UNITED STATES
Securities and Exchange Commission
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2021
or

☐ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____.

Commission File No.0-30379

CHEMBIO DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	88-0425691
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
555 Wireless Boulevard, Hauppauge, NY	11788
(Address of principal executive offices)	(Zip Code)

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

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

Securities registered pursuant to Section 12(g) of the Act:
None
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by checkmark whether the registrant has filed a report on and attestation to it's management's assessment of the effectiveness of internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☒ No ☐

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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 ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☒
	Emerging growth 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 ☐

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 the last business day of the registrant’s most recently completed fiscal quarter, the aggregate market value of voting and non-voting common equity held by non-affiliates was $0.

As of March 3, 2022, the registrant had 30,056,929 shares of common stock outstanding.

Documents Incorporated By Reference

Portions of the registrant’s proxy statement for its 2021 annual meeting of stockholders are incorporated by reference in Part III of this report.

TABLE OF CONTENTS

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

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

FORWARD-LOOKING STATEMENTS AND STATISTICAL ESTIMATES

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

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

Forward-looking statements and statistical estimates inherently involve risks and uncertainties that could cause actual results to differ materially from those predicted or expressed in this report. These risks and uncertainties include those described in "Item 1A. Risk Factors" of Part I of this report. You should interpret many of the identified risks and uncertainties as being heightened as a result of the ongoing and numerous adverse impacts of the COVID-19 pandemic. Investors are cautioned not to place undue reliance on any forward-looking statements 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. BUSINESS

Overview

We develop and commercialize point-of-care diagnostic tests used for the rapid detection and diagnosis of infectious diseases, including sexually transmitted disease, insect vector and tropical disease, COVID-19 and other viral and bacterial infections, enabling expedited treatment.
Our product portfolio is based upon our proprietary DPP technology, a diagnostic platform that provides high-quality, cost-effective results in 15 to 20 minutes using fingertip blood, nasal swabs and other sample types. The DPP technology platform addresses the rapid diagnostic test market, which includes infectious diseases such as STI's and HIV, Gastroenterology and Women's Health. Compared with traditional lateral flow technology, the DPP technology platform can provide:

- **Enhanced sensitivity and specificity:** This is achieved via our patented approach to separating the sample path from the buffer path, together with other patented and proprietary strategies, that differ significantly from traditional lateral flow test.

- **Advanced multiplexing capabilities:** Through advanced multiplexing, the DPP platform can detect and differentiate up to eight distinct test results from a single patient sample, which can deliver greater clinical value than other rapid tests currently on the market.

- **Objective results:** For some diagnostic applications, our easy-to-use, highly portable, battery-operated DPP Micro Reader optical analyzers can report accurate results in approximately 15 seconds, making it well-suited for decentralized testing where real-time results enable patients to be clinically assessed while they are still 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.

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

- *an emergency use authorization, or EUA, from the U.S. Food and Drug Administration, or FDA, as well as 510(k) clearance from the FDA, for the DPP SARS-CoV-2 Antigen test system;*

- *an EUA from the FDA for the DPP Respiratory Antigen Panel; and*

- *a Clinical Laboratory Improvement Amendment, or CLIA, waiver from the FDA for the DPP HIV-Syphilis test system.*

For additional information about our existing and proposed product offerings, please see "—Products" below. Our products are sold globally, directly and through distributors, to medical laboratories and hospitals, governmental and public health entities, nongovernmental organizations, medical professionals, and retail establishments. We continue to seek to expand our commercial distribution channels.

The extensive economic disruption caused by the COVID-19 pandemic, exacerbated by the market and regulatory complications we faced in seeking to develop and commercialize a portfolio of COVID-19 test systems, was reflected in our operating results for 2021, as total revenues were $47.8 million, an increase of 47.3% from 2020, and net product sales were $34.8 million, an increase of 40.3% from 2020. See “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Consolidated Results of Operations.”

In 2021 we continued to invest in automating our test manufacturing processes, all of which are now based in the United States. Among other actions, we expanded our manufacturing capabilities by validating and implementing automated lines. 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, we continued to execute a program to reduce operating expenses and better align our costs with revenues by eliminating positions that were no longer aligned with our strategy. Our cash and cash equivalents totaled $28.8 million at December 31, 2021, compared to $23.1 million at December 31, 2020.

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

Going Concern Considerations

Revenues during the twelve months ended December 31, 2021 did not meet the Company’s expectations. The Company’s increase in cash and cash equivalents over the year reflected its issuance of common stock in at-the-market offerings for net proceeds of $38.8 million (see Note 9 - Stockholder’s Equity). The Company continued to experience market, clinical trial and regulatory complications in seeking to develop and commercialize a portfolio of COVID-19 test systems during the continuing, but evolving, uncertainty of the COVID-19 pandemic. In the year ending on December 31, 2021, the Company continued to incur significant expenses in connection with pending legal matters (see Note 12 – Commitments, Contingencies, and Concentrations: Litigation), delayed achievement of milestones associated with government grant income, investments in inventory, and the continuing automation of manufacturing.

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

During the twelve months ended December 31, 2021, the Company undertook measures to increase its total revenues and improve its liquidity position. In particular, the Company received significant purchase orders from two customers (the “July Purchase Orders”). The Company had pursued the July Purchase Orders for an extended period of time. The July Purchase Orders consist of the following:

- On July 20, 2021, the Company received a $28.3 million purchase order from Bio-Manguinhos for the purchase of DPP SARS-CoV-2 Antigen tests for delivery during 2021 to support the urgent needs of Brazil’s Ministry of Health in addressing the COVID-19 pandemic. Bio-Manguinhos, is responsible for the development and production of vaccines, diagnostics and biopharmaceuticals, primarily to meet the demand of Brazil’s national public health system. As of December 31, 2021 $16.8 million was recognized in connection with this order.

- On July 22, 2021, the Company received a $4 million purchase order from the Partnership for Supply Chain Management, supported by The Global Fund, for the purchase of HIV 1/2 STAT-PAK Assays for shipment to Ethiopia into early 2022. As of December 31, 2021 $1.2 million was recognized in connection with this order.

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

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

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

The Company further considered how these factors and uncertainties could impact its ability over the next year to meet the obligations specified in the Credit Agreement with the Lender (each as defined in Note 13 – Long-Term Debt). Those obligations include covenants requiring: 1) minimum cash balance of $3.0 million and ii) minimum total revenue amounts for the twelve months preceding each quarter end. For the next year, the minimum total revenue requirements range from $42.0 million for the twelve months ending March 31, 2022 to $47.4 million for the twelve months ending December 31, 2022. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. In such an event, there can be no assurance that the Company would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, the Company would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. The Company's inability to raise additional capital on acceptable terms in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for its operations, could have a material adverse effect on its business, prospects, results of operations, liquidity and financial condition.

Accordingly, management determined the Company could not be certain that the Company's plans and initiatives would be effectively implemented within one year after the date on which the accompanying consolidated financial statements are being issued. Without giving effect to the prospect of raising additional capital pursuant to the ATM Agreement (as defined in Note 9 – Stockholders' Equity: Common Stock), increasing product revenue in the near future or executing other mitigating plans, many of which are beyond the Company's control, it is unlikely that the Company will be able to generate sufficient cash flows to meet its required financial obligations, including its debt service and other obligations due to third parties. The existence of these conditions raises substantial doubt about the Company's ability to continue as a going concern for the twelve-month period following the date on which the accompanying audited consolidated financial statements are being issued.

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

Industry

The DPP technology platform targets diagnostic disease states; (1) where rapid diagnosis impacts patient treatment and outcomes; (2) that are underserved by current diagnostic products due to performance or availability; (3) that present opportunities regionally, demographically or clinically. The Company is focused on test solutions associated with infectious diseases: respiratory viruses, sexually transmitted diseases, gastroenterology and insect-vector diseases.

Our product portfolio is marketed globally to NGO's, Ministries of Health, acute care hospitals, reference labs, outpatient clinics including urgent cares and physician offices. Our branded products have secured meaningful market share globally and include, SureCheck, Stat Pak and DPP. The Company will focus on internally developed products and pursue external opportunities to license novel technologies and products with the intent of leveraging Chembio's growing commercial infrastructure.

We currently are targeting lateral flow test solutions for infectious diseases: respiratory diseases, sexually transmitted diseases and mosquito-borne diseases. The market for lateral flow infectious disease tests is being driven by the high prevalence of infectious diseases globally, an increase in the elderly population, growing demand for rapid test results, and advancements in multiplexing.

Products

COVID-19 Diagnostic Test Systems

Prior to 2020, our broad portfolio of infectious disease products was focused principally on sexually transmitted disease and fever and tropical disease. In 2020 we shifted substantially all of our resources to leverage the DPP technology platform to address the acute and escalating need for diagnostic testing for COVID-19.

COVID-19 Antibody Test System

In January 2021 we announced the CE mark for both the DPP SARS-CoV-2 Antigen test system and the DPP SARS-CoV-2 IgM/IgG test system, providing regulatory approval to register and market the test systems in the European Union and other geographies that accept the CE mark.

COVID-19 Antigen Test System

In mid-2020 we began to focus on the development of a COVID-19 antigen test system based on DPP technology. In July 2020 we received a $628,071 grant from BARDA to assist us in developing, submitting and obtaining an EUA application for a COVID-19 point-of-care antigen system. In October 2020, with BARDA's support in accordance with its grant, we submitted to the FDA an EUA application for the DPP SARS-CoV-2 Antigen System, a test system that consists of a DPP SARS-CoV-2 Antigen test cartridge, a DPP Micro Reader optical analyzer and a minimally invasive nasal swab.

In November 2020 ANVISA approved the DPP SARS-CoV-2 Antigen test system for use in Brazil. In January 2021 we announced the CE mark for the DPP SARS-CoV-2 Antigen test system, providing regulatory approval to register and market the test systems in the European Union and other geographies that accept the CE mark.

In December 2020 we received a $12.7 million grant from BARDA, in part to support preparation of a submission in pursuit of FDA 510(k) clearance for the DPP SARS-CoV-2 Antigen System.

In January 2021 the FDA notified us 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 FDA has supplementally advised us of the type and nature of information it would need to receive in a subsequent EUA application in order for the DPP SARS-CoV-2 Antigen System to be prioritized for review, and we are engaged in testing and development in order to submit a new EUA application for a COVID-19 antigen test system.

During the year ending December 31, 2021 we performed the clinical trials and on December 2, 2021 we submitted the DPP SARS-CoV-2 Antigen test system to the FDA, as a de Novo submission.

COVID-19 and Influenza Respiratory Antigen Panel Test System

In the fourth quarter of 2020 we began developing a rapid, multiplex respiratory antigen panel point-of-care test system using DPP technology. BARDA designated a portion of its $12.7 million grant in December 2020 for use to support our development, submission and receipt of an EUA for this system.

During 2021, we developed and conducted clinical trials of the DPP Respiratory Antigen Panel, a test system being designed to provide simultaneous, discrete and differential detection of Influenza A, Influenza B and SARS-CoV-2 antigens from a single patient respiratory specimen, such as a nasal swab. The system is intended to enable appropriate clinical management of patients with suspected respiratory infections and to assist in the containment of COVID-19 cases during the flu season. This test system provides results in approximately 20 minutes and is run on the DPP Micro Reader. As of December 31, 2021, we have submitted a request for the EUA approval by the FDA which is currently under review. In addition, as of December 31, 2021, we submitted a request for approval to ANVISA in Brazil and CE in Europe, which has been approved as of the date of this filing.

As a result, we earned $12.5 million of the $12.7 million available under the BARDA Agreement, dated December 2, 2020 with the Biomedical Advanced Research and Development Authority, or BARDA (part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response) with the remaining $0.2 million having not been earned because it was contingent on our receiving an emergency use authorization for the DPP SARS-CoV-2 Antigen by December 2, 2021.

HIV-Syphilis Diagnostic Test Systems

On December 1, 2021, we received notice from the FDA that it would require additional data related to our Clinical Laboratory Improvement Amendment, or CLIA, waiver submission for the DPP HIV-Syphilis test system. We are in active discussions with the FDA in connection with the FDA's review of our submission and we intend to comply with the FDA's request for additional data. The process of seeking additional data will extend, for a currently undeterminable period, our process for seeking a CLIA waiver for the DPP HIV-Syphilis test system.

Core Products

We have obtained FDA approvals and, directly or through our partners, international regulatory approvals for infectious disease tests as follows:

Product	U.S.	International
DPP COVID-19 IgM/IgG System		✓
DPP SARS-CoV-2 IgM/IgG System		✓
DPP SARS-CoV-2 Antigen		✓
DPP HIV 1/2 Assay	✓	✓
DPP HIV-Syphilis System	✓	✓
DPP Syphilis Screen & Confirm Assay		✓
DPP ZCD IgM/IgG System		✓
DPP Dengue NS1 Antigen System		✓
DPP Dengue IgM/IgG System		✓
DPP Zika IgM System	✓	✓
DPP Zika IgM/IgG System		✓
DPP Chikungunya System		✓
DPP Ebola Antigen System	✓ EUA	
DPP Leishmaniasis Assay		✓
DPP Respiratory Antigen Panel		✓
DPP VetTB Assay	✓	
HIV 1/2 STAT-PAK Assay	✓	✓
Chagas STAT-PAK Assay		✓
SURE CHECK HIV 1/2 Assay	✓	✓
SURE CHECK HIV Self-Test		✓

Organic growth in our core infectious disease business is being driven by:

- growth in the overall market for point of care infectious disease tests;
- our increased market penetration in existing markets and channels, including in the United States, Latin America, Africa and Europe;
- our registration of existing and new products in unchartered countries and regions, such as selected countries in Latin America and Southeast Asia;
- our entry into new market segments, such as respiratory tests and international HIV Self-Testing; and
- advances in our product pipeline in infectious disease with key products including tests for COVID-19, a multiplex test for HIV and syphilis in the U.S. market and tests for dengue, zika and chikungunya.

We market and sell both stand-alone and multiplex tests for sexually transmitted infectious diseases, such as HIV and syphilis which continue to be major global public health issues. According to WHO estimates:

- HIV has claimed more than 36 million lives, including 680,000 in 2020. Approximately 37.7 million people were living with HIV at the end of 2020, and 1.5 million were newly infected during 2020.
- There were 18.0 million prevalent cases of syphilis as of 2012, and 5.6 million new infections were estimated to occur annually.
- Elimination of mother-to-child transmission, or MTCT, of both HIV and syphilis is a global health priority. In 2013, 1.9 million pregnant women were infected with syphilis worldwide. Congenital syphilis contributes significantly to infant mortality, accounting for 305,000 annual perinatal deaths worldwide in 2013. Globally, more than 1.4 million pregnant women were infected with HIV as of 2015, and MTCT of HIV is estimated to have resulted in over 150,000 infant cases in 2015.

We are seeking to address the global concerns related to HIV and syphilis co-infection through the development of a novel, multiplex test for both HIV and syphilis. We have developed a DPP HIV-Syphilis multiplex test and received regulatory approvals in the United States and a number of international markets, including Brazil, Europe, Africa, Malaysia and Mexico. We are pursuing a CLIA waiver for the DPP HIV-Syphilis test in the United States.

We also market and sell tests for selected fever and tropical diseases such as Chagas, ebola, leishmaniasis and Zika. The market for lateral flow mosquito-borne diseases includes established markets for disease such as dengue and malaria, which WHO estimates together account for more than 600 million annual infections worldwide. There are also a number of emerging markets for rapid point of care tests for infectious diseases such as burkholderia, chikungunya, lassa, leptospirosis, Marburg, rickettsia and Zika.

Since 2015 we have received over $25.1 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, The Oswaldo Cruz Foundation or FIOCRUZ, and the Foundation for Innovative New Diagnostics, or FIND, as well as U.S. government agencies such as Centers for Disease Control and Prevention, or CDC, the Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services, or BARDA, and the U.S. Department of Agriculture, or USDA.

Several tests in our infectious disease pipeline are approaching commercialization, and several have received initial regulatory approvals:

Product	Collaborator	Phase I Feasibility	Phase II Development	Phase III Verification & Validation	Phase IV Clinical & Regulatory	Phase V Commercial Launch
DPP HIV-Syphilis System (US)	Self-funded	✓	✓	✓	✓	PMA approved
DPP Dengue IgM/IgG System	Self-funded	✓	✓	✓	✓	CE and ANVISA
DPP Dengue NS1 Antigen System	Self-funded	✓	✓	✓	✓	CE and ANVISA pending
DPP Chikungunya IgM/IgG System	Self-funded	✓	✓	✓	✓	CE and ANVISA
DPP Zika Chikungunya Dengue IgM/IgG System	Self-funded	✓	✓	✓	✓	CE and ANVISA
DPP Ebola Antigen System	CDC	✓	✓	✓	✓	FDA-EUA
DPP Fever Assay Asia	FIND	✓	✓	✓	✓	
DPP Fever Assay Africa	Paul Allen Foundation	✓	✓	✓		
DPP Fever Assay Malaysia	Self-funded	✓	✓	✓	✓	
DPP SARS CoV-2 Antigen	BARDA	✓	✓	✓	✓	CE and ANVISA
DPP Respiratory Antigen Panel	BARDA	✓	✓	✓	✓	CE and ANVISA
DPP COVID-19 IgM/IgG System	Self-funded	✓	✓	✓	✓	CE and ANVISA
DPP SARS CoV-2 IgM/IgG System	Self-funded	✓	✓	✓	✓	CE

Sales Channels

Our products are sold globally, both directly and through distributors, to hospitals and clinics, physician offices, clinical laboratories, public health organizations, government agencies and consumers. Historically we marketed and sold our products only into a handful of countries and regions. During 2021, we expanded our U.S.-based sales, customer service, and marketing team to focus on the COVID-19, HIV-Syphilis, and future DPP platform product opportunities. With sales growth as an underlying objective, we are focused on increasing sales in geographies that support higher average selling prices. From lead generation through technical inquiries, Chembio has the internal resources to support customers through the commercial process including marketing, sales, sales support, order entry and product support.

