Change**
Clinical and regulatory affairs	**$ 765**	$ 323	$ (442)	$ 136.8%
Other research and development	**2,098**	1,636	(462)	28.2%
Total research and development	**$ 2,863**	$ 1,959	$ (904)	46.1%

The increase in research and development costs for the three months ended March 31, 2021 compared to the three months ended March 31, 2020 was primarily associated with work related to pursuing an emergency use authorization, or EUA, and 510(k) from the U.S. Food and Drug Administration, or FDA, for the DPP SARS-CoV-2 Antigen test system, and an EUA for the DPP Respiratory Panel, each pursuant to awards from BARDA.

Selling, General and Administrative Expense

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

The $1.9 million, or 46.4%, increase in selling, general and administrative expense for the three months ended March 31, 2021 compared to the three months ended March 31, 2020 principally reflected increased costs associated with (a) fees for legal services relating to shareholder litigation and for internal audit services, and (b) compensation costs related to our expanded U.S. commercial team.

Other Expense, net

Other expense, net consists principally of interest expense, net of interest income earned on our deposits. Other expense, net increased in the three months ended March 31, 2021 compared to the comparable period in 2020 due to interest accruing on long-term debt incurred on September 3, 2019, of which $20 million (carrying value of $18.3 million) was outstanding at March 31, 2020. For a description of this long-term debt, please see “—Liquidity and Capital Resources—Sources of Funds—Credit Agreement” below.

Income Tax Benefit

During the three months ended March 31, 2021, we recognized a tax benefit of $0.1 million related to losses generated by our foreign subsidiaries, which offsets the deferred tax liability balances recorded on acquisition date. As of March 31, 2021 and 2020, our U.S. deferred tax assets included a full valuation allowance.

Liquidity and Capital Resources

During the first quarter of 2021 we funded our business operations, including capital expenditures and working capital requirements, principally from cash and cash equivalents. Our operations used $7.2 million of cash. As of March 31, 2021, we had outstanding indebtedness (excluding leases) of $20 million (carrying amount of $18.3 million), consisting of loans of $20.0 million under a credit agreement entered into on September 3, 2019.

We continually evaluate our liquidity requirements, capital needs and availability of capital resources based on our operating needs and our planned growth initiatives, particularly in the light of our shift in business focus to COVID-19 diagnostic test systems. We believe our existing cash and cash equivalents will be sufficient to meet our anticipated cash needs for at least the next twelve months. Our future working capital needs will depend on many factors, including: the fact and timing of our receipt from the FDA of an EUA award for the DPP SARS-CoV-2 Antigen System or the DPP Respiratory Panel System; the fact and timing of our receipt from the FDA of a Clinical Laboratory Improvement Amendment certificate of waiver for the DPP HIV-Syphilis System; the rate of our business and revenue growth, including our ability to successfully build distribution channels and commercialize the COVID-19 diagnostic test systems in geographies (principally Europe) covered by our CE-Marks for those products, particularly if we are able to resume commercialization of COVID-19 diagnostic test systems in the United States; the occurrence and timing of regulatory approvals for other new products; 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 our sources of liquidity become insufficient to fund the growth of our business, we may need to reduce the level or slow the timing of our growth plans, which would likely curtail or delay the growth in our business contemplated by our operating plan and could impair or defer our ability to achieve profitability and generate cash flow, or to seek to raise additional funds through debt or equity financings, strategic relationships, or other arrangements, to the extent funding would be available to us on acceptable terms or at all. If we were to raise additional funds through the issuance of equity or convertible securities, the issuance could result in substantial dilution to existing stockholders, and the holders of those new securities may have rights, preferences and privileges senior to those of the holders of common stock. See Part II, Item IA, “Risk Factors” below.

Sources of Funds

Credit Agreement. On September 3, 2019, Chembio Diagnostics, Inc., as borrower, and certain of our subsidiaries, as guarantors, entered into a Credit Agreement and Guaranty, or the Credit Agreement, with Perceptive Credit Holdings II, LP, or the Lender.

- 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 a specified event of default has occurred and is continuing, the interest rate will increase by 4.0%. Accrued interest is payable on a monthly basis.

- Scheduled Repayment. No principal repayments are due prior to September 30, 2022, unless we elect to prepay principal as described under "—Optional Prepayment" below or principal is accelerated pursuant to a specified event of default. 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.

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

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

- Representations and Warranties; Financial and Other Covenants. In the Credit Agreement we made customary representations and warranties as well as customary affirmative and negative covenants, including covenants limiting additional indebtedness, liens, guaranties, mergers and acquisitions, substantial asset sales, investments and loans, sale and leasebacks, transactions with affiliates, and fundamental changes. The Credit Agreement also contains financial covenants requiring that (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. The minimum total revenue amounts, which range from $32.0 million to $50.1 million, were developed for purposes of the Credit Agreement and do not reflect the internal estimates and plans used by our management and board of directors to understand and evaluate our operating performance, to establish budgets, and to establish operational goals for managing our business. We therefore do not believe that the covenant requirements provide useful information to investors or others in enhancing an understanding of our future prospects.

Research and Development Awards. We routinely seek research and development programs that may be awarded by government, non-governmental organizations, and non-profit entities, including private foundations. Since 2015 we have received over $14.2 million of funding from some of the world's leading health organizations, which has helped us accelerate the expansion of our pipeline of infectious disease tests. Our collaborators have included Bill & Melinda Gates Foundation, The Paul G. Allen Family Foundation, FIOCRUZ and FIND, as well as U.S. government agencies such as Centers for Disease Control and Prevention, BARDA, and the U.S. Department of Agriculture. During the quarter ended March 31, 2021, we recognized grant income totaling $3.35 million from government, non-governmental organizations, and non-profit entities.

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

	March 31, 2021
	(in thousands)
Cash and cash equivalents	$ 14,351
Accounts receivable, net of allowance for doubtful amounts	2,414
Inventories, net	14,691
Prepaid expenses and other current assets	813
Total current assets	**32,269**
Less: Total current liabilities	(9,434)
Working capital	**$ 22,835**

On December 2, 2020, we were awarded a contract of $12.7 million from BARDA to assist us in (a) developing, and requesting an EUA from the FDA for, the DPP Respiratory Panel and (b) performing the clinical trials for, and submitting the DPP SARS-CoV-2 Antigen system to, the FDA for a 510(k).

Our cash and cash equivalents of $14.4 million at March 31, 2021, which included a restricted amount of $0.4 million, 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 $7.2 million of cash during the three months ended March 31, 2021, primarily due to the net loss adjusted for non-cash items of $3.2 million, a $2.2 million increase in inventory related to supply chain timelines, including materials for COVID-19 systems that were ordered but could not be cancelled following the previously disclosed revocation of an EUA from the FDA and in anticipation of regulatory approvals, a $1.6 million decrease in accounts payable and other accrued liabilities, and a $1.2 million decrease in deferred revenue. Those uses of cash were offset in part by a $0.9 million decrease in accounts receivable and a $0.1 million decrease in deposits and other assets.

Capital Expenditures. Our capital expenditures totaled $1.2 million in the three months ended March 31, 2021, of which $1.2 million related to investments in automated manufacturing equipment, facilities, and other fixed assets.

We have capital purchase obligations totaling $1.3 million for additional automated manufacturing equipment, with payments expected to become due during 2021 based on vendor performance milestones.

Effects of Inflation

Other than the impact of increases in minimum wage levels in New York, inflation and changing prices have not had a material effect on our business, and we do not expect that they will materially affect our business in the foreseeable future. Any impact of inflation on cost of revenue and operating expenses, especially employee compensation costs (including any effects of future increases in minimum wages levels in New York), may not be readily recoverable in the price of our product offerings.

2021 Plan

On January 14, 2021, the board of directors approved a restructuring plan (the "2021 Plan") to better align its business priorities. The 2021 Plan comprises the termination of employees primarily in the manufacturing department. These actions were intended to better align our cost structure with the skills and resources required to more effectively pursue opportunities in the marketplace and execute our long-term growth strategy.

Costs associated with the 2021 Plan are primarily related to severance and legal costs. Severance payouts are expected to be substantially completed by the end of the six months ending June 30, 2021. We expect to incur pre-tax charges of between $0.1 million and $0.2 million under the 2021 Plan.

Off-Balance Sheet Arrangements

As of March 31, 2021, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K under the Securities Exchange Act of 1934.

Significant Accounting Policies and Critical Accounting Estimates

There were no significant changes in our critical accounting estimates during the three months ended March 31, 2021 to augment the critical accounting estimates disclosed under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K, 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 Annual Report on Form 10-K and is updated in Note 3 to the condensed consolidated financial statements included elsewhere in this report.

ITEM 4. CONTROLS AND PROCEDURES

(a) **Disclosure Controls and Procedures**. Under the supervision and with the participation of our senior management, consisting of our principal executive officer and our principal financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, 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 March 31, 2021 our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our Exchange Act reports is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

(b) **Changes in Internal Control over Financial Reporting**. There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 under the Exchange Act that occurred during the three months ended March 31, 2021, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

This information is set forth under "Note 6—Commitments, Contingencies and Concentrations—Litigation" to the condensed consolidated financial statements elsewhere in this report is incorporated in this Item 1 by reference.

ITEM 1A. RISK FACTORS

You should carefully consider each of the following risk factors and all of the other information provided in this Form 10-Q in considering whether to make or continue to hold an investment in our common stock. The risks described below are those we currently believe may materially affect us. An investment in our Company involves a high degree of risk, and should be considered only by persons who can afford the loss of their entire investment. Although we believe that these risks are the most important for you to consider, you should read this section in conjunction with our financial statements, the notes to those financial statements and our management's discussion and analysis of financial condition and results of operations included in our periodic reports and incorporated into this Form 10-Q by reference. In the following discussion, COVID-19 Diagnostic Test Systems refers to the DPP SARS-CoV-2 IgM/IgG System, the DPP SARS-CoV-2 Antigen System and the DPP Respiratory Antigen Panel.

RISK FACTORS SUMMARY

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, results of operations, cash flows and prospects. The risks are discussed more fully below and include, but are not limited to, the risks summarized below.

Risks Related to Our Business and Our Industry

- the refocus of our business strategy to respond to COVID-19, including the successful development and market acceptance of the COVID-19 Diagnostic Test Systems;
- our allocation of substantially all of our resources to the development and production of COVID-19 Diagnostic Test Systems;
- the COVID-19 Diagnostic Test Systems not gaining industry acceptance;
- the negative impact of healthcare industry consolidation on our future revenues and operating results;
- the effects of existing or future shareholder litigation;
- our ability to retain key employees and attract additional qualified personnel;
- third-party reimbursement policies; and
- the vulnerability of our business to cyber-attacks.

Risks Related to Our Products

- our competitors developing more effective or successful products;
- the ability of our products to compete with the new or existing products of our competitors;
- the impact of COVID-19 mutations on the ability of the COVID-19 Diagnostic Test Systems adequately detecting COVID-19 or SARS-CoV-2 antigens;
- our ability to successfully introduce and market our products, particularly the COVID-19 Diagnostic Test Systems;
- timely implementation and operation of customized manufacturing automation equipment;
- variability and unpredictability due to lengthy sales cycles for our products;
- our customers not adopting rapid point-of-care diagnostic testing;
- the concentration of our customers; and
- our products not performing properly.

Financial, Economic and Financing Risks

- our incurrence of losses in recent years and uncertainty about our future profitability;
- the fluctuation of our financial results;
- our compliance with the terms of our Credit Agreement and Guaranty;
- our ability to generate sufficient cash to service our debt;
- increased interest expenses due to changes in LIBOR;
- the negative impact of changes in foreign currency exchange rates on our operating results; and
- basing our estimates or judgments related to critical accounting policies on assumptions that can change or prove to be incorrect.

Risks Related to Intellectual Property

- our ability to protect our proprietary technology; and
- the effect of future intellectual property disputes on our ability to sell products or use certain technologies.

Risks Related to Our Reliance on Third Parties

- our dependence on a limited number of third-party suppliers, including single source suppliers, for critical components and materials;
- the limitation on rights we receive from collaborations with strategic collaborators, and the exposure to risks outside of our control due to such collaborations;
- our ability to maintain existing distribution channels or develop new distribution channels; and
- our compliance with U.S. government contracts.

Risks Related to Regulations

- the impact on the COVID-19 Diagnostic Test Systems of regulatory changes by global regulators such as the FDA and ANVISA;
- our ability to receive and maintain necessary regulatory approvals for our products, particularly the COVID-19 Diagnostic Test Systems;
- the impact of governmental export controls on our ability to compete in international markets;
- our ability to comply with evolving regulatory requirements of the FDA and other global regulators, particularly with respect to the COVID-19 Diagnostic Test Systems;
- our ability to respond to changes in regulatory requirements;
- the effect of FDA regulation of laboratory-developed tests and genetic testing on demand for our products;
- disruptions at the FDA and other global regulators affecting the regulators' ability to hire, retain or deploy key leadership or personal or otherwise could prevent new and modified products from being developed, cleared, approved, authorized or commercialized;
- ongoing changes in healthcare regulation;
- a reduction or elimination in the types of government awards that partially support some of our programs;
- compliance with privacy, security and breach notification regulations;
- our ability to manufacture products in accordance with applicable requirements;
- the effect of healthcare fraud and abuse laws on our business; and
- increased exposure to regulatory, cultural and other challenges due to international expansion.

Risks Related to Ownership of Common Stock

- the limited liquidity of our common stock;
- the volatility of the price of our common stock;
- the effect of future issuances of common stock on the price of our common stock and our ability to raise funds in new equity offerings;
- the control management and larger stockholders exercise over us; and
- the depression of the market price of our common stock due to sale by existing stockholders, executive officers or directors.

General Risk Factors

- our ability to successfully generate the expected benefits of our acquisitions; and
- developments related to the U.K.'s referendum on membership in the E.U.; and
- legislative and regulatory changes.

RISK FACTORS

Risks Related to Our Business and Our Industry

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

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

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

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

Our near-term success is highly dependent on the success of the COVID-19 Diagnostic Test Systems, 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, and we do not currently have an application pending for any such EUA. Market and regulatory requirements continue to change at a rapid pace. The FDA has declined to review our most recent EUAs submitted for our revised DPP SARS-CoV-2 IgM/IgG System and DPP SARS-CoV-2 Antigen System based on then-effective prioritization guidance, which is subject to change. There can be no assurance that, if we make a submission of any future EUA application, we will meet the requirements of the prioritization guidance in effect at the time of the submission or otherwise be successful in obtaining an EUA that would permit us to offer and sell any COVID-19 Diagnostic Test System in the United States.

Even if we are able to obtain an EUA for any of the COVID-19 Diagnostic Test Systems that 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, 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 COVID-19 Diagnostic Test Systems 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 any of our COVID-19 Diagnostic Test Systems through a traditional approval pathway, we would be required to cease our commercialization efforts, which would substantially and negatively impact our business.

Since the first quarter of 2020 we have focused primarily on our COVID-19 Diagnostic Test Systems, and the failure of these products to find market acceptance would substantially harm our business and would adversely affect our revenue. If the COVID-19 Diagnostic Test Systems are not as successfully commercialized as expected, we may not be able to generate sufficient revenue to become profitable. Any failure of one of the COVID-19 Diagnostic Test Systems 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 COVID-19 diagnostic testing develops and grows. If the market develops in a manner that does not facilitate demand for our COVID-19 Diagnostic Test Systems, 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.

Initiating and completing clinical trials necessary to support a future EUA, 510(k), PMA, or de novo submission, will be time consuming, expensive, and have an uncertain outcome. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any test kit we advance into clinical trials may not have favorable results in later clinical trials.

Conducting successful clinical trials will require the enrollment of large numbers of subjects, and suitable subjects may be difficult to identify and recruit. Subject enrollment in clinical trials and completion of subject participation depends on many factors, including the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the indication of the underlying test kit, the availability of appropriate clinical trial investigators, support staff, and proximity of subjects to clinical sites and able to comply with the eligibility and exclusion criteria for participation in the clinical trial and subject compliance. In addition, subjects may not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products.

In addition, our clinical trials may in the future be affected by the COVID-19 pandemic. For example, subjects may choose not to enroll or continue participating in the clinical trial as a result of the pandemic. As a result, potential subjects in our clinical trials may choose to not enroll, not participate in follow-up clinical visits, or drop out of the trial as a precaution against contracting COVID-19. Further, some subjects may not be able or willing to comply with clinical trial protocols if quarantines impede subject movement or interrupt healthcare services. We are unable to predict with confidence the duration of any such potential subject enrollment delays and difficulties, whether related to COVID-19 or otherwise. Delays in subject enrollment or failure of subjects to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our test kits or result in the failure of the clinical trial.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA may require us to submit data on a greater number of subjects than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. In addition, despite considerable time and expense invested in our clinical trials, the FDA may not consider our data adequate for approval. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

We have been allocating a substantial portion of our resources to the development and commercialization of COVID-19 Diagnostic Test Systems, and our long-term business success could be negatively impacted by our diversion of resources from our legacy business of diagnostic testing for other infectious diseases.

In the first quarter of 2020 we began committing substantially all of our financial and personnel resources to the development, manufacturing and commercialization of COVID-19 Diagnostic Test Systems. Because we do not currently have an EUA from the FDA for any of the COVID-19 Diagnostic Test Systems, in the first quarter of 2021 we began allocating an increased portion of our resources to our legacy products. Our earlier and continuing resource allocation to the COVID-19 Diagnostic Test Systems may have negatively impacted, and may continue to negatively impact, our legacy product portfolio, as we have spent limited funds and time on updating pre-existing products and regulatory approvals and on completing products that were in development prior to our strategic decision to focus on COVID-19 Diagnostic Test Systems. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could dissipate; there is no guarantee that current or anticipated demand will continue, or if demand does continue, that we will be able to produce in quantities to meet the demand. We intend to continue to reestablish our legacy business, but there can be no assurance that we will be able to successfully recommence the development and commercialization of our legacy products and products under development.

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

We expect competition to continue to increase as other established and emerging companies enter the market, as customer requirements evolve, and as new products, services and technologies are introduced. The entrance of new competitors is being encouraged by governmental authorities, which are offering funding to support development of testing solutions for COVID-19. Some of our existing or new competitors may have strong relationships with current and potential customers, including governmental authorities that may help fund those competing entities through grant awards or other funding. As a result, those competitors may be able to respond more quickly to new or changing regulatory requirements, new or emerging technologies, and changes in customer requirements. We do not currently have, or have an application pending for, an EUA from the FDA for any of the COVID-19 Diagnostic Test Systems. Even if we succeed in obtaining approvals for commercialization for one or more of the COVID-19 Diagnostic Test Systems, those products may not compete favorably, and we may not be successful in the face of existing and new products and technologies offered by our existing competitors or new companies entering our markets. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

Shareholder 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 shareholder litigation. See Part I, Item 3. “Legal Proceedings” below for additional information regarding 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 lawsuits, 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.

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

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

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

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

Our future revenues and operating results may be negatively affected by ongoing consolidation in the healthcare industry.

There has been a significant amount of consolidation in the healthcare industry. This consolidation has increased the competition to provide goods and services to customers. In addition, group purchasing organizations and integrated health delivery networks have served to concentrate purchasing decisions for some customers, which has also placed pricing pressure on medical device suppliers. Due to ongoing consolidation, there could be additional pressure on the prices of our products.

Our continued growth depends on retaining our current key employees and attracting additional qualified personnel, and we may not be able to do so.

Our success depends to a large extent upon the skills and experience of our executive officers, sales, marketing, operations and scientific staff. We may not be able to attract or retain qualified employees due to the intense competition for qualified personnel among medical products businesses and academic and other research institutions, as well as to geographic considerations, our ability to offer competitive compensation and benefits, and other reasons.

If we are not able to attract and retain the necessary qualified personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to effectively manufacture, sell and market our products to meet the demands of our customers and strategic partners in a timely fashion, or to support internal research and development programs.

We have entered into employment contracts with our Chief Executive Officer, Richard Eberly, our Chief Science & Technology Officer, Javan Esfandiari, and our Chief Financial Officer, Neil Goldman. Due to the specific knowledge and experience of these executives regarding the industry, technology and market generally and to our company specifically, the loss of the services of any one of these executives could have a material adverse effect on us. We have not obtained a key man insurance policy on any officers other than Messrs. Eberly and Esfandiari.

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

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

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

To the extent that we are unable to collect our outstanding accounts receivable, our operating results could be materially harmed.

There may be circumstances and timing that require us to accept payment terms, including delayed payment terms, from distributors or customers, which, if not satisfied, could cause financial losses.

We generally accept payment terms which require us to ship product before the contract price has been paid fully, and there also are circumstances pursuant to which we may accept further delayed payment terms pursuant to which we may continue to deliver product. To the extent that these circumstances result in significant accounts receivables and those accounts receivables are not paid on a timely basis, or are not paid at all, especially if concentrated in one or two customers, we could suffer financial losses.

We believe our success depends in part on the continued funding of, and our ability to participate in, large testing programs in the United States and worldwide, the funding of which may be reduced or discontinued or otherwise be unavailable to us.

We believe it to be in our best interests to meaningfully participate in large testing programs. Moreover many of these programs are funded by governments and other donors, and there can be no assurance that funding will not be reduced or completely discontinued. Participation in these programs also requires alignment and engagement with the many other participants in these programs, including the World Health Organization, or WHO, the U.S. Centers for Disease Control and Prevention, the U.S. Agency for International Development, foreign governments and their agencies, non-governmental organizations, and HIV service organizations. If we are unsuccessful in our efforts to participate in these programs, our operating results could be materially harmed.