Automation of U.S. Manufacturing

We are automating our U.S. manufacturing processes and expanding our manufacturing capacity. Over the past three years, we have taken delivery of and completed validation of most of our automated manufacturing lines. These use vision-guided, robotic operation to improve inspection and quality control. As we transition from manual to automated assembly, we believe the reduced variable costs will improve product gross margins.

DPP Technology & Development

Our commercially available products employ either our patented DPP technology or traditional lateral flow technology. We believe products developed using our DPP technology can provide superior diagnostic performance compared with products that utilize traditional lateral flow technology.

Chembio's history of collaborations have proven the strength and capabilities of the DPP platform to address a diverse range of biomarkers. We are now focusing our R&D resources on delivering products to build a portfolio of COVID-19 tests and developing Chembio's new and expanded product portfolio focused on high average selling price, developed markets, established sales channels, and clinically accepted use cases, where the differentiated capabilities of DPP provide a competitive advantage.

Competition

Many of our competitors are significantly larger and have greater financial, research, manufacturing, and marketing resources. Important competitive factors include product quality, analytical performance, ease of use, price, customer service and reputation. Industry competition is based on these and the following additional factors:

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

We believe our scientific capabilities and proprietary know-how relating to our patented DPP technology and lateral flow technology are very strong, particularly for the development and manufacture of tests for the detection of infectious and other diseases.

Although we have no specific knowledge of any other competitors' products that could render our products obsolete, if we fail to maintain and enhance our competitive position or fail to introduce new products and product features, our customers may decide to use the products developed by our competitors, which could result in a loss of revenues and cash flow.

Human Capital

As of December 31, 2021, we had 337 full-time equivalent employees, of whom 46 were in administration, 241 were in manufacturing, 28 were in research and development, and 22 were in sales and marketing and customer service. Of these employees, approximately 297 were located in the United States, 22 were located in Germany and 18 were located in Brazil. We have never had a work stoppage, and none of our employees are represented by a labor organization or subject to any collective bargaining arrangements. We consider our employee relations to be good.

Our employees are one of our most important assets and set the foundation for our ability to achieve our strategic objectives, drive operational execution, deliver strong financial performance, advance innovation and maintain our quality and compliance programs. The success and growth of our business depends in large part on our ability to attract, retain and develop a diverse population of talented and high-performing employees at all levels of our organization.

Health, Wellness and Safety

The health, wellness and safety of our employees is a priority embedded at every level of our business. We provide our employees upfront and ongoing safety training to ensure that safety policies and procedures are effectively communicated and implemented. Personal protective equipment is provided to those employees where needed for the employee to safely perform their job function.

Since 2020, in response to the COVID-19 pandemic, we implemented safety protocols and new procedures to protect our employees, including more frequent deep cleaning of the facilities, social distancing and onsite COVID-19 testing.

Workforce Stability

Retaining and developing our employees is an important factor in our continued success and growth. We regularly evaluate our employee retention and turnover rates. With the contraction of the labor force as a result of the global pandemic, we have also experienced the effects of the labor shortage in our staffing. We expect the labor shortage to continue in 2022 and will continue to monitor and analyze retention closely to identify any areas of concern.

Compensation and Benefits

To succeed in a competitive labor market, we have recruitment and retention strategies that we focus on as part of the overall management of our business, including designing our compensation and benefits programs to be competitive and align with our strategic and stockholders' interests. Some of our key employee benefits include eligibility for health insurance, vacation time, a retirement plan, an employee assistance program, life and disability coverage. We also have procedures and processes focused on providing employees equitable compensation, regardless of race or gender or other personal characteristics.

Impact of the COVID-19 Pandemic

The COVID-19 pandemic has disrupted nearly every aspect of the global supply chain, including the manufacturing of some of the key supplies used in our tests. Many suppliers are experiencing shortages of required personnel as the result of the tight labor market and underlying raw material commodities. To fulfil our obligations, we have had to identify sources of supplies on a short timeframe and in a markedly increased quantity and have been required to seek to identify new sources of materials to replace or augment our past sources. Moreover, scarcity has caused increases in the cost of some supplies.

Governmental Regulation

Certain of our activities are subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug, and Cosmetic Act and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing, and export of diagnostic products. Our clinical laboratory customers are subject to oversight by Centers for Medicare and Medicaid Services, or CMS, pursuant to CLIA, as well as agencies in various states. 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.

FDA Approval/Clearance Requirements

Unless an exemption applies, each medical device that we market or wish to market in the United States must receive 510(k) clearance or Premarket Approval, or PMA. Medical devices that receive 510(k) clearance are “cleared” by the FDA to market, distribute, and sell in the United States. Medical devices that obtain a PMA by the FDA are “approved” to market, distribute and sell in the United States. We cannot be certain that 510(k) clearance or PMA approval will ever be obtained for any products that have not already obtained 510(k) clearance or PMA approval. Descriptions of the PMA and 510(k) clearance processes are provided below.

The FDA decides whether a device line must undergo either the 510(k) clearance or PMA based on statutory criteria that utilize a risk-based classification system. PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices and, in many cases, Class II medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. The FDA uses these criteria to decide whether a PMA or a 510(k) is appropriate, including the level of risk that the agency perceives is associated with the device and a determination by the agency of whether the product is a type of device that is similar to devices that are already legally marketed. Devices deemed to pose relatively less risk are placed in either Class I or II. In many cases, the FDA requires the manufacturer to submit a 510(k) requesting clearance (also referred to as a premarket notification), unless an exemption applies. The 510(k) must demonstrate that the manufacturer’s proposed device is “substantially equivalent” in intended use and in safety and effectiveness to a legally marketed predicate device. A “predicate device” is a pre-existing medical device to which equivalence can be drawn, that is either in Class I or Class II or is a Class III device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for submission of a PMA application.

Device classification depends on the device’s intended use and its indications for use. In addition, classification is risk-based, that is, the risk the device poses to the patient and/or the user is a major factor in determining the class to which it is assigned. Class I includes devices with the lowest risk and Class III includes those with the greatest risk.

Class I devices are those for which safety and effectiveness can be assured by adherence to the FDA’s general regulatory controls for medical devices, or the General Controls, which include compliance with the applicable portions of the FDA’s quality system regulations, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) process described below.

Class II devices are subject to the FDA’s General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) process. Pursuant to the Medical Device User Fee and Modernization Act of 2002, unless a specific exemption applies, 510(k) submissions are subject to user fees. Certain Class II devices are exempt from this premarket review process.

Class III includes devices with the greatest risk. Devices in this class must meet all of the requirements in Classes I and II. In addition, Class III devices cannot be marketed until they receive Premarket Approval.

The safety and effectiveness of Class III devices cannot be assured solely by the General Controls and the other requirements described above. These devices require formal clinical studies to demonstrate safety and effectiveness. Under the Medical Device User Fee and Modernization Act of 2002, PMA applications (and supplemental premarket approval applications) are subject to significantly higher user fees than 510(k) applications, and they also require considerably more time and resources.

Rapid HIV tests intended for diagnostic use are regulated as Class III devices. Responsibility for assuring the safety and effectiveness of these tests lies within the Center for Biologics Evaluation and Research's Office of Blood Research and Review, with oversight by the Blood Products Advisory Committee. Approved rapid HIV tests must meet the regulations in the 21 CFR 800 series subparts, under the investigational device exemption, or IDE and PMA pathways.

Premarket Approval Pathway

We manufacture, market and distribute three rapid HIV tests in the United States. Our HIV 1/2 STAT-PAK Assay, SURE CHECK HIV 1/2 Assay, and DPP HIV 1/2 Assay all have received FDA PMA approval. A PMA application must be supported by extensive data including, but not limited to, analytical, preclinical, clinical trials, manufacturing, statutory preapproval inspections, and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. Before a PMA is submitted, a manufacturer must apply for an Investigational Device Exemption ("IDE"). If the device presents a "significant risk," as defined by the FDA, to human health, the FDA requires the device sponsor to file an IDE application with the FDA and obtain IDE approval prior to initiation of enrollment of human subjects for clinical trials. The IDE provides the manufacturer with a legal pathway to perform clinical trials on human subjects where without the IDE, only approved medical devices may be used on human subjects.

The IDE application must be supported by appropriate data, such as analytical, animal and laboratory testing results, manufacturing information, and an Investigational Review Board, or IRB approved protocol showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. If the clinical trial design is deemed to have "non-significant risk," the clinical trial may be eligible for "abbreviated" IDE requirements. In some instances, clinical trials for in vitro diagnostic medical devices may be exempt from the more burdensome IDE requirements if certain labeling requirements are met.

A clinical trial may be suspended by either the FDA or the Investigational Review Board at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the study. Even if a study is completed, clinical testing results may not demonstrate the safety and efficacy of the device, or they may be equivocal or otherwise insufficient to obtain approval of the product being tested. After the clinical trials have been completed, if at all, and the clinical trial data and results are collected and organized, a manufacturer may complete a PMA application.

After a PMA application is sufficiently complete, the FDA will accept the application and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the "accepted application," although, generally, review of the application can take between one and three years, but it may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The preapproval inspections conducted by the FDA include an evaluation of the manufacturing facility to ensure compliance with the FDA's quality systems regulations or QSR, as well as inspections of the clinical trial sites by the Bioresearch Monitoring group to evaluate compliance with good clinical practice and human subject protections. New PMA applications or PMA supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. Significant changes to an approved PMA require a 180-day supplement, whereas less substantive changes may utilize a 30-day notice, or a 135-day supplement. Premarket approval supplements often require submission of the same type of information as a premarket approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original premarket approval application, and it may not require as extensive clinical data or the convening of an advisory panel.

Our HIV 1/2 STAT-PAK Assay PMA application number BP050009/0 and our SURE CHECK 1/2 HIV Assay PMA application number BP050010/0 were approved by the FDA in May 2006. Our DPP HIV 1/2 Assay PMA application number BP120032/0 was approved by the FDA in December 2012. Our DPP HIV Syphilis Assay PMA application number BP180191/0 was approved by the FDA in October 2020.

510(k) Clearance Pathway

We are currently developing products that either will or are likely to require an FDA 510(k) clearance. We anticipate submitting a 510(k) for each such product to demonstrate that such proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of a 510(k). The FDA's 510(k) clearance pathway usually takes from three to twelve months but could take longer. In some cases the FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

If a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, a PMA. The FDA requires each device manufacturer to determine whether the proposed change requires submission of a new 510(k) or a PMA, but the FDA can review any such decision and, if it disagrees with the manufacturer's determination, can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA of the modified device is obtained.

Clinical Laboratory Improvement Amendments of 1988

A manufacturer of a test categorized as moderately complex may request that categorization of the test be waived through a CLIA Waiver by Application, or CW, submission to the FDA. When a test is categorized as waived, it may be performed by laboratories with a Certificate of Waiver, such as a physician's office outreach setting. In a CW submission, the manufacturer provides evidence to the FDA that a test meets the CLIA statutory criteria for waiver CLIA, a walk-in clinic or an emergency room provides CMS authority over all laboratory testing, except research that is performed on humans in the United States. The Division of Laboratory Services, within the Survey and Certification Group under the CMS, has the responsibility for implementing the CLIA program.

The CLIA program is designed to establish quality laboratory testing by ensuring the accuracy, reliability and timeliness of patient test results. Under CLIA, a laboratory is a facility that does laboratory testing on specimens derived from humans and used to provide information for the diagnosis, prevention or treatment of disease, or impairment of, or assessment of health. Under the CLIA program, unless waived, laboratories must be certified by the government, satisfy governmental quality and personnel standards, undergo proficiency testing, be subject to inspections and pay fees. We have received a CLIA waiver for all of our lateral flow rapid HIV tests that we market in the United States. Specifically, the CLIA waiver was granted by the FDA for HIV 1/2 STAT-PAK in November 2006, for SURE CHECK HIV 1/2 in October 2007, and for DPP HIV 1/2 in October 2014.

Emergency Use Authorizations (EUA)

A formal request to issue an EUA generally should not be submitted until the Secretary of HHS has issued an EUA declaration under section 564(b)(1). In particular, although section 564 allows FDA to issue an EUA for preparedness purposes, in such cases the HHS Secretary must first declare that circumstances exist justifying such an authorization in advance of an actual emergency based on a formal determination of a significant potential for emergency or a material threat determination. During the effective period of the HHS Secretary's EUA declaration, FDA may authorize the introduction of a medical product into interstate commerce when the product is intended for use during an actual or potential emergency. EUA candidate products include medical products and uses that are not approved, cleared, or licensed under sections 505, 510(k), and 515 of the FD&C Act or section 351 of the PHS Act.

After the requisite determination and declaration have been issued, and after feasible and appropriate consultations, FDA may issue an EUA only if FDA concludes that the following four statutory criteria for issuance have been met for 1) Serious or Life-Threatening Disease or conditions, 2) evidence of effectiveness, 2) Risk –Benefit Analysis, 4) No Alternatives. A sponsor seeking an EUA can submit its formal request in the form of an EUA submission, which includes data for clinical studies, non-clinical laboratory studies to assess the safety and effectiveness of the product as well as the discussion of Risks and Benefits of the product.

FDA will specify the effective date of an EUA issued under section 564. In general, an EUA will remain in effect for the duration of the EUA declaration under which it was issued which describes termination of an EUA declaration and its impact on existing EUAs.

Pervasive and Continuing FDA Regulation

A host of regulatory requirements apply to our approved devices, including: the quality system regulation, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures; the Medical Reporting Regulations, which require manufacturers to report to the FDA specified types of adverse events involving their products; labeling regulations; and the FDA's general prohibition against promoting products for unapproved or "off-label" uses. Some Class II devices are subject to special controls-such as performance standards, post-market surveillance, patient registries, and FDA guidelines-that do not apply to Class I devices.

The regulatory requirements that apply to our approved products classified as medical devices include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the development and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our cleared devices;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and,
- notices of corrections or removals.

Our Medford, New York facility is currently registered as an establishment with the FDA. We and any third-party manufacturers are subject to announced and unannounced inspections by the FDA to determine our compliance with QSR and other regulations.

Government Regulation of Medical Devices for Animal Subjects

We currently offer two veterinary devices in the United States: DPP VetTB Assay for Cervids and DPP VetTB Assay for Elephants. Diagnostic tests for animal health infectious diseases, including our veterinary devices for the prevention and/or treatment of animal disease, are regulated in the U.S. by the Center for Veterinary Biologics within the U.S. Department of Agriculture Animal and Plant Health Inspection Service, or APHIS, under the Virus, Serum, and Toxin Act of 1913. As a requirement, our veterinary devices were approved by APHIS before they could be sold in the U.S.

The APHIS regulatory approval process involves the submission of product performance data and manufacturing documentation. Following regulatory approval to market a product, APHIS requires that each lot of product be submitted for review before release to customers. In addition, APHIS requires special approval to market products where test results are used in part for government-mandated disease management programs.

Climate Change and Environmental Laws

The medical device industry is increasingly becoming subject of scrutiny, stringent regulation and the demand for green, sustainable products. We are focused on monitoring these increasing requirements for efficient and accurate processes for hazardous substance handling, supplier disclosures, and regulatory reporting in order to comply with numerous global health and environmental regulatory requirements and restrictions.

We believe that we are in compliance in all material respects with all foreign, federal, state, and local environmental regulations applicable to our manufacturing facilities. The cost of ongoing compliance with such regulations does not have a material effect on our operations.

Intellectual Property

Intellectual Property Strategy

Our intellectual property strategy is to: (1) build our own intellectual property portfolio around our DPP technology and optical analyzers; (2) pursue licenses, trade secrets and know-how within the area of rapid point-of-care testing; and, (3) develop and acquire proprietary positions to certain reagents.