In December 2013 President Obama signed into law the President's Emergency Plan For AIDS Relief, or PEPFAR, Stewardship and Oversight Act, which is the most recent reauthorization of PEPFAR. However, unlike the 2008 PEPFAR authorization, which authorized approximately $45 billion in funding, the new law did not authorize a specific dollar amount for funding.

Developing testing guidelines could negatively affect sales of our products.

Government agencies may issue diagnostic testing guidelines or recommendations, which can alter the usage of our HIV testing products. New laws or guidelines, or changes to existing laws or guidelines, and the manner in which these new or changed laws and guidelines are interpreted and applied, could impact the degree to which our testing products are used. These developments could affect the frequency of testing, the number of people tested and whether the testing products are used broadly for screening large populations or in a more limited capacity. These factors could in turn affect the level of sales of our products and our results of operations.

Some of our programs are supported by government grant awards, which may not be available to us in the future.

We have received funding under grant award programs funded by governmental agencies such as the Biomedical Advanced Research and Development Authority, or 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. However, funding by these governmental agencies may 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 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 a contract from BARDA that includes funding milestones related to our development and pursuit of an EUA for a DPP Respiratory Antigen Panel and our submission to the FDA for 510(k) clearance and a CLIA-waiver and for the DPP SARS-CoV-2 Antigen System. Therefore, we cannot assure you that we will receive any future grant funding from any government agencies, or, that if received, we will receive the full amount of the particular grant award. Any such reductions could delay the development of our product candidates and the introduction of new products.

We could be exposed to liability if we experience security breaches or other disruptions, which could harm our reputation and business.

We may be subject to cyber-attacks whereby computer hackers may attempt to access our computer systems or our third-party IT service providers' systems and, if successful, misappropriate personal or confidential information. In addition, a contractor or other third party with whom we do business may attempt to circumvent our security measures or obtain such information, and may purposefully or inadvertently cause a breach involving sensitive information. We will continue to evaluate and implement additional protective measures to reduce the risk and detect cyber incidents, but cyber-attacks are becoming more sophisticated and frequent and the techniques used in such attacks change rapidly. Even though we take cyber-security measures that are continuously reviewed and updated, our information technology networks and infrastructure may still be vulnerable due to sophisticated attacks by hackers or breaches.

Even the most well protected IT networks, systems, and facilities remain potentially vulnerable because the techniques used in security breaches are continually evolving and generally are not recognized until launched against a target and, in fact, may not be detected. Any such compromise of our or our third party's IT service providers' data security and access, public disclosure, or loss of personal or confidential business information, could result in legal claims proceedings, liability under laws to protect, privacy of personal information, and regulatory penalties, disrupt our operations, require significant management attention and resources to remedy any damages that result, damage our reputation and customers willingness to transact business with us, any of which could adversely affect our business.

Our ability to efficiently operate our business is reliant on information technology, and any material failure, inadequacy, interruption or security breach of that technology could harm our business.

We rely heavily on complex information technology systems across our operations and on the internet, including for management of inventory, invoices, purchase orders, shipping, interactions with our third-party logistics providers, revenue and expense accounting, consumer call support, and various other processes and transactions. Our ability to effectively manage our business, coordinate the production, distribution and sale of our products, respond to customer inquiries, and ensure the timely and accurate recording and disclosure of financial information depends significantly on the reliability and capacity of these systems and the internet.

If any of the foregoing systems fails to operate effectively, problems with transitioning to upgraded or replacement systems, or disruptions in the operation of the internet, could cause delays in product sales and reduced efficiency of our operations. Significant expenditures could be required to fix any such problem.

If there is an increase in demand for our products, it could require us to expend considerable resources or harm our customer relationships if we are unable to meet that demand.

If there are significant or unexpected increases in the demand for our products, we may not be able to meet that demand without expending additional capital resources. This would increase our capital costs, which could negatively affect our earnings and liquidity in the short term. In addition, new manufacturing equipment or facilities may require FDA, WHO, and other regulatory approvals before they can be used to manufacture our products. To the extent we are unable to obtain or are delayed in obtaining such approvals, our ability to meet the demand for our products could be adversely affected. Furthermore, our suppliers may be unable or unwilling to expend the necessary capital resources or otherwise expand their capacity, which could negatively affect our business.

Our business could be negatively affected if we or our suppliers are unable to develop necessary manufacturing capabilities in a timely manner. If we fail to increase production volumes in a cost effective manner or if we experience lower than anticipated yields or production problems as a result of changes that we or our suppliers make in our manufacturing processes to meet increased demand, we could experience shipment delays or interruptions and increased manufacturing costs, which could also have a material adverse effect on our revenues and profitability.

If there are unexpected increases in demand for our products, we may be required to obtain additional raw materials in order to manufacture products to meet the increase in demand. However, some raw materials require significant ordering lead time and some are currently obtained from a sole supplier or a limited group of suppliers. It is also possible that one or more of our suppliers may become unwilling or unable to deliver materials to us. Any shortfall in our supply of raw materials and components, or our inability to quickly and cost-effectively obtain alternative sources for this supply, could have a material adverse effect on our ability to meet increased demand for our products. This could negatively affect our total revenues or cost of sales and related profits.

If we are unable to meet customer demand for our products, it could also harm our relationships with our customers and impair our reputation within the industry. This, in turn, could have a material adverse effect on our business.

Risks Related to Our Products

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

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

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

Numerous companies in the United States and internationally have introduced, or announced their intention to introduce, new products, services and technologies that could be used in substitution for the COVID-19 Diagnostic Test Systems. Many of those competitors are significantly larger, and have substantially greater financial, engineering and other resources, than us. In addition, our competitors may have or may develop products or technologies that currently or in the future will enable them to produce competitive products with greater capabilities or at lower costs than ours. If we are unable to compete effectively, we may fail to meet our strategic objectives, and our business, financial condition and operating results could be harmed. The success or failure, or perceived success or failure, of other companies may adversely impact our ability to obtain any future funding, or to ultimately commercialize, any of the COVID-19 Diagnostic Test Systems.

We operate in a fragmented, segmented, and rapidly changing industry, which is highly competitive with respect to numerous factors, and our success depends on our ability compete effectively with larger companies, develop new or enhance existing products, as well as acceptance of DPP over other diagnostic platform technologies.

Important competitive factors for our products include price, quality, performance, ease of use, and customer service. A few large corporations produce a wide variety of diagnostic tests and other medical devices and equipment. A larger number of mid-size companies generally compete only in the diagnostic industry and a significant number of small companies produce only a few diagnostic products. As a result, the diagnostic test industry is highly fragmented and segmented.

More generally, the point-of-care diagnostics industry is undergoing rapid technological changes, with frequent introductions of new technology-driven products and services. As new technologies become introduced into the point-of-care diagnostic testing market, we may be required to commit considerable additional efforts, time and resources to enhance our current product portfolio or develop new products. We may not have the available time and resources to accomplish this, and many of our competitors have substantially greater financial and other resources to invest in technological improvements. We may not be able to effectively implement new technology-driven products and services or be successful in marketing these products and services to our customers, which would materially harm our operating results.

Although we own DPP patents, lateral flow technology is still a competitive platform to DPP, and lateral flow technology has a lower cost of manufacture than DPP products. Although the DPP platform has shown improved sensitivity as compared with conventional lateral flow platforms in a number of studies, several factors go into the development and performance attributes of products. Therefore the ability of our products to successfully compete will depend on several other factors, including our having a patented rapid test platform technology that differentiates DPP from lateral flow as well as from other diagnostic platform technologies.

There can be no assurance that our DPP patents or our products incorporating those patents will not be challenged at some time in the future.

Our competitors may develop and commercialize more effective or successful products, and our research, development and commercialization efforts may not succeed.

We regularly commit substantial resources to research and development and the commercialization of our new or enhanced products. The research and development process usually takes a long time from inception to commercial launch. During each stage of this process there is a substantial risk that we will not achieve our goals in a timely fashion, or at all, and we may have to abandon a new or enhanced product in which we have invested substantial time and money. We expect to continue to incur significant costs related to our research and development activities.

Our products require significant development and investment prior to commercialization, including testing to demonstrate the products' performance capabilities, cost-effectiveness or other benefits. We must obtain regulatory approval before most products may be sold and additional development efforts on these products may be required before the products will be reviewed. However, regulatory authorities may not approve these products for commercial sale or may substantially delay or condition such approval. There may be little or no market for the product and entry into or development of new markets for our products may require an investment of substantial resources even if all applicable regulatory approvals are obtained. Furthermore, we may spend a significant amount of money on advertising or other activities and still fail to develop a market for the product. The success of our efforts may be affected by our ability to manufacture products in a cost-effective manner, whether we can obtain necessary intellectual property rights and protection and our ability to obtain reimbursement authorizations in the markets where the product will be sold. Therefore, if we fail to develop and gain commercial acceptance for our products, or if competitors develop more effective products or a greater number of successful new products, customers may decide not to purchase our products.

Our products may not be able to compete with new diagnostic products or existing products developed by well-established competitors, which would negatively affect our business.

The diagnostic industry is focused on the testing of biological specimens in a laboratory or at the point-of-care and is highly competitive and rapidly changing. Important competitive factors for our products include price, quality, performance, ease of use, and customer service.

A few large corporations produce a wide variety of diagnostic tests and other medical devices and equipment. A larger number of mid-size companies generally compete only in the diagnostic industry and a significant number of small companies produce only a few diagnostic products. As a result, the diagnostic test industry is highly fragmented and segmented.

Some of our principal competitors may have considerably greater financial, technical and marketing resources than we do. Several companies produce diagnostic tests that compete directly with our testing product line, including Abbott, OraSure Technologies, Quidel, ThermoFisher and Trinity Biotech. Some competitors offer broader product lines and may have greater name recognition than we have. These and other companies have or may have products incorporating molecular or other advanced technologies that over time could directly compete with our testing product line. We also face competition from certain of our distributors or former customers that have created or may decide to create, their own products to compete with ours.

As new products incorporating new technologies enter the market, our products may become obsolete. Competitors' products may be more effective or more effectively marketed and sold, including because they are offered as part of broader portfolios with existing marketing penetration. If our competitors' products take market share from our products through more effective marketing or competitive pricing, our revenues, margins and operating results could be adversely affected. In addition, our revenues and operating results could be negatively impacted if some of our customers internally develop or acquire their own sample collection devices and use those devices in place of our products in order to reduce costs.

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

Of the 263 manufacturers and commercial laboratories to receive an EUA for COVID-19 diagnostics as of March 31, 2021, 66 were for serology tests, 200 were for molecular tests, and 14 were for antigen tests. Customers or the industry as a whole could adopt alternative technologies for testing, including molecular point-of-care testing, which could result in lower demand for our antigen test. Various advances in the treatment and monitoring of patients could cause lower demand for 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.