DPP Intellectual Property

We have obtained patent coverage on our DPP technology, including numerous patents in the United States, and one or more patents in Australia, Brazil, Canada, China, Columbia, Eurasia (Russia), European Union (fourteen European countries), Hong Kong, Israel, India, Indonesia, Japan, Korea, Malaysia, Mexico, Poland, Singapore, South Africa, Thailand, and the United Kingdom. Additional patent applications on our DPP technology are pending in the United States, as well as in foreign countries such as Australia, Brazil, Canada, China, the European Union, India, Indonesia, Malaysia, Mexico, Peru, Singapore and Thailand.

DPP technology provides us with freedom to operate and enables us to develop tests with better performance and capabilities compared with tests built on traditional lateral flow platforms. These advantages have allowed us to enter into multiple technology collaborations based upon DPP technology, which we believe will provide new manufacturing and marketing opportunities. We have filed additional patent applications that we believe will strengthen the DPP intellectual property and have also filed for patent protection for certain other point-of-care technologies or applications thereof.

We have also obtained patent coverage on our optical-based analyzer technology in the United States as well as in several EU countries.

Trademarks

We have filed and obtained trademarks for our company name CHEMBIO and CHEMBIO DIAGNOSTIC SYSTEMS, INC. as well as for many of our products, including DPP, SURE CHECK, STAT-VIEW, STAT-PAK, and NEXT GENERATION DPP, as well as for the SampleTainer and DPP Micro Reader, which are used with certain DPP products. Our trademarks have been registered in the United States and certain other countries around the world.

Trade Secrets and Know-How

We have developed a substantial body of trade secrets and know-how relating to the development and manufacture of lateral flow and DPP-based diagnostic tests, including the sourcing and optimization of materials for such tests, and methods to maximize sensitivity, speed-to-result, specificity, stability and reproducibility of our tests. We possess proprietary know-how to develop tests for multiple conditions using colored particles. Our formulations enable long shelf lives of our rapid HIV and other tests, providing us with an important competitive advantage.

Rapid Diagnostic Technology and Reagent Licenses

We seek licenses and/or redesigns of products that we believe to be in our best interests. Because of the costs and other negative consequences of time consuming patent litigation, we often attempt to obtain a license on reasonable terms. The peptides used in our rapid HIV tests were licensed to us by one or more third parties. We also have licensed the antigens used in other tests including our Syphilis, Tuberculosis, Leptospirosis, Leishmaniasis and Chagas tests, and we may enter into other license agreements. In prior years, we concluded license agreements related to intellectual property rights owned by the United States associated with HIV-1 and a sub-license agreement for HIV-2 with Bio-Rad Laboratories N.A., the exclusive licensee of the Pasteur Institute's HIV-2 intellectual property estate.

Available Information

We are required to file annual, quarterly and current reports, proxy statements and other information with the U.S. Securities and Exchange Commission. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements and amendments to those documents filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, are also available free of charge on our website at www.chembio.com as soon as reasonably practicable after such reports are electronically filed with or furnished to the SEC.

Investors should note that we currently announce material information to our investors and others using filings with the SEC, press releases, public conference calls, webcasts or our website (www.chembio.com), including news and announcements regarding our financial performance, key personnel, our brands and our business strategy. Information that we post on our corporate website could be deemed material to investors. We encourage investors to review the information we post on these channels. We may from time to time update the list of channels we will use to communicate information that could be deemed material and will post information about any such change on www.chembio.com. The information on our website is not, and shall not be deemed to be, a part hereof or incorporated into this or any of our other filings with the SEC.

Corporate Information

Our principal executive offices are located at 555 Wireless Boulevard, Hauppauge, New York 11788. Our telephone number is (631) 924-1135. Our website address is www.chembio.com. The information contained in, or accessible through, our corporate website does not constitute part of this report.

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-K 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-K by reference.

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

- our ability to initiate and complete clinical trials necessary to support EUA, 510(k), PMA or de novo submissions;
- our allocation of a substantial portion of our resources to the development and production of our DPP SARS-CoV-2 Antigen system;
- uncertainty and competition in the diagnostic testing market, particularly with respect to COVID-19;
- the effects of the ongoing or future SEC investigation;
- the effects of existing or future stockholder litigation;
- impacts on our suppliers and employees due to the COVID-19 pandemic;
- the ability of our products to compete with the new or existing products of our competitors;
- the negative impact of healthcare industry consolidation on our future revenues and operating results;
- our ability to successfully manage the transition associated with the appointment of a new chief financial officer;
- our ability to retain key employees and attract additional qualified personnel;
- third-party reimbursement policies;
- our ability to collect our outstanding accounts receivable;
- the continued funding of, and ability to participate in, large testing program in the U.S.;
- developments in diagnostic testing guidelines or recommendations;
- our ability to obtain government grant awards; and
- the vulnerability of our business to cyber-attacks.

Risks Related to Our Products

- the COVID-19 Diagnostic Test Systems not gaining wide industry acceptance;
- 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;
- timely receipt and implementation of additional 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 liquidity limitations, including that we have concluded there is a substantial doubt about our ability to continue as a going concern;
- the impact of our liquidity and operational limitations on our ability to fulfill purchased orders;
- the 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 the Credit Agreement;
- 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 relate 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 of changes in CLIA, FDA, ANVISA, and other regulatory changes, on COVID-19 diagnostic tests;
- our ability to receive and maintain necessary regulatory approvals for our products;
- the impact of governmental export controls on our ability to compete in international markets;
- our ability to comply with FDA and other regulatory requirements;
- 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 government agencies affecting the ability of the FDA 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 ability of our stock price to meet the minimum bid price for continued listing on the Nasdaq capital market;
- 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;
- management's broad discretion as to the use of proceeds of the offering made pursuant to the ATM Agreement; 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 strategic transactions;
- costs associated with compliance with public company regulations; and
- terrorist attacks or natural disasters.

RISK FACTORS

Risks Related to Our Business and Our Industry

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

We do not currently have an Emergency Use Authorization, or EUA, from the U.S. Food and Drug Administration, or FDA, for any of the COVID-19 Diagnostic Test Systems or for our DPP Respiratory Panel, and we do not currently have an application pending for any such EUA. We also do not have a CLIA waiver from the FDA for our DPP HIV-Syphilis test system. Market and regulatory requirements continue to change at a rapid pace. The FDA has declined to review our most recent EUAs submitted for our 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 or CLIA waiver application, we will meet the requirements of the prioritization guidance in effect at the time of the submission or otherwise be successful in obtaining either (1) an EUA that would permit us to offer and sell the DPP SARS-CoV-2 Antigen test system or DPP Respiratory Panel in the United States or (2) a CLIA waiver for our DPP HIV-Syphilis test.

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

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

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

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

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

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 DPP SARS-CoV-2 Antigen test system, 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 the DPP SARS-CoV-2 Antigen test system. Because we do not currently have an EUA from the FDA for the DPP SARS-CoV-2 Antigen test system, starting 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 DPP SARS-CoV-2 Antigen test system 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 the DPP SARS-CoV-2 Antigen test system. 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.

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 DPP SARS-CoV-2 Antigen test system. 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. In addition, the production of an efficacious vaccine or other treatment for a disease underlying one of our products may reduce the demand for relevant diagnostic products. 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 the DPP SARS-CoV-2 Antigen test system.

We face risks related to an ongoing SEC investigation.

The SEC is conducting a non-public, fact-finding investigation relating to the May 2020 Offering and to the FDA's revocation in June 2020 of an EUA for the DPP COVID-19 IgM/IgG system that was issued in April 2020. We received subpoenas from the SEC in July 2020 and April 2021 seeking the production of documents in connection with this investigation. In addition, the SEC delivered subpoenas in April 2021 to five of our employees (including our three executive officers, who consist of our Chief Executive Officer and President, our Executive Vice President and Chief Financial Officer, and our Executive Vice President and Chief Scientific and Technology Officer). An additional subpoena was issued in June 2021 to our former Interim Chief Executive Officer and Executive Chair. Each subpoena requested the production of documents relating to the same matters as are the subject of the subpoenas we received.

We are unable to predict what the timing or outcome of the SEC investigation will be or what, if any, consequences the SEC investigation may have with respect to our company or the six individuals mentioned above. The SEC investigation could result in considerable legal expenses, divert management's attention from other business concerns and harm our business. If the SEC were to determine that legal violations occurred, we could be required to pay significant civil penalties or other amounts, and remedies or conditions could be imposed as part of any resolution. We can provide no assurances as to the outcome of the SEC investigation.

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

We may incur additional costs in connection with the defense or settlement of existing and any future stockholder litigation, including four stockholder lawsuits to date that have been brought against us. 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.

We expect competition 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.

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

The COVID-19 pandemic may continue to 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 continue to 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 continue to 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, manufacturing delays, or increased prices implemented by our suppliers. The COVID-19 pandemic has disrupted nearly every aspect of the global supply chain, including the manufacturing or delivery of some of the key supplies used in our tests. Many suppliers are experiencing shortages of required personnel as the result of the tight labor market and underlying raw material commodities. Some suppliers have been unable to deliver supplies in the quantity we need or at all. As a result, these suppliers may stop supplying us components and materials, limit the allocation of supply and equipment to us due to increased industry demand, or significantly increase their prices at any time with little or no advance notice. The adverse effect on our employees or suppliers could have an adverse impact on our business, results of operations and financial condition.

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 (Alere), OraSure Technologies 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 or a competitor's products may be more effective or more effectively marketed and sold. 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.

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.

We may not successfully manage the transition associated with the appointment of a new chief financial officer, which could have an adverse impact on us.

On October 18, 2021, we announced that Neil A. Goldman had notified the board of directors of his resignation as our Executive Vice President and Chief Financial Officer. On January 6, 2022, we announced that we had appointed Lawrence J. Steenvoorden as our Chief Financial Officer, effective as of January 5, 2022.

The effectiveness of our new Chief Financial Officer, and our senior leadership team generally, and any further transition as a result of these changes, could have a significant impact on our results of operations. Management transition is often difficult and inherently causes some loss of institutional knowledge, which could negatively affect our results of operations and financial condition. Our ability to execute our business strategies may be adversely affected by the uncertainty associated with these transitions.

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, Lawrence J. Steenvoorden. 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 United States 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 U.S. 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.

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

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

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

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

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

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 December 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 new 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 new 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.

Customer concentration creates risks for our business.

A significant portion of our revenues each year comes from a few large customers. Bio-Manguinhos constituted 51% of our total revenues in 2021 and 25% of our total revenues in 2020. We had another customer that accounted for 10% of our total revenues in 2021, and a third customer that accounted for 12% of our revenue in 2020. To the extent that Bio-Manguinhos or any other 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.

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 U.S. 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.

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

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

As described under “Part I, Item 1. Business─Overview”, “Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations-Substantial Doubt as to Going Concern Status” and “─Liquidity and Capital Resources”, management has determined we could not be certain that our plans and initiatives to increase our total revenues and improve our liquidity position would be effectively implemented within one year after the filing date of this report, when the consolidated financial statements accompanying this report, or the Accompanying Financial Statements, are being issued. Without giving effect to the prospect of raising additional capital pursuant to our at-the-market offerings under the ATM Agreement, increasing product revenue in the near future or executing other mitigating plans, many of which are beyond our control, it is unlikely that we will be able to generate sufficient cash flows to meet our required financial obligations, including our debt service and other obligations due to third parties. The existence of these conditions raises substantial doubt about our ability to continue as a going concern for the twelve-month period following the filing date of this report, when the Accompanying Financial Statements are being issued.

Our diagnostic test products require ongoing funding to continue our current development and operational plans, and we have a history of net losses. We intend to continue to expend substantial resources in the short term in connection with the July Purchase Orders (see “Part II, Item 7. Management’s Discussion and Analysis of Financial Condition”), but we may encounter challenges in fulfilling our obligations, and therefore receiving revenue, under those purchase orders. See “─Because of our liquidity and operational limitations, including the availability of staffing and supply chain resources that are necessary but outside of our control, we will not be able to timely fulfill all of the requirements of the July Purchase Order from Bio-Manguinhos and it is difficult to reliably estimate the extent to which we will be able to timely meet those requirements” below. We will also incur costs associated with research and development activity, corporate administration, business development, debt service, marketing and selling of our products, and litigation. In addition, other unanticipated costs may arise.

As of December 31, 2021, we had outstanding indebtedness of $20.0 million under the Credit Agreement. We may face further liquidity challenges if we are unable to meet obligations set forth in the Credit Agreement, including a financial covenant requiring that we achieve specified minimum total revenue amounts measured as of the end of each quarter. A breach of the minimum total revenue covenant or any other covenant in the Credit Agreement would result in a default under the Credit Agreement, which could enable the Lender to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. We cannot assure you that, in such an event, we would have sufficient assets to pay amounts due under the Credit Agreement. See “─The failure to comply with the terms of the Credit Agreement could result in a default under its terms and, if uncured, could result in action against our pledged assets and dilution of our stockholders” below.

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

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

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

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

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

In July 2021 we received the July Purchase Orders, which we had been pursuing for an extended period of time. See “Part II, Item 7. Management’s Discussion and Analysis of Financial Condition below. Our delivery of the full number of tests covered by each of the July Purchase Orders may be affected by limitations of our supply chain, staffing and liquidity, including matters that are outside our control. We have established internal plans designed to maximize the number of tests we can deliver timely, or at all, pursuant to the July Purchase Orders, and we expect to continue to revise those plans as we obtain new information. The number of uncertainties related to third parties - including the availability of required personnel, raw materials and other resources - currently preclude us, however, from reliably estimating the extent to which we will be able to fulfill the July Purchase Orders on time and at an acceptable cost, or at all. Our ability to generate revenue from the July Purchase Orders, and the margins we can realize from that revenue, will depend on the availability and cost of human, material and other resources required to build and deliver tests in accordance with the July Purchase Orders.

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

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

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

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 2021. 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 our 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 the Credit Agreement could result in a default under its terms and, if uncured, could result in action against our pledged assets and dilution of our stockholders.

On September 3, 2019, we and certain of our subsidiaries, as guarantors, entered into the Credit Agreement, under which we received a $20,000,000 senior secured term loan credit facility that was drawn in full on September 4, 2019. The Credit Agreement is secured by a first priority, perfected lien on substantially all of our property and assets, including our equity interests in our subsidiaries. See “Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations─Liquidity and Capital Resources─Sources of Funds─Credit Agreement.”

The Credit Agreement also contains financial covenants requiring that we (a) maintain aggregate unrestricted cash of not less than $3,000,000 at all times, which must be held in one or more accounts subject to the first priority perfected security interests of the Lender under the Credit Agreement, and (b) achieve specified minimum total revenue requirements for the twelve months preceding each quarter end. The minimum total revenue amounts over the next year increase from $42.0 million for the twelve months ending March 31, 2022 to $47.4 million for the twelve months ending December 31, 2022 (see note 13 to the Accompanying Financial Statements). These minimum revenue requirements were developed for purposes of the Credit Agreement and do not reflect the internal estimates and plans used by our management and board of directors to establish operational goals for managing our business. The minimum revenue requirements for the twelve months ending December 31, 2022 do not, for example, take into account the challenges we are facing in ramping up production, including hiring personnel and obtaining commitments from our supply chain as described above in “─Because of our liquidity and operational limitations, including the availability of staffing and supply chain resources that are necessary but outside of our control, we will not be able to timely fulfill all of the requirements of the July Purchase Orders and it is difficult to reliably estimate the extent to which we will be able to timely meet those requirements.”

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

- incur, assume or guarantee additional Indebtedness (as defined in the Credit Agreement);
- repurchase capital stock;
- make other restricted payments, including paying dividends and making investments;
- create liens;
- sell or otherwise dispose of assets, including capital stock of subsidiaries;
- enter into agreements that restrict dividends from subsidiaries;
- enter into mergers or consolidations; and
- enter into transactions with affiliates.

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

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. Our operations used $30.9 million in cash in 2021 and $18.9 million in 2020. If our cash flow and capital resources are insufficient to allow us to make scheduled payments on our debt, we may need to 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.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Our ability to utilize our federal net operating loss and tax credit carryforwards may be limited under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, or the Code. The limitations apply if we experience an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in the ownership of our equity by certain stockholders over a rolling three-year period). Similar provisions of state tax law may also apply to limit the use of our state net operating loss carryforwards.

We experienced an ownership change in 2004 and 2006, and we estimate a portion of our existing federal net operating loss carryforwards are subject to an annual limitation under Section 382 of the Code. Since our ownership change in 2006, we have not assessed whether an ownership change has subsequently occurred. If we have experienced an ownership change at any time since our ownership change in 2006, we may already be subject to limitations on our ability to utilize our net operating losses and other tax attributes generated before such additional ownership change to offset post-change taxable income. In addition, future changes in our stock ownership, which may be outside of our control, may trigger an ownership change and, consequently, the limitations under Sections 382 and 383 of the Code. As a result, if or when we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset such taxable income may be subject to limitations, which could adversely affect our future cash flows.

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.

Loans under the Credit Agreement 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 extended 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.

In response to concerns regarding the future of LIBOR, the Board of Governors of the Federal Reserve System and the Federal Reserve Bank of New York convened the Alternative Reference Rates Committee, or ARRC, to identify alternatives to LIBOR. The ARRC has recommended benchmark replacement procedures to assist issuers in continued capital market entry while safeguarding against LIBOR's discontinuation. The initial steps in the ARRC's recommended provision reference variations of the Secured Overnight Financing Rate, or SOFR. 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, 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, milestones and bill and hold arrangements; (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.

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 U.S. enacted sweeping changes to the U.S. patent system under the Leahy-Smith America Invents Act, including changes that would transition the U.S. 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.

Our U.S. government contracts are subject to future funding and the government's choice to exercise options, and may be terminated at the government's convenience.

Our contracts with the U.S. government are subject to future funding and are subject to the right of the government to terminate the contracts in whole or in part for its convenience. There is pressure for the U.S. government to reduce spending. The non-appropriation of funds or the termination for the government's convenience of our contracts could negatively affect our financial results. If levels of U.S. government expenditures and authorizations for emerging diseases decrease or shift to programs in areas where we do not offer products or are not developing product candidates, or if the U.S. government otherwise declines to exercise its options under its contracts with us, our business, revenues and other operating results would suffer.

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.

The 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, 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.

The EU landscape concerning medical devices recently evolved. On May 25, 2017, the E.U. Medical Devices Regulation entered into force, which repeals and replaces the Council Directive 93/42/EEC, or E.U. Medical Devices Directive, and Directive 90/385/EEC, or AIMDD. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable (i.e., without the need for adoption of E.U. member state laws implementing them) in all E.U. member states and are intended to eliminate current differences in the regulation of medical devices among E.U. member states. Devices lawfully placed on the market pursuant to the E.U. Medical Devices Directive or the AIMDD prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the E.U. Medical Devices Regulation with regard to registration of economic operators and of devices, post-market surveillance, market surveillance and vigilance requirements.

Subject to the transitional provisions, in order to sell our products in E.U. member states, our products must comply with the general safety and performance requirements of the E.U. Medical Devices Regulation, which repeals and replaces EU Medical Devices Directive and the AIMDD. Compliance with these requirements is a prerequisite to be able to affix the CE mark to our products, without which they cannot be sold or marketed in the EU. To demonstrate compliance with the general safety and performance requirements, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Except for low risk medical devices (Class I), where the manufacturer can self-assess the conformity of its products with the general safety and performance requirements (except for any parts which relate to sterility, metrology or reuse aspects), a conformity assessment procedure requires the intervention of a notified body. The notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the E.U. If we fail to comply with applicable laws and regulations, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the E.U.

We must inform the notified body that carried out the conformity assessment of the medical devices that we market or sell in the E.U. and the EEA of any planned substantial changes to our quality system or substantial changes to our medical devices that could affect compliance with the general safety and performance requirements laid down in Annex I to the E.U. Medical Devices Regulation or cause a substantial change to the intended use for which the device has been CE marked. The notified body will then assess the planned changes and verify whether they affect the products' ongoing conformity with the E.U. Medical Devices Regulation. If the assessment is favorable, the notified body will issue a new certificate of conformity or an addendum to the existing certificate attesting compliance with the general safety and performance requirements and quality system requirements laid down in the Annexes to the E.U. Medical Devices Regulation.

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 European and U.K. data protection requirements could increase our costs.

The E.U. 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 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 applies 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 have the ability to interpret the GDPR, which has the potential to create inconsistencies on a country-by-country basis. We have evaluated these new requirements and have implemented 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. Further, from January 1, 2021, we have to comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which may expose us to further compliance risk. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU member states to the UK without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision.

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.

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 common 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.

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. Although there is no affiliation between our management and our larger stockholders, they could exercise significant control over our company if they voted their shares in a similar manner.

The price of our common stock could continue to be volatile, and existing stockholders' investments in our common stock could lose value.

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. By way of example, during the year ended December 31, 2021, our common stock has traded at a low of $1.09 and a high of $7.97. As a result of this volatility, investors could experience losses on their investment in our common stock.

The stock market is subject to significant price and volume fluctuations, and the price of our common stock could fluctuate widely in response to several factors, including, but not limited to: our cash flows and cash position; the duration and severity of the COVID-19 pandemic; our quarterly or annual operating results; investment recommendations by securities analysts following our business or our industry; additions or departures of key personnel; changes in our business, earnings estimates or market perceptions of our competitors; our failure to achieve operating results consistent with securities analysts' projections; changes in industry, general market or economic conditions; and announcements of legislative or regulatory change.

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.

Since the stock price of our common stock has fluctuated in the past, has been recently volatile and may be volatile in the future, investors in our common stock could incur substantial losses. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. We are currently subject to securities class-action litigation as described in "—Legal Matters—Legal Proceedings" above. There can be no guarantee that our stock price will remain at current levels.

Securities of certain companies have recently 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 stockholders may lose a significant portion or all of their investments if they purchase our shares at a rate that is significantly disconnected from our underlying value.

Our stock price may in the future not meet the minimum bid price for continued listing on the Nasdaq Capital Market. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from The Nasdaq Capital Market.

Nasdaq Listing Rule 5450(a)(1), which we refer to as the Minimum Bid Price Rule, provides that the closing bid price for our common stock may not be below $1.00 per share for any period of 30 consecutive trading days to maintain our continued listing on The Nasdaq Capital Market. As of March 1, 2022, the closing bid price for our common stock was $0.97. Although we are currently in compliance with the Minimum Bid Price Rule, there can be no assurance that our common stock will continue to satisfy this rule. If we were to fail to comply with the Minimum Bid Price Rule in the future and became subject to delisting, such delisting from Nasdaq would adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

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.

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

On July 19, 2021, we entered into the ATM Agreement, pursuant to which we may sell from time to time, at our option, up to an aggregate of $60,000,000 of shares of common stock through Craig-Hallum, as sales agent. As of the filing date of this report, we have issued and sold pursuant to the ATM Agreement a total of 9,709,328 shares of common stock at a volume-weighted average price of $4.2011 per share for gross proceeds of $40.8 million and net proceeds, after giving effect to placement fees and other transaction costs, of $38.8 million. For additional information about the at-the-market offerings pursuant to the ATM Agreement, see "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations".

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

As of the close of business on March 1, 2022, our market capitalization was approximately $29.2 million. Existing stockholders may experience significant dilution in connection with our issuance and sale of up to $21.2 million of additional shares of common stock pursuant to the ATM Agreement. In addition, as of December 31, 2021, 3,386,393 shares of common stock were reserved for future issuance under our 2019 Omnibus Incentive Plan, 1,600,372 shares were subject to outstanding options, and 705,325 shares were subject to outstanding restricted and performance stock units. Stockholders will incur dilution upon vesting of restricted and performance stock units, and they may incur dilution upon exercises of stock options.

Management will have broad discretion as to the use of any net proceeds of the offering made pursuant to the ATM Agreement, and we may not use those net proceeds effectively.

Our management will have broad discretion in the application of the net proceeds of this offering made pursuant to the ATM Agreement and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business and could cause the price of our common stock to decline.

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 strategic transactions 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 transactions 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 a transaction 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 with a partner 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 a partner business; and (4) a strategic transaction 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 partner business.

If these factors occur, we may be unable to achieve all or a significant part of the benefits expected from a strategic transaction 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 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 Capital 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.

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. If our manufacturing operations were curtailed or shut down entirely, it would seriously harm our business

ITEM 2. PROPERTIES

Our U.S. manufacturing, administrative offices, and research facilities are located in leased space in Medford, New York, pursuant to a lease covering approximately 39,650 square feet and expiring on June 30, 2022, with an option to renew each year.

On February 5, 2019, we entered into a commercial real estate lease for new corporate headquarters comprised of 70,000 square feet of office, research and development, and warehouse space located in Hauppauge, New York. The lease has an initial term of eleven years that can be extended, at our option, for two additional terms of five years each. Rent under the lease, which is payable in monthly installments, totals approximately $900,000 for the initial year and then increases by approximately three percent each succeeding year.

Our European headquarters and Center of Excellence for Optical Technology is located in leased office and manufacturing space in Berlin, Germany. Our Southeast Asia manufacturing, warehouse, and commercial facilities are located in leased space in Kuala Lumpur, Malaysia and is currently inactive. Our Latin America manufacturing, warehouse, and commercial facilities are located in Rio de Janeiro, Brazil. We regularly review our real estate portfolio and develop footprint strategies to support our customers' global plans, while at the same time supporting our technical needs and controlling operating expenses.

ITEM 3. LEGAL PROCEEDINGS

This information is set forth under "Note 12 – Commitments, Contingencies And Concentrations – Litigation" to the Consolidated Financial Statements of this Annual Report on Form 10-K is incorporated herein by reference.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Listing Information

Our stock is listed on the NASDAQ Global Select Market of the NASDAQ Stock Market LLC under the symbol "CEMI."

Holders

As of February 23, 2022, there were 71 record owners of our Common Stock (including nominee holders such as banks and brokerage firms who hold shares for beneficial owners).

Recent Sales of Unregistered Securities

During the year ended December 31, 2021, we issued unregistered securities in connection with the 2020 Amended and Restated Agency & Commission Agreement from November 2020.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the year ended December 31, 2021.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

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

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

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

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

Global Competitiveness Program

We have achieved significant revenue growth in recent years while profitability has not been at levels as expected. We have taken steps including investments in automation to mitigate headwinds including labor availability, volatile capacity planning and implementation of operational efficiency targets to proactively monitor production with the overarching goal for profitable growth. To further accelerate and aggressively execute towards this goal to improve profitability, in the first quarter of 2022 we have initiated a Global Competitiveness Program. Our Global Competitiveness Program has been developed with the support of the Company's executive leadership team to ensure cross-functional alignment, commitment and accountability throughout the organization. The main pillars of the Global Competitiveness Program include the following:

- **Focus on higher margin business in growth markets**: Our pursuit of growth in markets with higher selling prices remains unchanged. We have recently completed an in-depth analysis of our product portfolio and profitability on both a product and regional basis. With this increased transparency at a product-level, we now have visibility to support customer pricing, marketing strategies and evaluate opportunities to increase prices. Furthermore, focus will be on recurring revenue streams of our core business by leveraging more recently established distributor and direct customer channels in the US and other key markets.

- **Lower manufacturing costs:** Automation and labor management is essential to scale unit volumes while also seeking additional ways to drive our manufacturing costs down. With improved visibility on our labor and material costs at a product-level, we will primarily target optimization of our lower margin business.

- **Reduce infrastructure costs:** This includes an in-depth evaluation of all support functions and external spend to reduce costs. Research & Development will be further aligned with our future innovation centered on core strategy, including DPP and expansion of product pipeline with a more disciplined approach to cost-benefit analysis, target markets, and competitor landscape.

- **Strategic review of non-core businesses and assets:** Our prior acquisitions have not achieved the business plans as originally planned. More specifically, emphasis will be on both our German and Brazilian subsidiaries with a reorientation for those businesses to achieve an independent path to profitability and alignment with the long-term strategic roadmap.

While these pillars establish a framework to improve our profitability, successful execution is dependent on many factors including future regulatory approvals, key relationships with long term customers and expansion in large markets including the US. We plan to aggressively implement these actions that underpin fundamentals for long-term profitable growth and sustainable shareholder value.

Substantial Doubt as to Going Concern Status

Factors and considerations with respect to our liquidity raised substantial doubt as to our ability to continue as a going concern through one year after the date that our financial statements are being issued.

Revenues during the twelve months ended December 31, 2021 did not meet our expectations. Our increase in cash and cash equivalents over the year reflected our issuance of common stock in at-the-market offerings for net proceeds of $38.8 million (see “Note 9 - Stockholder’s Equity” to the Consolidated Financial Statements of this Annual Report on Form 10-K is incorporated herein by reference).

We continued to experience market, clinical trial and regulatory complications in seeking to develop and commercialize a portfolio of COVID-19 test systems during the continuing, but evolving, uncertainty of the COVID-19 pandemic. In the year ending on December 31, 2021, we continued to incur significant expenses in connection with pending legal matters (see “Note 12 – Commitments, Contingencies, and Concentrations: Litigation” to the Consolidated Financial Statements of this Annual Report on Form 10-K is incorporated herein by reference), delayed achievement of milestones associated with government grant income, investments in inventory, and the continuing automation of manufacturing.

During the twelve months ended December 31, 2021, we undertook measures to increase our total revenues and improve our liquidity position. These measures included:

- On July 19, 2021, we entered into an At the Market Offering Agreement, or the ATM Agreement, with Craig-Hallum Capital Group LLC, or Craig-Hallum, pursuant to which we may sell from time to time, at our option, up to an aggregate of $60,000,000 of shares of common stock through Craig-Hallum, as sales agent. As of the filing date of this report, we have issued and sold pursuant to the ATM Agreement a total of 9,709,328 shares of common stock at a volume-weighted average price of $4.20 per share for gross proceeds of $40.8 million and net proceeds, after giving effect to placement fees and other transaction costs, of $38.8 million.

- We also received significant purchase orders from two customers, which we refer to as the July Purchase Orders. We had pursued the July Purchase Orders for an extended period of time. The July Purchase Orders consist of the following:

- On July 20, 2021, we received a $28.3 million purchase order from Bio-Manguinhos for the purchase of DPP SARS-CoV-2 Antigen tests for delivery during 2021 to support the needs of Brazil's Ministry of Health in addressing the COVID-19 pandemic. Bio-Manguinhos is responsible for the development and production of vaccines, diagnostics, and biopharmaceuticals, primarily to meet demands of Brazil's national public health system. As of December 31, 2021 $16.8 million was recognized in connection with this order.

- On July 22, 2021, we received a $4.0 million purchase order from the Partnership for Supply Chain Management, supported by The Global Fund, for the purchase of HIV 1/2 STAT-PAK Assays for shipment to Ethiopia into early 2022. As of December 31, 2021 $1.2 million was recognized in connection with this order.

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

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

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

We further considered how these factors and uncertainties could impact our ability over the next year to meet the obligations specified in the Credit Agreement and Guaranty, or the Credit Agreement, that we and certain of our subsidiaries, as guarantors, entered into with Perceptive Credit Holdings II, LP, or the Lender. Those obligations include (a) covenants requiring: i) minimum cash balance of $3 million and ii) minimum total revenue amounts for the twelve months preceding each quarter end. For the next year, the minimum total revenue requirements range from $42.0 million for the twelve months ending March 31, 2022 to $47.4 million for the twelve months ending December 31, 2022 and (b) an obligation requiring the payment of principal installments, commencing with the payment of $300,000 on September 30, 2022. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. In such an event, there can be no assurance that we would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, we would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. Our inability to raise additional capital on acceptable terms in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for our operations, could have a material adverse effect on our business, prospects, results of operations, liquidity and financial condition.

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

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

Consolidated Results of Operations

The results of operations for the years ended December 31, 2021 and 2020 were as follows:

	Year Ended December 31, (in thousands)			
	2021		2020	
TOTAL REVENUES	$ 47,818	100%	$ 32,470	100%
COSTS AND EXPENSES:				
Cost of product sales	34,496	72%	23,874	74%
Research and development expenses	12,487	26%	9,509	29%
Selling, general and administrative expenses	24,841	52%	21,038	65%
Impairment, restructuring, severance and related costs	7,048	15%	1,122	3%
Acquisition costs	-	0%	63	0%
	78,872		55,606	
LOSS FROM OPERATIONS	(31,054)		(23,136)	
OTHER (EXPENSE) / INCOME	(2,912)		(2,842)	
LOSS BEFORE INCOME TAX BENEFIT	(33,966)		(25,978)	
Income tax benefit	62		457	
NET LOSS	$ (33,904)	(71%)	$ (25,521)	(79%)

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during 2021 were $47.8 million, an increase of $15.3 million, or 47.3%, compared to 2020. The increase in total revenues reflected a $10 million, or 40.3%, increase in net product sales, which was principally comprised of (a) higher sales in Latin America, US and Africa, offset by lower sales in Europe and Asia; (b) decrease in R&D revenue of $3.7 million due to the completion of agreements in the early part of 2021; and (c) increase in grant income related to the BARDA $12.7 million agreement in the amount of $8.9 million.

Gross Product Margin

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

Gross product margin decreased by $0.7 million, or 73% compared to 2020. The following schedule calculates gross product margin:

	For the years ended December 31		Favorable/ (unfavorable)	% Change
	2021	2020		
	(in thousands)			
Net product sales	$ 34,737	$ 24,767	$ 9,970	40.3%
Less: Cost of product sales	(34,496)	(23,874)	(10,622)	44.5%
Gross product margin	$ 241	$ 893	$ (652)	(73.0)%
Gross product margin %	0.7%	3.6%		

In 2021, we invested in developing and offering products to address the COVID-19 pandemic, which we expected to have average selling prices greater than those of our legacy products. We also continued to invest in automation in order to reduce our reliance on manual labor and improve our product margins. The $0.7 million decrease in gross product margin was comprised of (a) $1.0 million from unfavorable product margins offset by (b) $0.3 million favorable product sales volume as described under “—Total Revenues” above. The $1.0 million decrease from unfavorable product margins principally reflected the increased labor and overhead costs and unfavorable mix of average selling prices.