COVID-19 is prone to genetic mutations that may impact the ability of the COVID-19 Diagnostic Test Systems to adequately detect COVID-19, SARS-CoV-2 antigens and antibodies, and could adversely affect demand for the COVID-19 Diagnostic Test Systems and harm our competitive position.

False test results are a risk with all laboratory tests, including COVID-19 diagnostic tests. False results can occur in the presence or absence of a mutation in the COVID-19 virus. Multiple variations of the virus that causes COVID-19 are circulating globally and within the United States, including variants of concern initially identified in California, Brazil, South Africa and the United Kingdom. In the presence of a mutation in the virus, false results can occur if a mutation occurs in the region of the virus that the test is designed to assess. False results may occur with the COVID-19 Diagnostic Test Systems in the presence or absence of one or more COVID-19 mutations. If false negatives occur with the COVID-19 Diagnostic Test Systems, it will may reduce customer confidence in the accuracy of the COVID-19 Diagnostic Test Systems and harm our competitive position.

For our business to succeed in the future, our current and future products must receive market acceptance.

Market acceptance, and the timing of such acceptance, of our products or technologies is necessary for our future success. To achieve market acceptance, we and our distributors will likely be required to undertake substantial efforts and spend significant funds to inform every one of the existence and perceived benefits of our products. We also may require government funding for the purchase of our products to help create market acceptance and expand the use of our products.

It may be difficult evaluate the market reaction to our products and our marketing efforts for products may not be successful. The government funding we receive may be limited for new products. As such, there can be no assurance that any products will obtain significant market acceptance and fill the market need that is perceived to exist on a timely basis, or at all.

We may not have sufficient resources to effectively introduce and market our products, which could materially harm our operating results.

Introducing and achieving market acceptance for our new products will require substantial marketing efforts and will require us and/or our contract partners, sales agents, and/or distributors to make significant expenditures of time and money. In some instances we will be significantly or totally reliant on the marketing efforts and expenditures of our contract partners, sales agents, and distributors. If they do not have or commit the expertise and resources to effectively market the products that we manufacture, our operating results will be materially harmed.

New developments in health treatments and non-diagnostic products may reduce or eliminate the demand for our products.

The development and commercialization of products outside of the diagnostics industry could adversely affect sales of our products. For example, the development of a safe and effective vaccine to COVID-19 or HIV or treatments for other diseases or conditions that our products are designed to detect, could reduce or eventually eliminate the demand for our HIV or other diagnostic products and result in a loss of revenues.

Our future success will depend on our ability to cost-effectively increase manufacturing production capacity through the implementation of additional customized manufacturing automation equipment.

If we successfully commercialize the COVID-19 Diagnostic Test Systems or other new products, one of our key challenges will be to increase our production capacity to meet sales demand while maintaining product quality and reducing production costs. Our primary strategy to cost-effectively increase product capacity has been to implement customized automation equipment, and we have entered into agreements to acquire additional customized automation equipment. The equipment we order may not be delivered in a timely manner, and, once delivered, the equipment may require significant time and effort in order to operate in the manner required to produce high quality products. We experienced significant unexpected delays before our current automation equipment operated in the manner for which it was designed. The investments we make in this equipment may not yield the anticipated labor and material efficiencies. If we are not successful in introducing COVID-19 Diagnostic Test Systems or other new products in accordance with our operating plans, we do not have the right to terminate the existing purchase orders for additional automation equipment and we may have excess capacity for a period of time. Our business, financial condition and results of operations could be harmed if we are unable to timely obtain automation equipment that meets our requirements or if there are significant increases in the costs of equipment.

Sales cycles for our products can be lengthy, which can cause variability and unpredictability in our business.

Some of our products may require lengthy and unpredictable sales cycles, which makes it more difficult to accurately forecast revenues in a given period and may cause revenues and operating results to vary from period to period. Our products may involve sales to large public and private institutions which may require many levels of approval and may be dependent on economic or political conditions and the availability of grant awards or other funding from government or public health agencies which can vary from period to period. There can be no assurance that purchases or funding from these agencies will occur or continue, especially if current negative economic conditions continue or intensify. As a result, we may expend considerable resources on unsuccessful sales efforts or we may not be able to complete transactions at all or on a schedule and in an amount consistent with our objectives.

We may face product liability claims for injuries.

The testing, manufacturing and marketing of medical diagnostic products involves an inherent risk of product liability claims. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease sales of our products. We cannot be sure that we will not incur liabilities in excess of the policy limits of our existing product liability insurance coverage or that we will be able to continue to obtain adequate product liability insurance coverage in the future at an acceptable cost, or at all. In addition, a defect in the design or manufacture of our products could have a material adverse effect on our reputation in the industry and subject us to claims of liability for injury and otherwise. Any substantial underinsured loss resulting from such a claim could have a material adverse effect on our profitability, and the damage to our reputation in the industry could have a material adverse effect on our business.

Our customers may not adopt rapid point-of-care diagnostic testing.

Rapid point-of-care tests are beneficial because, among other things, they can be administered by healthcare providers in their own facilities or used by consumers at home without sending samples to central laboratories. But currently the majority of diagnostic tests used by physicians and other healthcare providers in the United States are provided by clinical reference laboratories and hospital-based laboratories. In some international markets, such as Europe, diagnostic testing is performed primarily by centralized laboratories. Future sales of our products will depend, in part, on our ability to expand market acceptance of rapid point-of-care testing and successfully compete against laboratory testing methods and products. However, we expect that clinical reference and other hospital-based laboratories will continue to compete vigorously against our rapid point-of-care products. Even if we can demonstrate that our products are more cost effective, save time, or have better performance or other benefits, physicians, other healthcare providers and consumers may resist changing to rapid point-of-care tests and instead may choose to obtain diagnostic results through laboratory tests. If we fail to achieve and expand market acceptance of our rapid point-of-care diagnostic tests with customers, it would have a negative effect on our future sales growth.

Customer concentration creates risks for our business.

A significant portion of our revenues each year comes from a few large customers. To the extent that such a large customer fails to meet its purchase commitments, changes its ordering patterns or business strategy, or otherwise reduces its purchases or stops purchasing our products, or if we experience difficulty in meeting the demand by these customers for our products, our revenues and results of operations could be adversely affected.

If our products do not perform properly, it may affect our revenues, stock price and reputation.

Our products may not perform as expected. For example, a defect in one of our diagnostic products or a failure by a customer to follow proper testing procedures may cause the product to report inaccurate information. Identifying the root cause of a product performance or quality issue can be difficult and time consuming.

If our products do not to perform in accordance with the applicable label claims or otherwise in accordance with the expectations or needs of our customers, customers may switch to a competing product or otherwise stop using our products, and our revenues could be negatively affected. If this occurs, we may be required to implement holds or product recalls and incur warranty obligations. Furthermore, the poor performance by one or more of our products could have an adverse effect on our reputation, our continuing ability to sell products and the price of our common stock.

Financial, Economic and Financing Risks

We have incurred losses in recent years and we are uncertain about our future profitability and cash flow.

We incurred an operating loss every year from 2014 through 2020. Under our operating plans, we have made, and plan to continue to make, significant investments in our production capacity, including in expanding facilities and automating manufacturing, and in our sales and marketing, regulatory approval, and research and development activities. Our ability to achieve profitability and generate cash flow in the future will depend on our ability to increase sales of our existing products and to successfully introduce new and enhanced products into the marketplace, all while controlling and managing our expenses consistent with our operating plan.

Because we do not currently have an EUA from the FDA for any of the COVID-19 Diagnostic Test Systems, we have been unable to increase our revenues in accordance with our operating plan. As a result, our operating results have not met our expectations. If we experience a continuing delay in obtaining, or are unable to obtain, an EUA for one or more of out COVID-19 Diagnostic Test Systems, our operating results will be further harmed and we may not be able to generate the cash flow needed to fund the investments in our production capacity and other activities. In such an event, we will be required to implement one or both of the following:

- We could reduce the level, or otherwise delay the timing, of the anticipated investments in our production capacity and other activities, 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. Moreover, if we were to further reduce the number of our personnel, there can be no assurance that we would be able, when desirable, to successfully rehire or rebuild our workforce.
- We could raise additional funds through public or private financings, strategic relationships, or other arrangements, to the extent funding would be available to us on acceptable terms or at all. If we succeed in raising additional funds through the issuance of equity or convertible securities, then the issuance could result in substantial dilution to existing stockholders. Furthermore, the holders of these new securities or debt may have rights, preferences and privileges senior to those of the holders of our common stock.

In such circumstances, we also would need to forego acquisition opportunities, which could impede our ability to grow our business.

Our financial results may fluctuate.

From quarter to quarter and year to year, our operating results can fluctuate, which could cause our growth or financial performance to fail to meet the expectations of investors and securities analysts. Sales to our distributors and other customers may not meet expectations because of lower than expected customer demand or other factors, including continued economic volatility and disruption, reduced governmental funding, and other circumstances described elsewhere in this report. A variety of factors could also contribute to the variability of our financial results, including infrequent, unusual or unexpected changes in revenues or costs.

Different products provide dissimilar contributions to our gross product margin. Accordingly, our operating results could also fluctuate and be negatively affected by the mix of products sold and the relative prices and gross product margin contribution of those products. Failure to achieve operating results consistent with the expectations of investors and securities analysts could adversely affect our reputation and the price of our common stock.

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

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

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

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

In addition, the Credit Agreement also contain covenants requiring us and our subsidiaries to maintain cash and cash equivalents held in one or more accounts subject to the first priority perfected security interests of the lenders under the Credit Agreement of not less than $3,000,000. The Credit Agreement also provides for specified quarterly minimum consolidated net revenue covenants of us and our subsidiaries for the trailing twelve-month period ended on each such calculation date during the term of the Credit Agreement. A breach of any of these covenants would result in a default under the Credit Agreement. If an event of default under our Credit Agreements occurs, Perceptive could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. If we were unable to pay such amounts, Perceptive could proceed against the collateral pledged to them. We have pledged our inventory, accounts receivable, cash, securities, other general intangibles and the capital stock of certain subsidiaries to the lenders. In such an event, we cannot assure you that we would have sufficient assets to pay amounts due under the Credit Agreement.

Servicing our debt will require a significant amount of cash. Our ability to generate sufficient cash to service our debt depends on many factors beyond our control.