Research and Development

This category includes costs incurred for clinical and regulatory affairs and other research and development, as follows:

	For the years ended December 31		Favorable/ (unfavorable)	% Change
	2021	2020		
	(in thousands)			
Clinical and regulatory affairs	$ 5,109	$ 1,061	$ (4,048)	(381.5)%
Other research and development	7,378	8,448	1,070	12.7%
Total research and development	$ 12,487	$ 9,509	$ (2,978)	(31.3)%

The increase in clinical and regulatory affairs costs for 2021 as compared to 2020 was primarily associated with increased clinical trial costs related to the BARDA $12.7 million agreement which was completed on December 2, 2021. The decrease in other research and development costs was primarily related to the completion of R&D agreements in the early part of 2021.

Selling, General and Administrative Expense

Selling, general and administrative expenses include administrative expenses, sales and marketing costs (including commissions), and other corporate items. The $3.8 million, or 18.1%, increase in selling, general and administrative expenses for 2021 as compared to 2020 primarily reflected increased legal costs associated with the ongoing litigations, recruiting fees due to the ramp up in production that took place in the later part of 2021 and higher insurance costs.

Impairment, restructuring. severance and related costs

The Company recorded an impairment loss of $1.3 million during the second quarter of 2021, as the result of its write-off of the intangible assets, net, leasehold improvements, net and right-of-use assets for leases, net associated with its Malaysian operations that underwent a retrenchment during the second quarter of 2020.

In addition, the Company recorded an impairment loss of $4.6 million during the fourth quarter of 2021, as the result of a write down of finite-lived intangible assets ($2.0 million) and goodwill ($2.6 million) due to the substantial decrease in share price as of December 31, 2021. The low price per share value on December 31, 2021 caused the book value of the Company to exceed its market cap.

In light of the uncertainty of the timing and any receipt of those regulatory approvals, the timing of progress on and results of clinical trial programs, and the timing and any receipt of product orders from the commercialization of the COVID-19 Diagnostic Test Systems and other diagnostic test systems both within and outside the United States, during the second quarter of 2021, the Company engaged the services of an independent financial advisory firm (the “Financial Advisor”). The Financial Advisor worked with management to develop a forecast model to assess the amount and timing of the Company’s liquidity needs, assuming various business cases, and together with legal counsel advised the Company regarding alternative approaches to enhancing its liquidity position, participating in discussions with the Lender, and related matters. During the year ended December 31, 2021 and 2020, the Company incurred $1.1 and $0.4 million, respectively, related to these restructuring matters.

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

Acquisition Costs

Acquisition costs include legal, due diligence, audit, and related costs associated with acquisitions. The $0.1 million decrease in acquisition costs for 2021 as compared to 2020 reflected the fact that we completed acquisitions in 2020.

Other (Expense) / Income

Other (expense) / income was principally comprised of interest expense net of interest income. Interest expense increased by $0.1 million for 2021 as compared to 2020, due to the interest paid on the term loan debt we incurred in September 2019.

Income Tax Benefit

For 2021 we recognized a tax benefit of $0.1 primarily attributable to the loss generated by Chembio Diagnostics Germany. As of December 31, 2021 and 2020, the Company recorded a full valuation allowance against its net deferred tax assets.

Liquidity and Capital Resources

Our cash and cash equivalents totaled $28.8 million at December 31, 2021, an increase of $5.7 million from $23.1 million at December 31, 2020. We are obligated to maintain aggregate unrestricted cash of not less than $3,000,000 at all times under a covenant in the Credit Agreement.

During the year ended December 31, 2021, we funded our business operations, including capital expenditures and working capital requirements, principally from cash and cash equivalents and issuance of common stock in at-the-market offerings. Our operations used $30.9 million of cash during the twelve months ended December 31, 2021. In the first half of 2021, revenues did not meet our expectations, and the shortfall in revenues from the first two quarters was one of the principal reasons we issued common stock in the at-the-market offerings during the year ended December 31, 2021, which provided us with net proceeds of $38.8 million. This increase in cash and cash equivalents was offset in part as the result of (a) market, clinical trial and regulatory complications we faced in seeking to develop and commercialize a portfolio of COVID-19 test systems during the continuing, but evolving, uncertainty of the COVID-19 pandemic and (b) significant continuing expenses incurred in connection with pending legal matters (see “Note 12(e) – Commitments, Contingencies, and Concentrations – Litigation” in the Accompanying Financial Statements), delayed achievement of milestones associated with government grant income, investments in inventory, and, the continuing automation of U.S. manufacturing.

In light of the uncertainty of the timing and any receipt of regulatory approvals, the timing of progress on and results of clinical trial programs, and the timing and any receipt of product orders from the commercialization of our COVID-19 and other diagnostic test systems both within and outside the United States, during the year we engaged the services of an independent financial advisory firm. The financial advisory firm worked with management to develop a forecast model to assess the amount and timing of our liquidity needs, assuming various business cases and, together with legal counsel, advised us regarding alternative approaches to enhancing our liquidity position, participating in discussions with the Lender under our credit facility and related matters. We incurred fees related to these restructuring matters totaling $1.1 million in during the year.

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

We have undertaken plans and initiatives, including fulfillment of the July Purchase Orders (see "— Substantial Doubt as to Going Concern Status" above) and fundraising through "at-the-market" offerings (see "—Substantial Doubt as to Going Concern Status" above), designed to provide us with adequate liquidity to meet our obligations for at least the twelve-month period following the filing date of this report, when the Accompanying Financial Statements are being issued. Our execution of those plans and initiatives is dependent, however, on a number of operational performance factors, such as the effectiveness of our automated manufacturing operations, as well as numerous other factors that are beyond our control or that may not be addressable on terms acceptable to us, or at all. We have considered how the uncertainties around the delivery of the full number of tests covered by customer orders may be affected by limitations of our staffing, supply chain and liquidity, uncertainties regarding the achievement of milestones and related recognition of revenue under government grants from BARDA, and other matters outside our control. We further considered how those uncertainties could impact our ability to meet the obligations specified in the Credit Agreement over the next twelve months, which include (a) a covenant requiring minimum total revenues for the twelve months preceding each quarter end, which requirements range from $40.3 million for the twelve months ending December 31, 2021 to $47.4 million for the twelve months ending December 31, 2022 and (b) an obligation requiring the payment of principal installments, commencing with the payment of $300,000 on September 30, 2022. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. In such an event, there can be no assurance that we would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, we would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. Our inability to raise additional capital on acceptable terms or to otherwise generate cash in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for our operations, could have a material adverse effect on our business, prospects, results of operations, liquidity and financial condition.

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

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

We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends. We have not entered into, and do not expect to enter into, investments for trading or speculative purposes. Our accounts receivable, accounts payable and inventory balances fluctuate from period to period, which affects our cash flow from operating activities. The amounts of these fluctuations vary depending on cash collections, client mix, raw material lead times, the mix of vendor terms, the timing of shipment of our products and the invoicing of our research and development activities. As of December 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.

We continually evaluate our liquidity requirements, capital needs and availability of capital resources based on our operating needs and our planned growth initiatives. Our future working capital needs will depend on many factors, including the rate of our business and revenue growth, the availability and cost of human, material and other resources required to build and deliver products in accordance with our existing or future product orders, the timing of our continuing automation of U.S. manufacturing, and the timing of our investment in research and development as well as sales and marketing. If we are unable to increase our revenues and manage our expenses in accordance with our operating plan, we may need to reduce the level or slow the timing of the growth plans contemplated by our operating plan, which would likely curtail or delay the growth in our business contemplated by our operating plan and could impair or defer our ability to achieve profitability and generate cash flow, or to seek to raise additional funds through debt or equity financings, strategic relationships, or other arrangements. There can be no assurance that we would be able to complete any proposed financing on terms acceptable to us, or at all, or that we otherwise will be successful in any of our other endeavors to continue to be financially viable and continue as a going concern. Our inability to raise additional capital on acceptable terms could have a material adverse effect on our business, prospects, results of operations, liquidity and financial condition. If we were to raise additional funds through the issuance of equity or convertible securities, the issuance could result in substantial dilution to existing stockholders, and the holders of those new securities may have rights, preferences and privileges senior to those of the holders of common stock. Furthermore, any decline in the market price of our common stock could make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate.

Sources of Funds

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

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

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

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

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

As of the filing date of this report, we have issued and sold pursuant to the ATM Agreement a total of 9,709,328 shares of common stock at a volume-weighted average price of $4.20 per share for gross proceeds of $40.8 million and net proceeds, after giving effect to placement fees and other transaction costs, of $38.8 million. Additional shares of common stock may be issued and sold pursuant to the ATM Agreement for gross proceeds of up to $19.2 million, but we cannot provide any assurance that will be able to issue any additional shares under the ATM Agreement at an acceptable price or at all.

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

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

- *Interest Rate*. Principal outstanding under the Credit Agreement bears interest at a rate per annum equal to the sum of (a) the greater of the one month London Interbank Offered Rate and 2.5% plus (b) 8.75%. At any time at which an event of default (as described under "—Default Provisions" below) has occurred and is continuing, the interest rate will increase by 4.0%. Accrued interest is payable on a monthly basis. On December 31, 2021 the interest rate was 11.25%.

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

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

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

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

- *Representations and Warranties*. Financial and Other Covenants. In the Credit Agreement we made customary representations and warranties as well as customary affirmative and negative covenants, including covenants limiting additional indebtedness, liens, guarantees, mergers and acquisitions, substantial asset sales, investments and loans, sale and leasebacks, transactions with affiliates, and fundamental changes. The Credit Agreement also contains financial covenants requiring that (a) we maintain aggregate unrestricted cash of not less than $3,000,000 at all times and (b) we achieve specified minimum total revenue requirements for the twelve months preceding each quarter end. The minimum total revenue amounts range from $32.0 million to $50.1 million and, for the next year, range from $42.0 million for the twelve months ending March 31, 2022 to $47.4 million for the twelve months ending December 31, 2022. The minimum total revenue requirements were developed for purposes of the Credit Agreement and do not reflect the internal estimates and plans used by our management and board of directors to understand and evaluate our operating performance, to establish budgets, and to establish operational goals for managing our business. We therefore do not believe that the covenant requirements provide useful information to investors or others in enhancing an understanding of our future prospects.

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

Research and Development Awards. Under a contract we entered into with BARDA on December 2, 2020, a total of up to $12.7 million of awards were available from BARDA to assist us in (a) developing, and pursuing an EUA from the FDA for, the DPP Respiratory Antigen Panel and (b) performing the clinical trials for and submitting the DPP SARS-CoV-2 Antigen test system to the FDA for 510(k) clearance. Of the total awards available under this contract, we recognized government grant income totaling $10.9 million during the year ended December 31, 2021. The completion of milestones to earn the remaining awards are outside our control, and contingent to the EUA approval by the FDA.

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

	December 31, 2021
	(in thousands)
Cash and cash equivalents	$ 28,773
Accounts receivable, net	11,441
Inventories, net	12,920
Prepaid expenses and other current assets	1,710
Total current assets	54,844
Less: Total current liabilities	(15,282)
Working capital	$ 39,562

Our cash and cash equivalents at December 31, 2021, 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 $30.9 million of cash during the year ended December 31, 2021, primarily due to the net loss adjusted for non-cash items of $18.8 million. Those uses of cash were the result of $8.0 million increase in accounts receivable, a $4.5 million increase in inventory, $1.6 million decrease in deferred revenue and $0.9 million decrease in Prepaid and other current assets, offset in part by a $3.1 million increase in accounts payable and other accrued liabilities.

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

Capital Expenditures. Our capital expenditures totaled $1.9 million in the year ended December 31, 2021, all of which related to investments in automated manufacturing equipment, facilities, and other fixed assets. As of December 31, 2021, we had capital purchase obligations of $1.5 million related to additional automated manufacturing equipment, with payments expected to come due during 2022 based on vendor performance milestones.

Significant Accounting Policies and Critical Accounting Estimates

Our significant accounting policies are described in Note 2 – Significant Accounting Policies to the audited consolidated financial statements included herein. Certain of our accounting policies require the application of significant judgment by management in selecting the appropriate assumptions for calculating financial estimates. By their nature, these judgments are subject to an inherent degree of uncertainty. These judgments are based on our historical experience, terms of existing contracts, our evaluation of trends in the industry, information provided by our customers and information available from other outside sources, as appropriate. We consider an accounting estimate to be critical if (a) it requires us to make assumptions about matters that were uncertain at the time we were making the estimate and (b) changes in the estimate or different estimates that we could have selected would have had a material impact on our financial condition or results of operations.

The following listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by accounting principles generally accepted in the United States, with no need for management's judgment in their application. There are also areas in which management's judgment in selecting any viable alternative would not produce a materially different result.

Revenue Recognition

We recognize revenue for product sales in accordance with Financial Accounting Standards Board Accounting Standards Codification, or ASC, 606, *Revenue from Contracts with Customers*. Revenues from product sales are recognized when the customer obtains control of our product, which occurs at a point in time, typically upon tendering to the customer. We expense incremental costs of obtaining a contract as and when incurred because the expected amortization period of the asset that it would have recognized is one year or less or the amount is immaterial. Freight and distribution activities on products are performed after the customer obtains control of the goods. We have made an accounting policy election to account for shipping and handling activities that occur either when or after goods are tendered to the customer as a fulfillment activity, and therefore recognizes freight and distribution expenses in cost of product sales. We exclude certain taxes from the transaction price (*e.g.*, sales, value added and some excise taxes).

Estimates of variable consideration and the determination of whether to include estimated amounts in the transaction price are based on all information (historical, current, and forecasted) that is reasonably available to us, taking into consideration the type of customer, the type of transaction, market events and trends, and the specific facts and circumstances of each arrangement.

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

From time to time the Company engages in bill-and-hold arrangements, whereby the Company manufactures and sells its product and at the customer's request stores the product at the Company's warehouse. Even though the product remains in the Company's possession, a sale is recognized at the point in time when the customer obtains control of the product. Control is transferred to the customer in bill and hold transactions when: customer acceptance specifications have been met, legal title has transferred, the customer has a present obligation to pay for the product and the risk and rewards of ownership have transferred to the customer. Additionally, all the following bill and hold criteria would have to be met in order for control to be transferred to the customer:

(a) The reason for the bill-and-hold arrangement must be substantive (for example, the customer has requested the arrangement).
(b) The product must be identified separately as belonging to the customer.
(c) The product currently must be ready for physical transfer to the customer.
(d) The entity cannot have the ability to use the product or to direct it to another customer.

Goodwill

We periodically review goodwill for impairment indicators. We review goodwill for impairment annually in the fourth quarter or more frequently if events or changes in circumstances indicate that goodwill might be impaired. We perform the goodwill impairment review at the reporting unit level. We perform a qualitative assessment of whether it is more likely than not that a reporting unit's fair value is less than its carrying amount. If not, no further goodwill impairment testing is performed. If so, we perform the step discussed hereafter. Our qualitative assessment involves significant estimates, assumptions, and judgments, including, macroeconomic conditions, industry and market conditions, our financial performance, reporting unit specific events and changes in our share price.

If the fair value of the reporting unit is *greater* than its carrying amount, goodwill is not considered to be impaired. We would recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, provided the impairment charge does not exceed the total amount of goodwill allocated to the reporting unit.

The company operates as a single operating segment and has one reporting unit. During the year ended December 31, 2021, the Company performed a quantitative analysis and determined that the carrying value exceeded its fair value by $2.6 million, on December 31, 2021.

Recently Issued Accounting Pronouncements

Refer to Note 2 – Significant Accounting Policies to the audited consolidated financial statements included herein for a complete description of recent accounting standards that we have not yet been required to implement which may be applicable to our operations. Additionally, the significant accounting standards that have been adopted during the year ended December 31, 2021 are described.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Consolidated Financial Statements and schedules that constitute Item 8 are attached at the end of this report. An index to the Consolidated Financial Statements and supplemental schedules are also included on page F-1 of this report.

ITEM 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined by Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of December 31, 2021. Based on the evaluation of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2021 at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer and effected by the board of directors, management and other personnel 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 and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. As a result, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, our management evaluated the effectiveness of our internal control over financial reporting as of December 31, 2021. In making their assessment of internal control over financial reporting, our management used the criteria described in the 2013 Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Our evaluation included documenting, evaluating and testing of the design and operating effectiveness of our internal control over financial reporting. Based on this evaluation, we concluded that our controls over financial reporting were effective as of December 31, 2021.

Previously Identified Material Weaknesses in Internal Control Over Financial Reporting

None.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Securities Exchange Act of 1934 during the period covered by this Annual Report on Form 10-K that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Internal Control

Management, including the Company's Chief Executive Officer and Chief Financial Officer, does not expect that the Company's internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of internal control can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Also, any evaluation of the effectiveness of internal controls in future periods are subject to the risk that those internal controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies and procedures may deteriorate.

ITEM 9B. Other Information

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required in response to this Item 10 is incorporated herein by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A of the Exchange Act not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required in response to this Item 11 is incorporated herein by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A of the Exchange Act not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required in response to this Item 12 is incorporated herein by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A of the Exchange Act not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required in response to this Item 13 is incorporated herein by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A of the Exchange Act not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required in response to this Item 14 is incorporated herein by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A of the Exchange Act not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) See "Item 8. Financial Statements and Supplementary Data – Index to Consolidated Financial Statements" above.

(b) Exhibits

Exhibit No.	Description
3.1	Articles of Incorporation, as amended, of Chembio Diagnostics, Inc. (incorporated herein by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q filed on July 29, 2010)
3.2	Amended and Restated Bylaws, of Chembio Diagnostics, Inc. (incorporated herein by reference to Exhibit 3.2 to the Current Report on Form 8-K filed on September 17, 2018)
4.1	Warrant to Purchase Common Stock dated as of September 3, 2019, issued by Chembio Diagnostics, Inc. to Perceptive Credit Holdings II, LP (incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on September 5, 2019)
4.2	Description of Securities (incorporated herein by reference to Exhibit 4.2 to the Annual Report on Form 10-K filed on March 11, 2021)
10.1(a)*	2008 Stock Incentive Plan, as amended (incorporated herein by reference to Attachment B to the Proxy Statement on Form DEF 14A filed on 2012)
10.1(b)*	Form of Option for 2008 Stock Incentive Plan (incorporated herein by reference to Exhibit 4.4 to the Quarterly Report on Form 10-Q filed on May 8, 2014)
10.2(a)*	2014 Stock Incentive Plan (incorporated herein by reference to Attachment A to the Proxy Statement on Form DEF 14A filed on April 29, 2014)
10.2(b)*	Form of Option for 2014 Stock Incentive Plan (incorporated herein by reference to Exhibit 4.7 to the Quarterly Report on Form 10-Q filed on August 7, 2014)
10.3*	2019 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Annual Report on Form 10-K filed on March 13, 2020)
10.4*	Restated Annual Incentive Bonus Plan of Chembio Diagnostics, Inc., adopted as of March 15, 2019 (incorporated herein by reference to Exhibit 10.3 to the Annual Report on Form 10-K filed on March 18, 2019)
10.5*	Outside Director Compensation Policy of Chembio Diagnostics, adopted as of December 15, 2020 (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on December 17, 2020)
10.6(a)*	Employment Agreement, dated as of March 4, 2020 and effective as of March 16, 2020 between Chembio Diagnostics, Inc. and Richard L. Eberly (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on March 20, 2020)
10.6(b)*	Amendment No. 1 dated February 9, 2022 between Chembio Diagnostics, Inc. and Richard L. Eberly, amending the Employment Agreement dated March 4, 2020 (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on February 14, 2022)
10.7(a)*	Employment Agreement dated March 5, 2016 between Chembio Diagnostics, Inc. and Javan Esfandiari (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on March 14, 2016)
10.7(b)*	Amendment No. 1 dated March 20, 2019 between Chembio Diagnostics, Inc. and Javan Esfandiari, amending the Employment Agreement dated March 5, 2016 (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on March 25, 2019)
10.7(c)*	Amendment No. 2 dated November 30, 2021 between Chembio Diagnostics, Inc. and Javan Esfandiari, amending the Employment Agreement dated March 5, 2016 (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on December 6, 2021)
10.8(a)*	Employment Agreement dated December 18, 2017 between Chembio Diagnostics, Inc. and Neil A. Goldman (incorporated herein by reference to Exhibit 10.4 to the Annual Report on Form 10-K filed on March 8, 2018).
10.8(b)*	Amendment No. 1 dated January 21, 2019 between Chembio Diagnostics, Inc. and Neil A. Goldman, amending Employment Agreement dated December 18, 2017 (incorporated herein by reference to Exhibit 10.01 to the Current Report on Form 8-K filed on January 25, 2019)
10.9*	Employment Agreement, dated as of December 30, 2021 and effective as of January 5, 2022, between Chembio Diagnostics, Inc. and Lawrence J. Steenvoorden (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on January 6, 2022)
10.10*	Offer Letter dated October 19, 2016 between Worldwide Workplace Ireland and Robert Passas, with respect to employment by Chembio Diagnostics Systems, Inc. (incorporated herein by reference to Exhibit 10.4 to the Current Report on Form 8-K filed on October 22, 2018)
10.11	Separation and Release Agreement, dated January 7, 2020, between Chembio Diagnostics, Inc. and John J. Sperzel III (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on January 9, 2020)
10.12(a)	Lease Agreement, dated February 15, 2017, between Horseblock Associates and Chembio Diagnostics, Inc. with respect to 3661 Horseblock Road, Medford, New York, as amended (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on October 22, 2018)
10.12(b)	Agreement of Sublease dated February 5, 2019 between Chembio Diagnostic Systems Inc., as sublessor, and Reliance Communications of New Jersey, LLC, as sublessee, with respect to 3661 Horseblock Road, Medford, New York, as amended (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on February 11, 2019)
10.13	Lease Agreement, dated February 4, 2013, between Sherwood Corporate Center LLC and Chembio Diagnostics, Inc. with respect to 91-1A Colin Drive, Holbrook, New York, as amended on September 19, 2017 (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on October 22, 2018)
10.14	Lease Agreement dated February 5, 2019 between Myra Properties, LLC, as lessor, and Chembio Diagnostic Systems Inc., as lessee, with respect to 555 Wireless Boulevard, Hauppauge, New York (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on February 11, 2019)
10.15†	Credit Agreement and Guaranty dated as of September 3, 2019, among Chembio Diagnostics, Inc., as the Borrower, the Guarantors from time to time party thereto, and Perceptive Credit Holdings II, LP and its successors and assigns party thereto, as Administrative Agent and as a Lender (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 5, 2019)
10.16	At the Market Offering Agreement, dated July 19, 2021, between Chembio Diagnostics, Inc. and Craig-Hallum Capital Group LLC (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on July 19, 2021)
14.1	Ethics Policy (incorporated herein by reference to Exhibit 14.1 to the Annual Report on Form 10-KSB filed on March 30, 2006)
21.1	List of Subsidiaries of Chembio Diagnostics, Inc.

23.1	Consent of EY, Independent Registered Public Accounting Firm
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

* Indicates management contract or compensatory plan.

† Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. We hereby undertake to furnish copies of the omitted exhibits and schedules upon request by the Securities and Exchange Commission, provided that we may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934 for the exhibits and schedules so furnished.

** The certifications attached as Exhibit 32.1 accompany the Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CHEMBIO DIAGNOSTICS, INC.

March 3, 2022 By /s/ Richard L. Eberly
Richard L. Eberly
Chief Executive Officer and President

In accordance with the requirements of the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
/s/ Richard L. Eberly Richard L. Eberly	Chief Executive Officer and President (Principal Executive Officer)	March 3, 2022
/s/ Lawrence J. Steenvoorden Lawrence J. Steenvoorden	Chief Financial Officer (Principal Financial & Accounting Officer)	March 3, 2022
 Katherine L. Davis	Chair of the Board	
/s/ David W. K. Acheson David W. K. Acheson	Director	March 3, 2022
/s/ David W. Bespalko David W. Bespalko	Director	March 3, 2022
/s/ John G. Potthoff John G. Potthoff	Director	March 3, 2022

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
Index to Consolidated Financial Statements

—INDEX—

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Chembio Diagnostics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Chembio Diagnostics, Inc. (and subsidiaries) (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive loss**,** stockholders' equity and cash flows for the years ended December 31, 2021 and 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. As explained below, auditing the Company's evaluation of its ability to continue as a going concern was a critical audit matter.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

Revenue Recognition – Transfer of Control

Description of the Matter

For the year ended December 31, 2021, the Company recognized $34.7 million of net product revenue. As discussed in Note 2 to the consolidated financial statements, product revenue is recognized when the customer obtains control of the Company's product in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services.

Auditing the determination of transfer of control to recognize revenue was especially complex due to the variability in the terms and conditions within certain customer contracts. Customer contracts must be carefully evaluated for terms that may affect the timing or measurement of revenue recognition, including any bill-and-hold arrangements.

How We Addressed the Matter in Our Audit

To test the transfer of control, our audit procedures included, among others, testing that the Company recorded revenue in accordance with the terms and conditions of the contract by testing a sample of customer contracts. As part of this testing, we inspected the executed customer contract to identify the performance obligation and when the transfer of control occurred. We evaluated the Company's assessment as to when the performance obligation was fulfilled, and that revenue was properly recognized within the correct period. Our procedures also included inspecting third-party evidence of transfer of control to the customer, and where appropriate, we also confirmed with customers contract terms and conditions. We also performed cut-off testing around period end in order to test that revenue was properly recognized in the correct period.

Going Concern

Description of the Matter

As discussed in Note 2, the determination as to whether the Company can continue as a going concern includes consideration of management's operating plan and anticipated timing of future cash flows. The Company's Credit Agreement contains covenants that, among other items, require the Company to maintain a minimum cash balance and meet certain minimum revenue requirements. This matter is also described in the "Going Concern Uncertainty" section of our report. Management is required to make subjective judgments and assumptions in concluding on going concern uncertainty.

Auditing the Company's going concern assessment is complex because it involves a high degree of auditor judgment to assess the reasonableness of the cash flow forecasts used in the Company's going concern analysis. In particular, the cash flows are sensitive

to changes related to significant assumptions, such as the estimation of the future cash to be used in operations, projected net revenue, projected earnings before interest, taxes, depreciation and amortization, and compliance with debt covenants. The Company's ability to achieve forecasted results is judgmental given the unpredictability of its customers spending habits as a result of the COVID-19 pandemic.

How We Addressed the Matter in Our Audit

To test the future cash flow forecasts, we performed audit procedures that included, among others, evaluating and testing the significant assumptions discussed above and the underlying data used by the Company in its analysis. This testing included inquiries with management, comparison of prior period forecasts to actual results, consideration of contrary evidence impacting management's forecasts, and the Company's financing arrangements in place as of the report date.

Goodwill and Long-Lived Assets Impairment

Description of the Matter

As discussed in Notes 2 and 14 to the consolidated financial statements, the Company identified indicators of impairment, which resulted in the Company assessing the value of goodwill and its long-lived asset group for recoverability. The Company's analysis resulted in goodwill and long-lived asset impairment charges of $2.6 million and $2.0 million, respectively.

Auditing the Company's measurement of impairment involved a high degree of subjectivity as estimates underlying the determination of fair values were based on assumptions about future economic conditions. Significant assumptions used in the Company's fair value estimates included projected net revenue and projected earnings before interest, taxes, depreciation and amortization.

How We Addressed the Matter in Our Audit

To test the future economic conditions, as part of our audit, we assessed the methodologies and significant assumptions used in the impairment tests, among other procedures. We tested the significant assumptions discussed above, as well as the completeness and accuracy of the underlying data used in the valuations. In order to reflect the uncertainty inherent in the projections, we performed our own sensitivity analyses by increasing or decreasing the significant assumptions and evaluated the potential impact on the fair value. In addition, we tested the reconciliation of the fair value of the reporting unit developed by management to the market capitalization of the Company as of the valuation date and evaluated the implied control premium for reasonableness.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2020.
Jericho, New York
March 3, 2022

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
AS OF

	December 31, 2021	December 31, 2020
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 28,772,892**	$ 23,066,301
Accounts receivable, net of allowance for doubtful accounts of $243,042 and $296,793 at December 31, 2021 and 2020, respectively	**11,441,107**	3,377,387
Inventories, net	**12,920,451**	12,516,402
Prepaid expenses and other current assets	**1,710,194**	778,683
TOTAL CURRENT ASSETS	**54,844,644**	39,738,773
FIXED ASSETS:		
Property, plant and equipment, net	**8,556,773**	8,688,403
Finance lease right-of-use assets, net	**191,870**	233,134
OTHER ASSETS:		
Operating right-of-use assets, net	**5,891,906**	6,112,632
Intangible assets, net	**-**	3,645,986
Goodwill	**3,022,787**	5,963,744
Deposits and other assets	**744,215**	509,342
TOTAL ASSETS	**$ 73,252,195**	$ 64,892,014
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 13,127,993**	$ 10,042,790
Deferred revenue	**-**	1,606,997
Current portion of long term debt	**1,200,000**	-
Operating lease liabilities	**886,294**	642,460
Finance lease liabilities	**68,176**	58,877
TOTAL CURRENT LIABILITIES	**15,282,463**	12,351,124
OTHER LIABILITIES:		
Long-term operating lease liabilities	**5,976,151**	6,327,143
Long-term finance lease liabilities	**139,678**	185,239
Long-term debt, less current portion, net	**17,589,003**	18,182,158
Deferred tax liability	**-**	69,941
TOTAL LIABILITIES	**38,987,295**	37,115,605
COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding	**-**	-
Common stock - $0.01 par value; 100,000,000 shares authorized, 30,104,986 and 20,223,498 shares issued and outstanding at December 31, 2021 and 2020, respectively	**301,050**	202,235
Additional paid-in capital	**165,772,636**	124,961,514
Accumulated deficit	**(131,009,860)**	(97,106,331)
Treasury stock – 48,057 and 41,141 shares at cost, at December 31, 2021 and 2020, respectively	**(206,554)**	(190,093)
Accumulated other comprehensive loss	(592,372)	(90,916)
TOTAL STOCKHOLDERS' EQUITY	**34,264,900**	27,776,409
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 73,252,195**	$ 64,892,014

See accompanying notes to consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	December 31,	
	2021	2020
REVENUES:		
Product revenue	**$ 34,737,444**	$ 24,767,149
R&D revenue	**1,159,381**	4,851,562
Government grant income	**10,891,726**	2,018,924
License and royalty revenue	**1,029,901**	832,562
TOTAL REVENUES	**47,818,452**	32,470,197
COSTS AND EXPENSES:		
Cost of product sales	**34,495,802**	23,874,487
Research and development expenses	**12,487,424**	9,508,494
Selling, general and administrative expenses	**24,840,611**	21,037,701
Impairment, restructuring, severance and related costs	**7,047,779**	1,122,310
Acquisition costs	**-**	63,497
	78,871,616	55,606,489
LOSS FROM OPERATIONS	**(31,053,164)**	(23,136,292)
OTHER (EXPENSE) INCOME:		
Interest expense, net	**(2,912,415)**	(2,841,830)
LOSS BEFORE INCOME TAX BENEFIT	**(33,965,579)**	(25,978,122)
Income tax benefit	**62,050**	456,794
NET LOSS	**$ (33,903,529)**	$ (25,521,328)
Basic and diluted loss per share	**$ (1.40)**	$ (1.34)
Weighted average number of shares outstanding, basic and diluted	**24,299,465**	19,085,691

See accompanying notes to consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	December 31,	
	2021	2020
Net loss	**$ (33,903,529)**	$ (25,521,328)
Other comprehensive loss:		
Foreign currency translation adjustments	**(501,456)**	(100,760)
COMPREHENSIVE LOSS	**$ (34,404,985)**	$ (25,622,088)

See accompanying notes to consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2021, AND 2020

	Common Stock		Additional Paid-in-Capital	Treasury Stock		Accumulated Deficit	AOCL	Total
	Shares	Amount	Amount	Shares	Amount	Amount	Amount	Amount
Balance at December 31, 2019	17,733,617	$ 177,335	$ 95,433,077	-	$ -	$ (71,585,003)	$ 9,844	$ 24,035,253
Common Stock:								
Issuance of stock, net	2,619,593	26,196	28,410,544	-	-	-	-	28,436,740
Restricted stock issued	81,773	819	128,356	-	-	-	-	129,175
Restricted stock compensation, net	(470,174)	(4,702)	617,919	-	-	-	-	613,217
Shares tendered for withholding taxes	-	-	(296,667)	-	-	-	-	(296,667)
Options:								
Exercised	5,528	55	(55)	-	-	-	-	-
Stock option compensation	-	-	480,779	-	-	-	-	480,779
Treasury Stock	-	-	190,093	(41,141)	(190,093)	-	-	-
Warrant exercised	253,161	2,532	(2,532)	-	-	-	-	-
Comprehensive loss	-	-	-	-	-	-	(100,760)	(100,760)
Net loss	-	-	-	-	-	(25,521,328)	-	(25,521,328)
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:								
Issuance of stock, net	9,709,328	97,093	38,714,865	-	-	-	-	38,811,958
Restricted stock issued	135,908	1,359	105,582	-	-	-	-	106,941
Restricted stock compensation, net	-	-	1,160,953	-	-	-	-	1,160,953
Shares tendered for withholding taxes	-	-	(145,225)	-	-	-	-	(145,225)
Options:								
Exercised	36,252	363	85,192	-	-	-	-	85,555
Stock option compensation	-	-	873,294	-	-	-	-	873,294
Treasury stock	-	-	16,461	(6,916)	(16,461)	-	-	-
Comprehensive loss	-	-	-	-	-	-	(501,456)	(501,456)
Net loss	-	-	-	-	-	(33,903,529)	-	(33,903,529)
Balance at December 31, 2021	30,104,986	$ 301,050	$ 165,772,636	(48,057)	$ (206,554)	$ (131,009,860)	$ (592,372)	$ 34,264,900