Our ability to make payments on and to refinance our debt, to fund planned capital expenditures, and to maintain sufficient working capital depends on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control. We cannot assure you that our business will generate sufficient cash flow from operations or from other sources in an amount sufficient to enable us to service our debt or to fund our other liquidity needs. In the year ended December 31, 2020, our operations used $18.9 million in cash. If our cash flow and capital resources are insufficient to allow us to make scheduled payments on our debt, we may need seek additional capital or restructure or refinance all or a portion of our debt on or before the maturity thereof, any of which could have a material adverse effect on our business, financial condition or results of operations. We cannot assure you that, if needed, we would be able to refinance any of our debt on commercially reasonable terms or at all, or that the terms of that debt will allow any of the above alternative measures or that these measures would satisfy our scheduled debt service obligations. If we are unable to generate sufficient cash flow to repay or refinance our debt on favorable terms, it could significantly adversely affect our financial condition. Our ability to restructure or refinance our debt will depend on the condition of the capital markets and our financial condition. Any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. There can be no assurance that we will be able to obtain any financing when needed.

The LIBOR calculation method may change, and LIBOR is expected to be phased out after 2021, which may adversely affect our interest expenses under the Credit Agreement and Guaranty.

Loans under the Credit Agreement and Guaranty bear interest at a rate per annum equal to the sum of (a) the greater of the one-month London Interbank Offered Rate, or LIBOR, 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 July 27, 2017, the U.K. Financial Conduct Authority announced that it will no longer require banks to submit rates for the calculation of LIBOR after 2021. On November 30, 2020, ICE Benchmark Administration, or IBA, the administrator of LIBOR, with the support of the United States Federal Reserve and the United Kingdom's Financial Conduct Authority, announced plans to consult on ceasing publication of USD LIBOR on December 31, 2021 for only the one week and two month USD LIBOR tenors, and on June 30, 2023 for all other USD LIBOR tenors. While this announcement extends the transition period to June 2023, the United States Federal Reserve concurrently issued a statement advising banks to stop new USD LIBOR issuances by the end of 2021. In light of these recent announcements, the future of LIBOR at this time is uncertain and any changes in the methods by which LIBOR is determined or regulatory activity related to LIBOR's phaseout could cause LIBOR to perform differently than in the past or cease to exist.

At this time, no consensus exists as to what rate or rates will become accepted alternatives to LIBOR, although The U.S. Federal Reserve, in conjunction with the Alternative Reference Rates Committee, is considering replacing U.S. dollar LIBOR with the Secured Overnight Financing Rate, or SOFR, a newly created index, calculated with a broad set of short-term repurchase agreements backed by treasury securities. It is not possible to predict the effect of these changes, other reforms or the establishment of alternative reference rates in the United States or elsewhere.

Pursuant to the Credit Agreement and Guaranty, if LIBOR becomes unavailable in the future, an alternative benchmark rate will apply. To the extent our interest rates increase as a result, our interest expense will increase, in which event we may have difficulties making interest payments and funding our other fixed costs, and our available cash flow for general corporate requirements may be adversely affected.

Our operating results may be negatively affected by changes in foreign currency exchange rates.

In the past our exposure to foreign currency exchange rate risk has not been material. Nevertheless, sales of our products are subject to currency risks, since changes in the values of foreign currencies relative to the value of the U.S. dollar can render our products comparatively more expensive. The fluctuations in the exchange rate could negatively impact international sales of our products, as could changes in the general economic conditions.

The revenues and expenses of our Malaysian, German and Brazilian subsidiaries are recorded in Malaysian Ringgit, in Euros and Brazilian Real, respectively. Revenues and expenses denominated in foreign currencies are translated into U.S. dollars for purposes of reporting our consolidated financial results, and, consequently, our operating results reflect exposure to foreign currency exchange rates, which could increase in the future.

Our foreign subsidiaries' revenues and expenses and the translation of their financial results into U.S. dollars may be negatively affected by fluctuations in the exchange rate. Favorable movement in exchange rates have benefited us in prior periods. However, where there are unfavorable currency exchange rate fluctuations, our consolidated financial statements could be negatively affected. Furthermore, fluctuations in exchange rates could affect year-to-year comparability of operating results. In the past, we have not generally entered into hedging instruments to manage our currency exchange rate risk, but we may need to do so in the future. However, our attempts to hedge against these risks may not be successful. If we are unable to successfully hedge against unfavorable foreign currency exchange rate movements, our consolidated financial results may be adversely impacted.

We operate in countries where there is or may be widespread corruption.

We have a policy in place prohibiting our employees, distributors and agents from engaging in corrupt business practices, including activities prohibited by the U.S. Foreign Corrupt Practices Act. Nevertheless, because we work through independent sales agents and distributors outside the United States, we do not have control over the day-to-day activities of such independent agents and distributors. In addition, in the donor-funded markets in Africa where we sell our products, there is significant oversight from PEPFAR, the Global Fund, and advisory committees comprised of technical experts concerning the development and establishment of national testing protocols. This is a process that includes an overall assessment of a product that includes extensive evaluations of product performance, as well as price and delivery. In Brazil, where we have had numerous product collaborations with FIOCRUZ, the programs through which our products may be deployed are all funded by the Brazilian Ministry of Health. Although FIOCRUZ is affiliated with the Brazilian Ministry of Health, which is FIOCRUZ's sole customer, FIOCRUZ is not the exclusive supplier for the Ministry of Health. However, because each of our previous collaborations with FIOCRUZ incorporates a technology transfer aspect, we believe we have a competitive advantage versus other suppliers to the Brazilian Ministry of Health, assuming other aspects of our product offering through FIOCRUZ are otherwise competitive in comparison. We have no knowledge or reason to know of any activities by our employees, distributors or sales agents of any actions which could be in violation of the FCPA, although there can be no assurance of this. In addition, corruption is a problematic factor in doing business in Brazil, and, to the extent bribery and similar practices continue to exist in Brazil, we may be at a competitive disadvantage in gaining business in Brazil, particularly when competing with non-U.S. companies.

Our subsidiary Chembio Diagnostics Malaysia Sdn. Bhd. is located in Malaysia. There have been numerous high-profile corruption cases, and corruption is one of the most problematic factors for doing business in Malaysia. While the Malaysian government has acknowledged the problem, it appears that endemic corruption is continuing and that market-based principles are not applied in cases involving individuals with high-level political access. To the extent bribery and similar practices continue to exist in Malaysia, U.S. companies such as ours, which are subject to U.S. laws making it illegal to pay bribes to foreign officials, may make us less competitive in winning business in Malaysia when competing with non-U.S. companies.

We base our estimates or judgments relating to critical accounting policies on assumptions that can change or prove to be incorrect.

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States and our discussion and analysis of financial condition and results of operations is based on such statements. The preparation of financial statements requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We continuously evaluate significant estimates used in preparing our financial statements, including those related: to (1) revenue recognition, including uncertainties related to variable consideration and milestones; (2) stock-based compensation; (3) allowance for uncollectible accounts receivable; (4) inventory reserves and obsolescence; (5) customer sales returns and allowances; (6) contingencies; (7) income taxes; (8) goodwill and intangibles; (8) business acquisition; and (10) research and development costs.

For example, for the quarter ended June 30, 2020, our cost of product sales included the cost of COVID-19 systems that were produced and shipped outside the United States, but for which revenue was not recognized in the quarter. We decided we were unable to recognize the revenue from those shipments in the second quarter due to the GAAP requirement that we have a high degree of confidence that it is probable that a significant reversal in revenue will not occur in the future. Many factors can affect such a decision, including, for example, actions of third parties and other considerations that are outside our influence or control. As a result, we recognized negative gross margin in the quarter.

Our estimates are based on historical experience and various other assumptions that we believe to be reasonable, as set forth in our discussion and analysis of financial condition and results of operations, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these and other estimates if our assumptions change or if actual circumstances differ from those in our assumptions. If our operating results fall below the expectations of securities analysts and investors, the price of our common stock may decline.

Risks Related to Intellectual Property

Our success depends on our ability to protect our proprietary technology. We rely on trade secret laws and agreements with our key employees and other third parties to protect our proprietary rights, and we cannot be sure that these laws or agreements will adequately protect our rights.

Our industry places considerable importance on obtaining patent, trademark and trade secret protection, as well as other intellectual property rights, for new technologies, products and processes. Our success depends, in part, on our ability to develop and maintain a strong intellectual property portfolio or obtain licenses to patents and technologies, both in the United States and in other countries. If we cannot continue to develop, obtain and protect intellectual property rights, our revenues and gross profits could be adversely affected. Moreover, our current and future licenses or other rights to patents and other technologies may not be adequate for the operation of our business.

As appropriate, we intend to file patent applications and obtain patent protection for our proprietary technology. These patent applications and patents will cover, as applicable, compositions of matter for our products, methods of making those products, methods of using those products and apparatuses relating to the use or manufacture of those products. However, there have been changes to the patent laws and proposed changes to the rules of the U.S. Patent and Trademark Office, which may impact our ability to protect our technology and enforce our intellectual property rights. For example, in 2011, the United States enacted sweeping changes to the U.S. patent system under the Leahy-Smith America Invents Act, including changes that would transition the United States from a “first-to-invent” system to a “first-to-file” system and alter the processes for challenging issued patents. These changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

We believe that factors such as the technological and creative skills of our personnel, strategic relationships, new product developments, frequent product enhancements and name recognition are essential to our success. All our management personnel are bound by non-disclosure agreements. If personnel leave our employment, in some cases we would be required to protect our intellectual property rights pursuant to common law theories which may be less protective than provisions of employment, non-competition or non-disclosure agreements.

We seek to protect our proprietary products under trade secret and copyright laws, enter into license agreements for various materials and methods employed in our products, and enter into strategic relationships for distribution of the products. These strategies afford only limited protection. We currently have some foreign patents issued, and we are seeking additional patent protection in several other foreign jurisdictions for our DPP and optical technology. We have licenses to reagents (antigens and peptides) used in several of our products and products under development. Despite our efforts to protect our proprietary assets, and respect the intellectual property rights of others, we participate in several markets where intellectual property rights protections are of little or no value. This can place our products and our company at a competitive disadvantage.

Moreover, issued patents remain in effect for a fixed period and after expiration will not provide protection of the inventions they cover. Once our patents expire, we may be faced with increased competition, which could reduce our revenues. We may also not be able to successfully protect our rights to unpatented trade secrets and know-how.

To facilitate development and commercialization of a proprietary technology base, we may need to obtain additional licenses to patents or other proprietary rights from other parties. Obtaining and maintaining these licenses, which may not be available, may require the payment of up-front fees and royalties. In addition, if we are unable to obtain these types of licenses, our product development and commercialization efforts may be delayed or precluded.

Any future intellectual property disputes could require significant resource and limit or eliminate our ability to sell products or use certain technologies.

We may be required to expend substantial resources in asserting or protecting our intellectual property rights, or in defending suits related to intellectual property rights. We may seek to enforce our patents or other intellectual property rights through litigation. Such litigation is prevalent and is expected to continue. In our business, there are a large number of patents and patent applications similar to our products, and additional patents may be issued to third parties relating to our product areas. We, our customers or our suppliers may be sued for infringement of patents or misappropriation of other intellectual property rights with respect to one or more of our products. We may also have disputes with parties that license patents to us if we believe the license is no longer needed for our products or the licensed patents are no longer valid or enforceable.

There are a large number of patents in our industry, and the claims of these patents appear to overlap in many cases. Therefore there is a significant amount of uncertainty regarding the extent of patent protection and infringement. Companies may have pending patent applications, which are typically confidential for the first eighteen months following filing that cover technologies we incorporate in our products. Accordingly, we may be subjected to substantial damages for past infringement or be required to modify our products or stop selling them if it is ultimately determined that our products infringe a third party's proprietary rights. In addition, governmental agencies could commence investigations or criminal proceedings against our employees or us relating to claims of misuse or misappropriation of another party's proprietary rights.

If we are involved in litigation or other legal proceedings with respect to patents or other intellectual property and proprietary technology, it could adversely affect our revenues, results of operations, market share and business because (1) it could consume a substantial portion of managerial and financial resources; (2) its outcome would be uncertain and a court may find that our patents are invalid or unenforceable in response to claims by another party or that the third-party patent claims are valid and infringed by our products; (3) the pendency of any litigation may in and of itself cause our distributors and customers to reduce or terminate purchases of our products; (4) a court could award a preliminary and/or permanent injunction, which would prevent us from selling our current or future products; and (5) an adverse outcome could subject us to the loss of the protection of our patents or to liability in the form of past royalty payments, penalties, reimbursement of litigation costs and legal fees, special and punitive damages, or future royalty payments, any of which could significantly affect our future earnings.

Under certain contracts with third parties, we may indemnify the other party if our products or activities have actually or allegedly infringed upon, misappropriated or misused another party's proprietary rights. Furthermore, our products may contain technology provided to us by third parties, and we may be unable to determine in advance whether such technology infringes the intellectual property rights of a third party. These other parties may also not be required or financially able to indemnify us in the event that an infringement or misappropriation claim is asserted against us.

There may also be other types of disputes that we become involved in regarding intellectual property rights, including state, federal or foreign court litigation, and patent interference, patent reissue, patent reexamination, or trademark opposition proceedings in the United States Patent and Trademark Office. Opposition or revocation proceedings could be instituted in a foreign patent office as well. These proceedings permit certain persons to challenge the validity of a patent on the grounds that it was known from the prior art. The filing of such proceedings, or the issuance of an adverse decision in such proceedings, could result in the loss of valuable patent rights that could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Risks Related to Our Reliance on Third Parties

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

We purchase certain HIV antigens, a syphilis antigen, COVID-19 antibodies and antigens, the nitrocellulose, and certain other critical components used in our STAT-PAK, STAT-VIEW, SURE CHECK and DPP product lines from a sole or limited number of sources. If for any reason these suppliers become unwilling or unable to supply our antigen, nitrocellulose, or other critical component needs, we believe that alternative supplies could be obtained at a competitive cost. However, a change in any of the antibodies, antigens, nitrocellulose or other critical components used in our products would require additional development work and clinical trials, as well as approval by the FDA and other regulatory agencies. In addition, it may be difficult to find such an alternate supply source in a reasonable time period or on commercially reasonable terms, if at all. As a result, the termination or limitation of our relationship with one or more of these suppliers could require significant time to complete, increase our costs, and disrupt or discontinue our ability to manufacture and sell the affected products. In addition, governmental purchasers or funding programs in a particular country may require that we purchase key components from suppliers in that country, which could significantly limit our ability to obtain the components with the quality, and at the price, we seek.

With some of these suppliers, we do not have long-term agreements and instead purchase components and materials through a purchase order process. As a result, these suppliers may stop supplying us components and materials, limit the allocation of supply and equipment to us due to increased industry demand, or significantly increase their prices at any time with little or no advance notice. Our reliance on a limited number of suppliers could also result in delivery problems, reduced control over product pricing and quality, and our inability to identify and qualify another supplier in a timely manner.

Moreover, some of these suppliers may experience financial difficulties that could prevent them from supplying us with components or subassemblies used in the design and manufacture of our products. In addition, these suppliers may experience manufacturing delays or shut downs due to circumstances beyond their control, such as complications related to COVID-19, labor issues, political unrest or natural disasters.

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

Our ability to grow our business will be limited if we fail to maintain existing distribution channels or develop new distribution channels.

We collaborate with laboratories, diagnostic companies and distributors in order to sell our products. The sale of our products depends in large part on our ability to sell products to these customers and on the marketing and distribution abilities of the companies with which we collaborate and work with.

Relying on distributors or third parties to market and sell our products could negatively impact our business for various reasons, including: (1) we may not be able to find suitable distributors for our products on satisfactory terms, or at all; (2) agreements with distributors may prematurely terminate or may result in litigation between the parties; (3) our distributors or other customers may not fulfill their contractual obligations and distribute our products in the manner or at the levels we expect; (4) our distributors may prioritize their own private label products that compete with our products; (5) our existing distributor relationships or contracts may preclude or limit us from entering into arrangements with other distributors; and (6) we may not be able to negotiate new or renew existing distribution agreements on acceptable terms, or at all.

We will try to maintain and expand our business with distributors and customers and make every effort to require that they fulfill their contractual obligations, but there can be no assurance that such companies will do so or that new distribution channels will be available on satisfactory terms. If we are unable to do so, our business will be negatively impacted.

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 Zika, and our growth strategy may target sales to U.S. government entities. As a result of 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. 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.

A violation of specific laws and regulations could result in the imposition of fines and penalties or the termination of our contracts, as well as suspension or debarment. The suspension or debarment in any particular case may be limited to the facility, contract or subsidiary involved in the violation or could be applied to our entire enterprise in certain severe circumstances. Even a narrow scope suspension or debarment could result in negative publicity that could adversely affect our ability to renew contracts and to secure new contracts, both with the U.S. government and private customers, which could materially and adversely affect our business and results of operations. Fines and penalties could be imposed for failing to follow procurement integrity and bidding rules, employing improper billing practices or otherwise failing to follow rules relating to billing on cost-plus contracts, receiving or paying kickbacks, or filing false claims, among other potential violations. In addition, we could suffer serious reputational harm and the value of our common stock could be negatively affected if allegations of impropriety related to such contracts are made against us.

Risks Related to Regulations

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

Our COVID-19 Diagnostic Test Systems are subject to regulations of the FDA and other regulatory requirements, including ANVISA, Brazil's health regulatory agency. The regulations regarding the manufacture and sale of COVID-19 Diagnostic Test Systems may be unclear and are subject to recurring change. Newly promulgated regulations could require changes to COVID-19 Diagnostic Test Systems, necessitate additional procedures, or make it impractical or impossible for us to market COVID-19 Diagnostic Test Systems for certain uses, in certain markets, or at all. The FDA and other regulatory authorities also have the ability to impose new or additional requirements relating to the COVID-19 Diagnostic Test Systems. The implementation of such changes or new or additional requirements may result in a substantial additional costs and could delay or make it more difficult or complicated to sell our products.

On February 4, 2020, the U.S. Department of Health and Human Services issued a declaration that the threat to public health posed by COVID-19 justify the emergency use of unapproved in vitro diagnostics for the detection or diagnosis of SARS-CoV-2. Under Section 564 of the Food, Drug, and Cosmetic Act, because the U.S. Department of Health and Human Services has issued this declaration, the Commissioner of the FDA is authorized to issue EUAs to permit certain developers of SARS-CoV-2 diagnostics to begin offering the tests for detection and diagnosis of COVID-19 without having completed the normally applicable FDA review and clearance or approval process for marketing authorization. We received an EUA for the DPP COVID-19 IgM/IgG System on April 14, 2020, which was subsequent revoked by the FDA on June 16, 2020. Such revocation precludes the sale of DPP COVID-19 IgM/IgG Systems in the United States unless and until a further regulatory approval or authorization is obtained. We have not received a subsequent EUA for any of the COVID-19 Diagnostic Test Systems, and we do not currently have an application pending for any such EUA. Moreover, market and regulatory requirements continue to change at a rapid pace. The FDA has announced, for example, that it intends to update its EUA templates with additional considerations related to the impact of genetic variants on test performance as the FDA learns more about the COVID-19 disease and its knowledge in this area progresses. The time required to obtain marketing authorizations and other approvals from regulatory authorities is unpredictable. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can change, and do often change, during development, which makes it difficult to predict with any certainty how they will be applied. If we make future submissions to the FDA, we may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA policy during the period of FDA regulatory review. There can be no assurance that if we are to make a submission of any future EUA application, we will be successful in obtaining an EUA that would permit us to offer and sell any COVID-19 Diagnostic Test System in the United States.

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

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

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

Because we may not be able to obtain or maintain the necessary regulatory approvals for some of our products, we may not generate revenues in the amounts we expect, or in the amounts necessary to continue our business. Our existing products as well as our manufacturing facility must meet quality standards and are subject to inspection by a number of domestic regulatory and other governmental and non-governmental agencies.

All of our proposed and existing products are subject to regulation in the United States by the FDA, the U.S. Department of Agriculture, and/or other domestic and international governmental, public health agencies, regulatory bodies or non-governmental organizations. In particular, we are subject to strict governmental controls on the development, manufacture, labeling, distribution and marketing of our products. The process of obtaining required approvals or clearances varies according to the nature of, and uses for, a specific product. These processes can involve lengthy and detailed laboratory testing, human or animal clinical trials, sampling activities, and other costly, time-consuming procedures. The submission of an application to a regulatory authority does not guarantee that the authority will grant an approval or clearance for that product. Each authority may impose its own requirements and can delay or refuse to grant approval or clearance, even though a product has been approved in another country.

The time taken to obtain approval or clearance varies depending on the nature of the application and may result in the passage of a significant period of time from the date of submission of the application. As an example, the time required to obtain an EUA from the FDA for COVID-19 tests has lengthened markedly over the past months due to, among other things, application volume. Delays in the approval or clearance processes increase the risk that we will not succeed in introducing or selling the subject products, and we may determine to devote our resources to different products.

Changes or developments in government regulations, policies or interpretations could increase our costs and could require us to undergo additional trials or procedures, or could make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all. 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 EUA was granted on April 14, 2020. We do not currently have an EUA from the FDA for any of the COVID-19 Diagnostic Test Systems, and we do not currently have an application pending for any such EUA. Moreover, FDA regulations, policies and procedures with respect to COVID-19 tests may be significantly impacted by the availability of vaccines for COVID-19 and changes in the FDA's prioritization guidance. Similarly, the regulatory pathway to 510(k) clearance by the FDA for COVID-19 tests is unclear in light of limited FDA feedback resulting in part from the FDA's constrained resources.