See accompanying notes to consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED

	December 31, 2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	**$ 38,093,984**	$ 34,736,133
Cash paid to suppliers and employees	**(65,273,967)**	(50,238,409)
Cash paid for operating leases	**(1,404,532)**	(1,139,944)
Cash paid for finance leases	**(20,077)**	(19,987)
Interest and taxes, net	**(2,281,124)**	(2,225,031)
Net cash used in operating activities	**(30,885,716)**	(18,887,238)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of and deposits on fixed assets	**(1,824,285)**	(3,961,369)
Patent application costs	**(33,398)**	(205,493)
Net cash used in investing activities	**(1,857,683)**	(4,166,862)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock, net	**38,811,958**	28,436,740
Proceeds from option exercises	**85,555**	-
Principal payments for finance leases	**(61,867)**	(51,166)
Payments on note payable	**-**	(180,249)
Stimulus package loan	**-**	2,978,315
Payment of stimulus package loan	**-**	(2,978,315)
Payments of tax withholdings on stock award	**(145,225)**	(441,723)
Net cash provided by financing activities	**38,690,421**	27,763,602
Effect of exchange rate changes on cash	**(240,431)**	85,447
INCREASE IN CASH AND CASH EQUIVALENTS	**5,706,591**	4,794,949
Cash and cash equivalents - beginning of the period	**23,066,301**	18,271,352
Cash and cash equivalents - end of the period	**$ 28,772,892**	$ 23,066,301
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net Loss	**$ (33,903,529)**	$ (25,521,328)
Adjustments:		
Depreciation and amortization	**2,930,976**	2,697,126
Share based compensation	**2,431,982**	1,223,171
Benefit from deferred tax liability	**(69,941)**	(396,385)
Provision for (recovery of) doubtful accounts	**(53,751)**	270,193
Non-cash inventory changes	**4,054,701**	3,543,515
Impairment charges	**5,880,741**	-
Changes in assets and liabilities:		
Accounts receivable	**(8,009,969)**	283,939
Inventories	**(4,458,750)**	(6,461,887)
Prepaid expenses and other current assets	**(931,510)**	(85,670)
Deposits and other assets	**(234,874)**	34,195
Accounts payable and accrued liabilities	**3,085,205**	4,043,896
Deferred revenue	**(1,606,997)**	1,481,997
Net cash used in operating activities	**$ (30,885,716)**	$ (18,887,238)
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	**$ -**	$ 472,651
Contingent liability earnout	$ -	$ 1,011,261

See accompanying notes to consolidated financial statements

NOTE 1 — DESCRIPTION OF BUSINESS:

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

Our product portfolio is based upon our proprietary DPP technology, a diagnostic platform that provides high-quality, cost-effective results in 15 to 20 minutes using fingertip blood, nasal swabs and other sample types. The DPP technology platform addresses the rapid diagnostic test market, which includes infectious diseases such as STI's and HIV, Gastroenterology and Women's Health. Compared with traditional lateral flow technology, the DPP technology platform can provide:

- **Enhanced sensitivity and specificity:** This is achieved via our patented approach to separating the sample path from the buffer path, together with other patented and proprietary strategies, that differ significantly from traditional lateral flow test.

- **Advanced multiplexing capabilities:** Through advanced multiplexing, the DPP platform can detect and differentiate up to eight distinct test results from a single patient sample, which can deliver greater clinical value than other rapid tests currently on the market.

- **Objective results:** For some diagnostic applications, our easy-to-use, highly portable, battery-operated DPP Micro Reader optical analyzers can report accurate results in approximately 15 seconds, making it well-suited for decentralized testing where real-time results enable patients to be clinically assessed while they are still 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.

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

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

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES:

(a) ***Basis of Presentation:***

The accompanying consolidated financial statements include the accounts of Chembio and its subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Going Concern Considerations

Revenues during the twelve months ended December 31, 2021 did not meet the Company's expectations. The Company's increase in cash and cash equivalents over the year reflected its issuance of common stock in at-the-market offerings for net proceeds of $38.8 million (see Note 9 - Stockholder's Equity). The Company continued to experience market, clinical trial and regulatory complications in seeking to develop and commercialize a portfolio of COVID-19 test systems during the continuing, but evolving, uncertainty of the COVID-19 pandemic. For the year ending December 31, 2021, the Company continued to incur significant expenses in connection with pending legal matters (see Note 12 – Commitments, Contingencies, and Concentrations: Litigation), delayed achievement of milestones associated with government grant income, investments in inventory, and the continuing automation of manufacturing.

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

During the twelve months ended December 31, 2021, the Company undertook measures to increase its total revenues and improve its liquidity position. In particular, the Company received significant purchase orders from two customers (the "July Purchase Orders"). The Company had pursued the July Purchase Orders for an extended period of time. The July Purchase Orders consist of the following:

- On July 20, 2021, the Company received a $28.3 million purchase order from Bio-Manguinhos for the purchase of DPP SARS-CoV-2 Antigen tests for delivery during 2021 to support the urgent needs of Brazil's Ministry of Health in addressing the COVID-19 pandemic. Bio-Manguinhos is responsible for the development and production of vaccines, diagnostics and biopharmaceuticals, primarily to meet the demand of Brazil's national public health system. As of December 31, 2021 $16.8 million was recognized in connection with this order.

- On July 22, 2021, the Company received a $4 million purchase order from the Partnership for Supply Chain Management, supported by The Global Fund, for the purchase of HIV 1/2 STAT-PAK Assays for shipment to Ethiopia into early 2022. As of December 31, 2021 $1.2 million was recognized in connection with this order.

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

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

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

The Company further considered how these factors and uncertainties could impact its ability over the next year to meet the obligations specified in the Credit Agreement with the Lender (each as defined in Note 13 – Long-Term Debt). Those obligations include covenants requiring: i) minimum cash balance of $3.0 million and ii) minimum total revenue amounts for the twelve months preceding each quarter end. For the next year, the minimum total revenue requirements range from $42.0 million for the twelve months ending March 31, 2022 to $47.4 million for the twelve months ending December 31, 2022. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. In such an event, there can be no assurance that the Company would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, the Company would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. The Company's inability to raise additional capital on acceptable terms in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for its operations, could have a material adverse effect on its business, prospects, results of operations, liquidity and financial condition.

Accordingly, management determined the Company could not be certain that the Company's plans and initiatives would be effectively implemented within one year after the date on which the accompanying consolidated financial statements are being issued. Without giving effect to the prospect of raising additional capital pursuant to the ATM Agreement (as defined in Note 9 – Stockholders' Equity: Common Stock), increasing product revenue in the near future or executing other mitigating plans, many of which are beyond the Company's control, it is unlikely that the Company will be able to generate sufficient cash flows to meet its required financial obligations, including its debt service and other obligations due to third parties. The existence of these conditions raises substantial doubt about the Company's ability to continue as a going concern for the twelve-month period following the date on which the accompanying audited consolidated financial statements are being issued.

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

(b) ***Use of Estimates:***

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make assumptions and estimates that affect the amounts reported in the consolidated financial statements and accompanying notes. Judgments and estimates of uncertainties are required in applying the Company's accounting policies in certain areas. Generally, matters subject to estimation and judgment include accounts receivable realization, inventory obsolescence, asset impairments, recognition of revenue, useful lives of intangible and fixed assets, stock-based compensation, and deferred tax asset valuation allowances. Due to the inherent uncertainty involved in making estimates, actual results reported in future periods may be based upon amounts that differ from those estimates.

(c) ***Fair Value of Financial Instruments:***

The carrying value for cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate fair value due to the immediate or short-term maturity of these financial instruments. Included in cash and cash equivalents is $25.0 million and $16.0 million as of December 31, 2021 and 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 million (carrying value of $18.8 million) and $20 million (carrying value of $18.2 million) as of December 31, 2021 and 2020, respectively, is a Level 2 fair value measurement under the hierarchy, and the carrying value approximates fair value.

Fair value measurements of all financial assets and liabilities that are being 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.

As of December 31, 2020, the Company was contractually obligated to maintain a restricted cash balance of $1 million 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 has fully performed under the purchase order as of December 31, 2021.

(e) ***Concentrations of Credit Risk:***

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and trade receivables. The Company places its cash with well-known financial institutions and, at times, may maintain balances in excess of the FDIC insurance limit.

(f) ***Inventory:***

Inventories are stated at the lower of cost or net realizable value with cost being determined using a standard cost method, which approximates average cost. Average cost consists primarily of material, labor and manufacturing overhead expenses (including fixed production-overhead costs). The Company analyzes its inventory levels quarterly and writes down, in the applicable period, inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected customer demand.

(g) ***Fixed Assets:***

Fixed assets are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, which range from three to seven years. Leasehold improvements are amortized over the useful life of the asset or the lease term, whichever is shorter. Deposits paid for fixed assets are capitalized and not depreciated until the related asset is placed in service.

(*h*) ***Valuation of Long-Lived Assets and Intangible Assets:***

Long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the related carrying amounts may not be recoverable. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment. If there are indications of impairment, the Company uses future undiscounted cash flows of the related asset or asset grouping over the remaining life in measuring whether the assets are recoverable. In the event such cash flows are not expected to be sufficient to recover the recorded asset values, the assets are written down to their estimated fair value. A $3.3 and $0 million impairment of long-lived intangible assets was recorded for the years ended December 31, 2021 and 2020 (see Note 14 - Asset Impairment, Restructuring, Severance and related costs).

(i) ***Revenue Recognition:***

The Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. The Company recognizes revenue following the five-step model prescribed under Accounting Standards Update ("ASU") 2014-09: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligation.

Product Revenue

Revenue from product sales are recognized and commissions are accrued when the customer obtains control of the Company's product, which occurs at a point in time, typically upon tendering the product to the customer. The Company expenses incremental costs of obtaining a contract as and when incurred because the expected amortization period of the asset that it would have recognized is one year or less or the amount is immaterial. Freight and distribution activities on products are performed when the customer obtains control of the goods. The Company has made an accounting policy election to account for shipping and handling activities that occur either when or after goods are tendered to the customer as a fulfillment activity, and therefore recognizes freight and distribution expenses in cost of product sales. The Company excludes certain taxes from the transaction price (e.g., sales, value added and some excise taxes).

The Company's contracts with customers often include promises to transfer products or services to a customer. Determining whether products and services are considered distinct performance obligations that should be accounted for separately versus together may require judgment. Typical products sold are diagnostic tests and typical services performed are R&D studies. Revenues from product sales are recognized at a point-in-time and revenues from R&D studies are recognized ratably over the period of the agreement, unless the related performance obligations indicate otherwise.

Judgment is required to determine the stand-alone selling price ("SSP") for each distinct performance obligation. SSP is directly observable and the Company can use a range of amounts to estimate SSP, as it sells products and services separately, and can determine whether there is a discount to be allocated based on the relative SSP of the various products and services, for the various geographies.

From time to time the Company engages in bill-and-hold arrangements, whereby the Company manufactures and sells its product and at the customer's request stores the product at the Company's warehouse. Even though the product remains in the Company's possession, a sale is recognized at the point in time when the customer obtains control of the product. Control is transferred to the customer in bill and hold transactions when: customer acceptance specifications have been met, legal title has transferred, the customer has a present obligation to pay for the product and the risk and rewards of ownership have transferred to the customer. Additionally, all the following bill and hold criteria would have to be met in order for control to be transferred to the customer:

(a) The reason for the bill-and-hold arrangement must be substantive (for example, the customer has requested the arrangement).
(b) The product must be identified separately as belonging to the customer.
(c) The product currently must be ready for physical transfer to the customer.
(d) The entity cannot have the ability to use the product or to direct it to another customer.

The Company's payment terms vary by the type and location of the Company's customer and products or services offered. Payment terms differ by jurisdiction and customer, but payment is generally required in a term ranging from 30 to 60 days from date of shipment or satisfaction of the performance obligation.

Reserves for Discounts and Allowances

Revenue from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with the Company's customers.

Product revenue reserves, which are classified as a reduction in product revenue, are generally related to discounts and returns. Estimates of variable consideration and the determination of whether to include estimated amounts in the transaction price are based on all information (historical, current, and forecasted) that is reasonably available to the Company, taking into consideration the type of customer, the type of transaction, market events and trends, and the specific facts and circumstances of each arrangement. The transaction price, which includes variable consideration reflecting the impact of discounts, allowances and returns may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the revenue recognized will not occur in a future period. Actual amounts may ultimately differ from the Company's estimates. If actual results vary, the Company adjusts these estimates, which could have an effect on revenue and earnings in the period of adjustment.

License and Royalty Revenues

The Company receives royalty revenue on sales by its licensee of products covered under patents that the Company owns. The Company does not have future performance obligations under this license arrangement. The Company records revenue based on estimates of the sales that occurred during the relevant period as a component of license and royalty revenue. The relevant period estimates of sales are based on interim data provided by the licensee and analysis of historical royalties that have been paid to the Company, adjusted for any changes in facts and circumstances, as appropriate. Differences between actual and estimated royalty revenue are adjusted for in the period in which they become known, typically the following quarter. Historically, adjustments have not been material when compared to actual amounts paid by licensees.

R&D Revenue

All contracts with customers are evaluated under the five-step model described above. Such contracts are further described in Note 7 - Revenue. Grants are invoiced and revenue is recognized ratably as that is the depiction of the timing of the transfer of services. The R&D study, which encompasses various phases of product development processes: design feasibility & planning, product development and design optimization, design verification, design validation and process validation, and pivotal studies, is also recognized ratably.

For certain contracts that represent non-governmental grants where the funder does not meet the definition of a customer, the Company recognizes revenue when earned in accordance with Accounting Standards Codification ("ASC") Topic 958.

Government Grant Income

Chembio receives government grants in support of R&D activities that are not associated with a customer-vendor relationship and therefore falls outside the scope of ASC 606. Because there is no authoritative guidance under U.S. GAAP on accounting for government grants received, Chembio applies Topic 958 - Not-for-profit entities guidance by analogy. In June 2018, the Financial Accounting Standards Board (the "FASB") issued ASU 2018-08, Not-for-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made. This ASU clarifies the guidance presented in ASC Topic 958, "Not-for-Profit Entities," for evaluating whether a transaction is reciprocal (i.e., an exchange transaction) or non reciprocal (i.e., a contribution) and for distinguishing between conditional and unconditional contributions. The ASU also clarified the guidance used by entities other than not-for-profits to identify and account for contributions made. Government grants are invoiced and revenue is recognized as milestones are achieved, conditions are removed and approval from grantor is obtained.

In July 2020, the Company was awarded a grant of $0.6 million from BARDA to develop a SARS-CoV-2 Ag System. The Company earned $0.2 and $0.4 million for the years ended December 31, 2021 and 2020, respectively, and was recorded as government grant income.

In December 2020, the Company was awarded a grant of $12.7 million from BARDA to support the development and pursuit of FDA EUA for a rapid, multiplex DPP Respiratory Antigen Panel point-of-care test system. The Company earned $10.9 and $1.6 million for the years ended December 31, 2021 and 2020, respectively, and was recorded as government grant income. Culmulative through December 31, 2021, the Company recognized $12.5 million under this agreement, and the remainder $0.2 million is subject to obtaining the EUA for the DPP SARs-COV-2 Antigen test.

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 $1.6 million was earned and recognized as product sales during the year ended December 31, 2021. At December 31, 2021, the Company reported $0 in deferred revenue.

(j) ***Loss Per Share:***

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

There were 705,325 and 603,531 restricted shares awards outstanding as of December 31, 2021 and 2020, respectively, that were not included in the calculation of diluted income per share for the year ended December 31, 2021 and 2020, because their effect would have been anti-dilutive. There were 1,600,372 and 974,778 options outstanding as of December 31, 2021 and 2020 respectively, that were not included in the calculation of diluted income per share for the twelve months ended December 31, 2021 and 2020, respectively, because their effect would have been anti-dilutive.

(k) ***Research and Development:***

Research and Development (R&D) include product development, program management, clinical trials and regulatory costs and are expensed when incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

(l) ***Stock-Based Compensation:***

The Company grants share options to employees and non-employee members of the Company's board of directors as compensation for services performed. Employee and non-employee members of the board of directors' awards of share-based compensation are accounted for in accordance with ASC 718, Compensation - Stock Compensation, or ASC 718. ASC 718 requires all share-based payments to employees and non-employee directors, including grants of share options, to be recognized in the consolidated statement of operations and comprehensive loss based on their grant date fair values.

The grant date fair value of share options is estimated using the Black-Scholes option valuation model. The fair value of restricted stock and performance/restricted stock unit awards are determined on the date of grant or the date of issuance, as applicable.