Changes in government regulations may adversely affect our financial condition and results of operations because we may have to incur additional expenses if we are required to change or implement new testing, manufacturing and control procedures. If we are required to devote resources to develop such new procedures, we may not have sufficient resources to devote to research and development, marketing, or other activities that are critical to our business. We are, for example, expending resources to modify the design of the COVID-19 Diagnostic Test System to achieve performance targets consistent with the FDA's performance criteria issued subsequent to the granting of our original EUA.

We can manufacture and sell our products only if we comply with regulations and quality standards established by government agencies such as the FDA and the U.S. Department of Agriculture as well as by non-governmental organizations such as the International Organization for Standardization, or ISO, and WHO. We have implemented a quality control system that is intended to comply with applicable regulations. Although FDA approval is not required for the export of our products, there are export regulations promulgated by the FDA that specifically relate to the export of our products that require compliance with the FDA's quality system requirements, or QSRs, and that also require meeting certain documentary requirements regarding the approval of the product in export markets. We also may be subject to import regulations in connection with international sourcing of components and materials incorporated in the manufacturing of our products.

If we do not comply with FDA or other regulatory requirements, we may be required to suspend production or sale of our products or institute a recall, which could result in higher costs and a loss of revenues.

Regulations of the FDA and other federal, state and foreign regulatory agencies have significant effects on many aspects of our operations and the operations of our suppliers and distributors, including packaging, labeling, manufacturing, adverse event reporting, recalls, distribution, storage, advertising, promotion and record keeping. We are subject to routine inspection by the FDA and other agencies to determine compliance with FDA regulatory requirements, including QSRs, in the United States and other applicable regulations worldwide, including ISO standards. We believe that our facilities and procedures are in material compliance with the FDA requirements and ISO standards, but the regulations may be unclear and are subject to change, and we cannot be sure that the FDA or other regulators will agree with our compliance with these requirements. The FDA and foreign regulatory agencies may require post-marketing testing and surveillance to monitor the performance of approved or cleared products or impose conditions on any product clearances or approvals that could restrict the distribution or commercial applications of those products. Regulatory agencies may impose restrictions on our or our distributors' advertising and promotional activities or preclude these activities altogether if a noncompliance is believed to exist. In addition, the subsequent discovery of previously unknown problems with a product may result in restrictions on the product or additional regulatory actions, including withdrawal of the product from the market.

Our inability to comply with the applicable requirements of the FDA can result in, among other things, 483 notices, warning letters, administrative or judicially imposed sanctions such as injunctions, recall or seizure of products, civil penalties, withdrawal of product registrations, total or partial suspension of production, refusal to grant premarket clearance for devices, a determination that a device is not approvable, marketing clearances or approvals, or criminal prosecution. For example, in February 2020, we received a "not approvable" letter from the FDA with respect to our premarket approval submission on our DPP HIV-Syphilis multiplex test for commercial use in the United States, in June 2020 we received notice from the FDA that the EUA for the DPP COVID-19 IgM/IgG System had been revoked, and in January 2021 we received notice from the FDA that it was declining to review the DPP SARS-CoV-2 Antigen System based on its updated prioritization guidance, under which review of the system was not a priority. The ability of our suppliers to supply critical components or materials and of our distributors to sell our products could also be adversely affected if their operations are determined to be out of compliance. Such actions by the FDA and other regulatory bodies could adversely affect our revenues, costs and results of operations.

We must frequently make judgment decisions with respect to compliance with applicable laws and regulations. If regulators subsequently disagree with how we have sought to comply with these regulations, we could be subjected to substantial civil and criminal penalties, as well as product recall, seizure or injunction with respect to the sale of our products. Our reputation could be substantially impaired if we are assessed any civil and criminal penalties and limit our ability to manufacture and market our products which could have a material adverse effect on our business.

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, 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 do not currently have an EUA from the FDA for any of the COVID-19 Diagnostic Test Systems, and we do not currently have an application pending for any such EUA. 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.

Demand for our products may be affected by FDA regulation of laboratory-developed tests.

Regulatory responsibility over instruments, test kits, reagents and other devices used to perform diagnostic testing by clinical laboratories is covered by the FDA, including our Micro Reader analyzer. The FDA has previously taken the position that it has regulatory authority over laboratory-developed tests, or LDTs, but has exercised enforcement discretion by not regulating most LDTs performed by high complexity CLIA-certified laboratories. LDTs are tests designed, developed, and performed in-house by a laboratory. These laboratories are subject to CLIA regulation but such laboratories have previously not been subject to regulation by the FDA under the agency's medical device requirements.

The FDA announced that it would begin regulating LDTs, and in October 2014 the FDA issued proposed guidance on the regulation of LDTs for public comment. In November 2016, however, the FDA announced it would not finalize the proposed guidance prior to the end of the Obama administration. In January 2017 the FDA released a discussion paper synthesizing public comments on the 2014 draft guidance documents and outlining a possible approach to regulation of LDTs. The discussion paper has no legal status and does not represent a final version of the LDT draft guidance documents. We cannot predict what policies the Biden administration will adopt with respect to LDTs. If the FDA increases regulation of LDTs, it could make it more difficult for laboratories and other customers to continue offering LDTs that involve molecular testing. This, in turn, could reduce demand for our products and adversely impact our revenues.

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

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

Separately, in response to the global COVID-19 pandemic, on January 29, 2021, the FDA announced its intention to resume inspections of manufacturing facilities and products, that would be deemed "mission-critical." The FDA's assessment of whether an inspection is mission-critical considers many factors related to the public health benefit of U.S. patients having access to the product subject to inspection. These factors include, but are not limited to, whether the products have received breakthrough therapy designation or regenerative medicine advanced therapy designation, or are products used to diagnose, treat, or prevent a serious disease or medical condition for which there is no other appropriate substitute. Both for-cause and pre-approval inspections can be deemed mission-critical. When determining whether to conduct a mission-critical inspection, FDA takes into account concerns about the safety of its investigators, employees at a site or facility, and where applicable, clinical trial participants and other patients at investigator sites. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

In addition to FDA requirements, we are subject to numerous other federal, state and foreign government regulations, compliance with which could increase our costs and affect our operations.

In addition to the FDA regulations previously described, other federal, state and foreign laws and regulations may restrict our ability to sell products in those jurisdictions.

We must comply with numerous laws related to safe working conditions, environmental protection, disposal of hazardous substances, fire hazard control, manufacturing practices and labor or employment practices. Compliance with these laws or any new or changed laws regulating our business could result in substantial costs. Due to the number of laws and regulations governing our industry, and the actions of a number of government agencies that could affect our operations, it is impossible to reliably predict the full nature and impact of these laws and regulations. To the extent the costs and procedures associated with complying with these laws and requirements are substantial or it is determined that we do not comply, our business and results of operations could be adversely affected.

Ongoing changes in healthcare regulation could negatively affect our revenues, business and financial condition.

There have been several proposed changes in the United States at the federal and state level for comprehensive reforms regarding the payment for, the availability of and reimbursement for healthcare services. These proposals have ranged from fundamentally changing federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under government-funded programs, to minor modifications to existing programs. One example is the Patient Protection and Affordable Care or the Affordable Care Act, the Federal healthcare reform law enacted in 2010.

Healthcare reform initiatives will continue to be proposed, and may reduce healthcare related funding in an effort. It is impossible to predict the ultimate content and timing of any healthcare reform legislation and its resulting impact on us. If significant reforms are made to the healthcare system in the United States, or in other jurisdictions, those reforms may increase our costs or otherwise negatively effect on our financial condition and results of operations.

In April 2017 the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the European Union Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the European Economic Area, or EEA, member States, the regulations would be directly applicable (without the need for adoption of EEA member State laws implementing them) in all EEA member States in order to eliminate current differences in the regulation of medical devices among EEA member States. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The Medical Devices Regulation will, however, only become fully applicable three years after publication (in May 2020). Once applicable, the Medical Devices Regulation will, among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the E.U.; and
- strengthen rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

Once applicable, the Medical Devices Regulation may impose increased compliance obligations for us to access the E.U. market.

We may incur additional costs if we do not comply with privacy, security and breach notification regulations.

We believe that we are not a covered entity nor a business associate of a covered entity and are not responsible for complying with the Health Insurance Portability and Accountability Act of 1996, or HIPAA. Even though we likely are not a covered entity under HIPAA, we do have in place administrative, technical and physical safeguards to protect the privacy and security of consumers' personal information. We are required to comply with varying state privacy, security and breach reporting laws. If we fail to comply with existing or new laws and regulations related to properly transferring data containing consumers' personal information, we could be subject to monetary fines, civil penalties or criminal sanctions. Also, there are other federal and state laws that protect the privacy and security of consumers' personal information, and we may be subject to enforcement by various governmental authorities and courts resulting in complex compliance issues. We could incur damages under state laws pursuant to an action brought by a private party for the wrongful use or disclosure of consumers' personal information.

Failure to comply with recent European data protection requirements could increase our costs.

The E.U. has adopted a comprehensive overhaul of its data protection regime from the prior national legislative approach to a single European Economic Area Privacy Regulation called the General Data Protection Regulation, or GDPR, which came into effect on May 25, 2018. The new E.U. data protection regime extends the scope of the E.U. data protection law to all foreign companies processing data of E.U. residents. It imposes a strict data protection compliance regime with severe penalties of up to the greater of 4% of worldwide turnover and €20 million and includes new rights such as the "portability" of personal data. Although the GDPR will apply across the E.U. without a need for local implementing legislation, as had been the case under the prior data protection regime, local data protection authorities will still have the ability to interpret the GDPR, which has the potential to create inconsistencies on a country-by-country basis. We are evaluating these new requirements and implementing a plan to ensure compliance. Complying with the enhanced obligations imposed by the GDPR may result in significant costs to our business and require us to amend certain of our business practices. Further, we have no assurances that violations will not occur, particularly given the complexity of the GDPR, as well as the uncertainties that accompany new, comprehensive legislation.

If we are not able to manufacture products in accordance with applicable requirements, it could adversely affect our business.

Our products must meet detailed specifications, performance standards and quality requirements. As a result, our products and the materials used in their manufacture or assembly undergo regular inspections and quality testing. Factors such as defective materials or processes, mechanical failures, human errors, environmental conditions, changes in materials or production methods, and other events or conditions could cause our products or the materials used to produce or assemble our products to fail inspections and quality testing or otherwise not perform in accordance with our label claims or the expectations of our customers.

If we are not able to meet the applicable specifications, performance standards, quality requirements or customer expectations could adversely affect our ability to manufacture and sell our products or comply with regulatory requirements. These events could, in turn, adversely affect our revenues and results of operations.

Healthcare fraud and abuse laws could adversely affect our business and results of operations.

There are various federal and state laws targeting fraud and abuse in the healthcare industry to which we are subject, including anti-kickback laws, laws constraining the sales, false claims laws, marketing and promotion of medical devices by limiting the kinds of financial arrangements that manufacturers of these products may enter into with physicians, hospitals, laboratories and other potential purchasers of medical devices. There are other laws we are subject to that require us to report certain transactions between it and healthcare professionals. Violations of these laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in government healthcare programs. Many of the existing requirements are new and have not been definitively interpreted by state authorities or courts, and available guidance is limited. We could face enforcement action and fines and other penalties, and could receive adverse publicity, unless and until we are in full compliance with these laws, all of which could materially harm us. Furthermore, changes in or evolving interpretations of these laws, regulations, or administrative or judicial interpretations, may require us to change our business practices or subject our business practices to legal challenges, which could have a material adverse effect on our business, financial condition and results of operations.

Our compliance with regulations governing public companies is complex and expensive.

Public companies are subject to various laws and regulations, which have increased the scope, complexity and cost of corporate governance, reporting and disclosure practices. For example, we are subject to the Sarbanes-Oxley Act of 2002, The Dodd-Frank Wall Street Reform and Consumer Protection Act and the requirements of The NASDAQ Global Market. The implementation of certain aspects of these laws and regulations has required and will continue to require substantial management time and oversight and may require us to incur significant additional accounting and legal costs. We continually review changes with respect to new and proposed rules and cannot predict or estimate the amount of additional costs, and the timing of such costs, we may incur. There are several interpretations of these laws and regulations, in many cases due to their lack of specificity, and as a result, their application in practice may change as new guidance is provided by regulatory and governing bodies. This may result in continuing uncertainty regarding compliance matters and higher costs. We are committed to maintaining high standards of corporate governance and public disclosure, but if we fail to comply with any of these requirements, legal proceedings may be initiated against us, which may adversely affect our business.

If we expand our international presence, it may increase our risks and expose our business to regulatory, cultural or other challenges.

There are several of factors that could adversely affect the performance of our business and/or cause us to incur substantially increased costs because of our international presence and sales, including: (1) uncertainty in the application of foreign laws and the interpretation of contracts with foreign parties; (2) cultural and political differences that favor local competitors or make it difficult to effectively market, sell and gain acceptance of our products; (3) exchange rates, currency fluctuations, tariffs and other barriers, extended payment terms and dependence on international distributors or representatives; (4) trade protection measures, trade sanctions and import/export licensing requirements; (5) our inability to obtain or maintain regulatory approvals or registrations for our products; (6) economic conditions, political instability, the absence of available funding sources, terrorism, civil unrest, war and natural disasters in foreign countries; (7) reduced protection for, or enforcement of, our patents and other intellectual property rights in foreign countries; (8) our inability to identify international distributors and negotiate acceptable terms for distribution agreements; and (9) restrictions on our ability to repatriate investments and earnings from foreign operations.

Economic, cultural and political conditions and foreign regulatory requirements may slow or prevent the manufacture of our products in countries other than the United States. Interruption of the supply of our products could reduce revenues or cause us to incur significant additional expenses in finding an alternative source of supply. Foreign currency fluctuations and economic conditions in foreign countries could also increase the costs of manufacturing our products in foreign countries.

Risks Related to Ownership of Common Stock

Our common stock may have limited liquidity, and investors may not be able to sell as much stock as they want at prevailing market prices or at all.

The liquidity of our common stock depends on several factors, including our financial results and overall market conditions, so it is not possible to predict whether this level of liquidity will continue, be sustained, or decrease. Decreased trading volume in our stock would make it more difficult for investors to sell their shares in the public market at any given time at prevailing prices. Our management and larger stockholders exercise significant control over our company.

The price of our common stock could continue to be volatile.

The price of our common stock has been volatile, subject to rapid and substantial decreases in stock price, and may be volatile in the future. During the first quarter of 2021, the closing price of our common stock ranged from $7.97 on February 9, 2021 to $3.40 on March 30, 2021, with no discernable announcements or developments by us or third parties. On January 26, 2021, the intra-day sales price of our common stock fluctuated between a reported low sale price of $6.34 and a reported high sales price of $8.75. The following factors, among others, could have a significant impact on the market for our common stock: (1) the performance of our business; (2) clinical results with respect to our products or those of our competitors; (3) the gain or loss of significant contracts and availability of funding for the purchase of our products; (4) actions undertaken by the Congress or the Presidential Administration; (5) changes in our relations with our key customers, distributors or suppliers; (6) developments in patent or other proprietary rights; (7) litigation or threatened litigation; (8) general market and economic conditions; (9) the relatively low trading volume for our common stock; (10) changes in competition; (11) complaints or concerns about the performance or safety of our products and publicity about those issues, including publicity expressed through social media or otherwise over the internet; (12) failure to achieve, or changes in, financial estimates by securities analysts and comments or opinions about us by securities analysts or major stockholders; (13) announcement of regulatory or enforcement actions by the FDA or other agencies against us, our products or our customers; (14) changes in our operating results; (15) terrorist attacks, civil unrest, war and national disasters; and (16) other factors unrelated to our operating performance or prospects.

Overall, the stock market has experienced price and volume fluctuations that have affected the market price of our common stock, as well as the stock of many other similar companies. Such price fluctuations are generally unrelated to the operating performance of the specific companies whose stock is affected.

After the volatility in the market price of a company’s stock, class action litigation has occurred against the issuing company, which could cause us to incur substantial costs and could divert the attention and resources of our management, each of which could have a material adverse effect on our revenue and earnings. Any adverse determination in this type of litigation could also subject us to significant liabilities.

Our common stock may become the target of a “short squeeze.”

Securities of certain companies have increasingly experienced significant and extreme volatility in stock price due to short sellers of shares of common stock, known as a “short squeeze.” Short squeezes have caused extreme volatility in those companies and in the market and have led to the price per share of those companies to trade at a significantly inflated rate that is disconnected from the underlying value of the company. Sharp rises in a company’s stock price may force traders in a short position to buy the stock to avoid even greater losses. Many investors who have purchased shares in those companies at an inflated rate face the risk of losing a significant portion of their original investment as the price per share has declined steadily as interest in those stocks have abated. There can be no assurance that we will not, in the future be, a target of a short squeeze, and you may lose a significant portion or all of your investment if you purchase our shares at a rate that is significantly disconnected from our underlying value.

Any future issuances of shares of our common stock by us could harm the price of our common stock and our ability to raise funds in new equity offerings.

Any future sales of a substantial number of our shares of common stock or other equity-related securities, or the perception that such sales may occur, could adversely affect the price of our common stock, and could impair our ability to raise capital through future offerings of equity or equity-related securities.

Sales of our common stock by existing stockholders, executive officers or directors could depress the market price of our common stock.

If our existing stockholders, officers or directors sell our common stock in the public market, or the perception that such sales may occur, it could negatively affect the price of our common stock. We are unable to estimate the number of shares of our common stock that may actually be resold in the public market since this will depend on the market price for our common stock, the individual circumstances of the sellers and other factors.

Institutional stockholders own significant amounts of our common stock. If one or more of these stockholders sell large portions of their holdings in a relatively short time, the prevailing price of our common stock could be negatively affected. In addition, it is possible that one or more of our executive officers or non-employee members of our Board of Directors could sell shares of our common stock during an open trading window. These transactions and the perceived reasons for these transactions could have a negative effect on the prevailing market price of our common stock.

We do not intend to pay cash dividends on our common stock.

We do not expect to pay any cash dividends on our common stock and currently intend to retain our earnings, if any, to finance the expansion of our business. Therefore, the success of an investment in our common stock will depend entirely upon any future increase in value of our common stock. There is no guarantee that our common stock will gain value or even maintain the price at which investors purchased their shares.

General Risk Factors

We may not generate the expected benefits of future acquisitions or investments, and they could disrupt our ongoing business, distract our management, increase our expenses and negatively affect our business.

As a way for us to grow our business, we may pursue strategic acquisitions or investments. These activities, and their impact on our business, are subject to many risks, including the following: (1) the benefits expected to be derived from an acquisition or investment may not materialize and could be affected by numerous factors, such as regulatory developments, insurance reimbursement, our inexperience with new businesses or markets, general economic conditions and increased competition; (2) we may be unable to successfully integrate an acquired company's personnel, assets, management, information technology systems, accounting policies and practices, products and/or technology into our business; (3) we may not be able to accurately forecast the performance or ultimate impact of an acquired business; and (4) an acquisition may result in the incurrence of unexpected expenses, stockholder lawsuits, the dilution of our earnings or our existing stockholders' percentage ownership, or potential losses from undiscovered liabilities not covered by an indemnification from the seller(s) of the acquired business.

If these factors occur, we may be unable to achieve all or a significant part of the benefits expected from an acquisition or investment. This may adversely affect our financial condition, results of operations and ability to grow our business or otherwise achieve our financial and strategic objectives.

Our business may be negatively affected by terrorist attacks or natural disasters.

Terrorist attacks or natural disasters could cause economic instability. These events could negatively affect economic conditions both within and outside the United States and harm demand for our products. The operations of our customers and suppliers could be negatively impacted and eliminate, reduce or delay our customers' ability to purchase and use our products and our suppliers' ability to provide raw materials and finished products.

Our facilities, including some pieces of manufacturing equipment and our computer systems, may be difficult to replace. Various types of disasters, including fires, earthquakes, floods and acts of terrorism, may affect our facilities and computer systems. In the event our existing facilities or computer systems are affected by man-made or natural disasters, we may have difficulty operating our business and may be unable to manufacture products for sale or meet customer demands or sales projections.

We have consolidated our U.S. operations, including all of our manufacturing operations, at our facilities in Medford, New York, and Hauppauge, New York, and we are not seeking to maintain redundant manufacturing or other facilities at another site. This consolidation could heighten the adverse impact of any terrorist attack or natural disaster that were to occur at our Medford or Hauppauge facilities, which are approximately 16 miles apart. In particular, if our manufacturing operations were curtailed or shut down entirely, it would seriously harm our business. There can be no assurance that all or a substantial portion of the costs and expenses were would incur from a terrorist attack or natural disaster would be covered by our existing casualty, business interruption or other insurance policies.

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 Inline XBRL document)

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SIGNATURES

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

Chembio Diagnostics, Inc.

Date: May 6, 2021

By: /s/ Richard L. Eberly

Richard L. Eberly
Chief Executive Officer and President

Date: May 6, 2021

By: /s / Neil A. Goldman

Neil A. Goldman
Chief Financial Officer and Executive Vice President

Exhibit 31.1

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

I, Richard L. Eberly, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 6, 2021

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

Exhibit 31.2

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

I, Neil A. Goldman, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 6, 2021

/s/ Neil A. Goldman

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Chembio Diagnostics, Inc. for the quarterly period ended March 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge on the date hereof:

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

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

Date: May 6, 2021

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

Date: May 6, 2021

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

The foregoing certification is being furnished solely pursuant to 18 U.S.C. § 1350 and is not being filed as part of the Report or as a separate disclosure document.