The grant date fair value is calculated based on assumptions with respect to (i) the fair value of the Company's common stock on the grant date; (ii) expected volatility of the Company's common stock price, (iii) the periods of time over which the optionees are expected to hold their options prior to exercise (expected term), (iv) expected dividend yield on the Company's common stock, and (v) risk-free interest rates.

The expected volatility is calculated based on historical data of the Company's common stock. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. Risk-free interest rates are based on quoted U.S. Treasury rates for securities with maturities approximating the option's expected term. The expected term of share options granted to the optionees is determined using the average of the vesting period and contractual life of the option.

Stock based compensation is generally recognized on a straight-line basis over the service period of the grant and is reduced for actual forfeitures in the period in which the forfeiture occurs.

(m) ***Income Taxes:***

The Company accounts for income taxes under an asset and liability approach that recognizes deferred tax assets and liabilities based on the difference between the financial statement carrying amounts and the tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse.

The Company follows a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. The guidance relates to, among other things, classification, accounting for interest and penalties associated with tax positions, and disclosure requirements. Any interest and penalties accrued related to uncertain tax positions are recorded in tax expense.

The Company assesses the realizability of its net deferred tax assets on an annual basis. If, after considering all relevant positive and negative evidence, it is more likely than not that some portion or all of the net deferred tax assets will not be realized, the Company will reduce the net deferred tax assets by a valuation allowance. The realization of net deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of net operating loss carryforwards.

(n) ***Goodwill***

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

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

The company operates as a single operating segment and has one reporting unit. During the year ended December 31, 2021, the Company performed a quantitative analysis and determined that the carrying value exceeded its fair value by $2.6 million, on December 31, 2021 and recorded an impairment charge.

(*o*) ***Allowance for Doubtful Accounts:***

The Company records allowances for doubtful accounts for the estimated probable losses on uncollectible accounts receivable. The allowance is based upon the credit worthiness of the Company's customers, the Company's historical experience, the age of the receivable and current market and economic conditions. Receivables are written off against these allowances in the period they are determined to be uncollectible.

(*p*) ***Acquisition Costs:***

Acquisition costs are expensed when incurred and include primarily professional services, related to acquisition activities.

(q) ***Foreign Currency Translation:***

The functional currency of a foreign subsidiary is the local currency. Assets and liabilities of foreign subsidiaries that use a currency other than U.S. dollars as their functional currency are translated to U.S. dollars at end of period currency exchange rates. The consolidated statements of operations of foreign subsidiaries are translated to U.S. dollars at average period currency exchange rates. The effect of translation for foreign subsidiaries is generally reported in other comprehensive income.

(r) ***Leases:***

The Company accounts for leases in accordance with ASC 842. The Company determines if an arrangement is a lease at contract inception. A lease exists when a contract conveys the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. The definition of a lease embodies two conditions: (1) there is an identified asset in the contract that is land or a depreciable asset (i.e., property, plant, and equipment), and (2) the Company has the right to control the use of the identified asset. The Company accounts for the lease and non-lease components as a single lease component.

From time to time the Company enters into direct financing lease arrangements that include a lessee obligation to purchase the leased asset at the end of the lease term, a bargain purchase option, or provides for minimum lease payments with a present value of 90% or more of the fair value of the leased asset at the date of lease inception.

Operating leases where the Company is the lessee are included in right-of-use ("ROU") assets and lease obligations are included on the Company's consolidated balance sheets. The lease obligations are initially and subsequently measured at the present value of the unpaid lease payments at the lease commencement date and subsequent reporting periods.

Finance leases where the Company is the lessee are included in ROU assets and lease obligations on the Company's consolidated balance sheets. The lease obligations are initially measured in the same manner as for operating leases and are subsequently measured at amortized cost using the effective interest method.

Key estimates and judgments include how the Company determined (1) the discount rate used to discount the unpaid lease payments to present value, (2) lease term and (3) lease payments. ASC 842 requires a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. As most of the Company's leases where it is the lessee do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The Company's incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. The Company uses the implicit rate when readily determinable.

The lease term for all of the Company's leases includes the noncancelable period of the lease plus any additional periods covered by either a lessee option to extend (or not to terminate) the lease that is reasonably certain to be exercised, or an option to extend (or not to terminate) the lease controlled by the lessor.

The ROU asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for lease payments made at or before the lease commencement date less any lease incentives received. For operating leases, the ROU asset is subsequently measured throughout the lease term at the carrying amount of the lease liability, minus any accrued lease payments, less the unamortized balance of lease incentives received. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

For finance leases, the ROU asset is subsequently amortized using the straight-line method from the lease commencement date to the earlier of the end of its useful life or the end of the lease term unless the lease transfers ownership of the underlying asset, or the Company is reasonably certain to exercise an option to purchase the underlying asset. In those cases, the ROU asset is amortized over the useful life of the underlying asset. Amortization of the ROU asset is recognized and presented separately from interest expense on the lease liability.

The Company has elected not to recognize ROU assets and lease liabilities for all short-term leases that have a lease term of 12 months or less at lease commencement. Lease payments associated with short-term leases are recognized as an expense on a straight-line basis over the lease term.

Impairment charges for the Malaysian facility right-of-use asset recorded during the years ended December 31, 2021 was $0.1 and $0 million, respectively (see Note 14 - Asset Impairment, Restructuring, Severance and related costs).

(s) ***Recent Accounting Pronouncements Affecting the Company:***

Recently Adopted

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

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

ASU 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.

Not Yet Adopted

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

In November 2021, the FASB issued ASU 2021-10, Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance, which aims to provide increased transparency by requiring business entities to disclose information about certain types of government assistance they receive in the notes to the financial statements. The disclosure requirements in ASC 832 only apply to transactions with a government that are accounted for by analogizing to either a grant model (for example, in International Accounting Standard (IAS) 20, Accounting for Government Grants and Disclosure of Government Assistance), or a contribution model (for example, in ASC 958-605, Not-for-Profit Entities – Revenue Recognition). The FASB broadly defined "government assistance" in ASC 832 to ensure that assistance received from most types of governmental entities or other related organizations would be disclosed. Entities are required to provide the new disclosures prospectively for all transactions with a government entity that are accounted for under either a grant or a contribution accounting model and are reflected in the financial statements at the date of initially applying the new amendments, and to new transactions entered into after that date. Retrospective application of the guidance is permitted. The guidance in ASU 2021-10 is effective for financial statements of all entities, for annual periods beginning after December 15, 2021, with early application permitted. The Company continues to assess all potential impact of the standard and will disclose the nature and reason for any elections that the Company makes.

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

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

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

NOTE 3 — INVENTORIES:

Net inventories consist of the following at December 31:

	December 31	
	2021	2020
Raw Materials	**$ 7,306,095**	$ 5,955,215
Work in Process	**3,556,878**	2,549,516
Finished Goods	**2,057,478**	4,011,671
	$ 12,920,451	$ 12,516,402

During the year ended December 31, 2021, the Company recognized inventory adjustments related to expired and obsolete items totaling $4.1 million.

NOTE 4 — FIXED ASSETS:

Fixed assets consist of the following at December 31:

	December 31	
	2021	2020
Machinery and Equipment	**$ 12,500,235**	$ 10,996,869
Furniture and Fixtures	**6,631**	25,418
Computer Equipment	**465,576**	446,300
Leasehold Improvements	**2,933,159**	3,158,074
Enterprise Business Systems	**2,953,221**	2,741,806
Subtotal:	**18,858,822**	17,368,467
Less: Accumulated Depreciation and Amortization	**(10,302,049)**	(8,680,064)
	$ 8,556,773	$ 8,688,403

Depreciation expense for the 2021 and 2020 years totaled $1,801,481 and $1,227,860, respectively.

Effective May 2021, the Company discontinued its operations in Malaysia. Impairment charges recorded for the Malaysian fixed assets, net for the year ended December 31, 2021 and 2020 were $0.1 and $0 millions, respectively.

As of December 31, 2021 and 2020, the Company has purchased manufacturing equipment that is not yet in use and therefore has not been depreciated, aggregating $1,970,652 and $3,011,273, respectively. These balances are reflected under the Machinery and Equipment line on the table above.

NOTE 5 — ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:

Accounts payable and accrued liabilities consist of the following at December 31:

	December 31	
	2021	2020
Accounts Payable - suppliers	**$ 7,745,592**	$ 5,727,781
Accrued Commissions & Royalties	**1,359,691**	807,708
Accrued Payroll	**494,258**	277,908
Accrued Vacation	**421,416**	417,238
Accrued Bonuses	**1,378,706**	1,193,985
Accrued Professional Fees	**522,935**	511,681
Accrued Expenses - Other	**1,205,395**	1,106,489
	$ 13,127,993	$ 10,042,790

NOTE 6 — REVENUE:

Disaggregation of Revenue

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

The following tables disaggregates total revenues for the period ending December 31, 2021:

	Exchange Transactions	Non-Exchange Transactions	Total
Net product revenue	$ 34,737,444	$ -	$ 34,737,444
R&D revenue	1,159,381	-	1,159,381
Government grant income	-	10,891,726	10,891,726
License and royalty revenue	1,029,901	-	1,029,901
	$ 36,926,726	$ 10,891,726	$ 47,818,452

The following tables disaggregates total revenues for the period ending December 31, 2021 by region:

	Total
Africa	$ 5,562,788
Asia	664,579
Europe & Middle East	5,179,267
Latin America	18,418,983
United States	17,992,835
	$ 47,818,452

The following tables disaggregates total revenues for the period ending December 31, 2020:

	Exchange Transactions	Non-Exchange Transactions	Total
Net product revenue	$ 24,767,149	$ -	$ 24,767,149
R&D revenue	4,851,562	-	4,851,562
Government grant income	-	2,018,924	2,018,924
License and royalty revenue	832,562	-	832,562
	$ 30,451,273	$ 2,018,924	$ 32,470,197

The following tables disaggregates total revenues for the period ending December 31, 2020 by region:

	Total
Africa	$ 4,890,370
Asia	824,488
Europe & Middle East	9,905,437
Latin America	9,841,773
United States	7,008,129
	$ 32,470,197

Deferred Revenue

From time to time the Company may receive prepayment from customers for products to be manufactured and shipped at future dates. Customer payments in advance of the applicable performance obligation are deferred and recognized in accordance with ASC 606.

As of December 31, 2021 and 2020, there were $0 and $1,606,997 unearned advanced revenues, respectively.

NOTE 7 — INCOME TAXES:

The components of loss before income taxes consisted of the following:

	Year Ending December 31,	
	2021	2020
United States operations	**$ (26,858,325)**	$ (23,384,133)
International operations	**(7,107,254)**	(2,593,989)
(Loss) before taxes	**$ (33,965,579)**	$ (25,978,122)

The (benefit from) provision for income taxes for the years ended December 31, 2021 and 2020 is comprised of the following:

	Year Ending December 31,	
	2021	2020
Current		
Federal	**$ -**	$ (66,906)
State	**7,891**	6,497
Foreign	**-**	-
Total current (benefit) provision	**7,891**	(60,409)
Deferred		
Federal	-	-
State	-	-
Foreign	**(69,941)**	(396,385)
Total deferred (benefit) provision	**(69,941)**	(396,385)
Total (benefit) provision	**$ (62,050)**	$ (456,794)

A reconciliation of the Federal statutory rate to the effective rate applicable to loss before income taxes is as follows:

	Year Ending December 31,	
	2021	2020
Federal income tax at statutory rates	**21.00%**	21.00%
State income taxes, net of federal benefit	**0.18%**	(0.02)%
Nondeductible expenses	**(2.04)%**	(0.19)%
Foreign rate differential	**0.32%**	0.47%
Change in valuation allowance	**(19.60)%**	(19.37)%
Other	**0.32%**	(0.13)%
Income tax benefit	**0.18%**	1.76%

The Company had an ownership change as described in Internal Revenue Code Sec. 382 during 2004 (“2004 change”). As a result, the Company’s net operating losses prior to the 2004 change of $5,832,516 were subject to an annual limitation of $150,608 and for the first five (5) years are entitled to a BIG (Built-In-Gains) of $488,207 per year. These net operating losses expire in 2022 through 2024.

The Company had a second ownership change during 2006 (“2006 change”). The net operating losses incurred between the 2004 change and the 2006 change of $8,586,861 were subject to an annual limitation of $1,111,831 and for the first five (5) years are entitled to a BIG of $1,756,842 per year. These net operating losses expire in 2024 through 2026.

After applying the above limitations, at December 31, 2019, the Company has post-change net operating loss carry-forwards of approximately $26,362,574 which expire between 2022 and 2037 and $59,787,076 which do not expire. In addition the Company has research and development tax credit carryforwards of approximately $1,651,529 for the year ended December 31, 2021, which expire between 2022 and 2036.

The Company has state net operating loss carryforwards of approximately $4,458,041 which generally expire between 2035 and 2040. The Company has foreign net operating loss carryforwards of approximately $7,666,504 which generally expire between 2025 and 2029.

Deferred tax assets and liabilities as of December 31 are as follows:

	Year Ending December 31,	
	2021	2020
Inventory reserves	**$ 333,551**	$ 461,709
Accrued expenses	**374,673**	130,291
Net operating loss carry-forwards	**20,401,828**	14,844,798
Research and development credit	**1,651,529**	1,696,870
Stock-based compensation	**259,106**	398,900
Interest Expense	**1,221,171**	602,187
Lease obligations	**1,504,433**	1,583,814
Intangibles	**137,142**	-
Total deferred tax assets	**25,883,433**	19,718,569
Right-of-use assets	**(1,294,519)**	(1,340,914)
Depreciation	**(560,754)**	(254,366)
Intangibles	**-**	(821,363)
Total deferred tax liabilities	**(1,855,273)**	(2,416,643)
Net deferred tax assets before valuation allowance	**24,028,160**	17,301,926
Less valuation allowances	**(24,028,160)**	(17,371,867)
Net noncurrent deferred tax liabilities	**$ -**	$ (69,941)

The Company does not provide for U.S. income taxes on unremitted earnings of foreign subsidiaries as its present intention is to reinvest the unremitted earnings in the Company's foreign operations. At December 31, 2021 there were no unremitted earnings of foreign subsidiaries.

Interest and penalties, if any, related to income tax liabilities are included in income tax expense. As of December 31, 2021, the Company does not have any uncertain tax positions.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, ("CARES Act"), was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in tax years 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years. In addition to the NOL changes, the CARES Act contains modifications on the limitation of business interest for tax years beginning in 2019 and 2020. The modifications to Section 163(j) increase the allowable business interest deduction from 30% of adjusted taxable income to 50% of adjusted taxable income. This modification did not effect the Company's interest expense limitation. Overall the CARES ACT did not have a significant impact on the Company since it maintains a full valuation allowance.

NOTE 8 — GOODWILL AND INTANGIBLE ASSETS:

Following is a table that reflects changes in Goodwill:

Beginning balance January 1, 2021	$ 5,963,744
Changes in foreign currency exchange rate	(373,204)
Impairment	(2,567,753)
Balance at December 31, 2021	$ 3,022,787

Intangible assets consist of the following at:

		December 31,2021				December 31, 2020		
	Weighted Average Remaining Life	**Cost**	**Accumulated Amortization**	**Impairment**	**Net Book Value**	Cost	Accumulated Amortization	Net Book Value
Intellectual property	-	$ 1,636,724	$ 546,252	$ 1,090,472	$ -	$ 1,638,699	$ 472,190	$ 1,166,509
Developed technology	-	1,944,500	828,681	1,115,819	-	2,102,526	594,186	1,508,340
Customer contracts/relationships	-	1,254,344	477,661	776,683	-	1,323,424	423,093	900,331
Trade names	-	110,853	43,696	67,157	-	115,318	44,512	70,806
		$ 4,946,421	$ 1,896,290	$ 3,050,131	$ -	$ 5,179,967	$ 1,533,981	$ 3,645,986

Intellectual property, developed technology, customer contracts/relationships and trade names were being amortized over 10, 7, 10 and 11 years, respectively. Amortization expense for the year ended December 31, 2021 and 2020 was $479,988 and $588,962, respectively.

As of December 31, 2021, the Company determined indicators of impairment existed. As a result, the Company recognized an impairment loss of its finite-lived intangible assets totaling $3.1 million (Intellectual Property $1.1 million, Developed Technology $1.1 million, Customer Contracts $0.8 million and Trademark $0.1 million).

NOTE 9 — STOCKHOLDERS' EQUITY:

(a) ***Common Stock***

In April 2020, the Company closed on an underwritten public offering of 2,619,593 shares of its common stock, including the underwriter's exercise of its overallotment of 281,125 shares, at $11.75 per share. The net proceeds of the offering, after deducting the underwriter's discounts and other offering expenses payable by the Company, was approximately $28.4 million.

On July 19, 2021, Chembio entered into an At the Market Offering Agreement (the "ATM Agreement") with Craig-Hallum Capital Group LLC ("Craig-Hallum"), pursuant to which Chembio may sell from time to time, at its option, up to an aggregate of $60,000,000 of shares of common stock through Craig-Hallum, as sales agent. During the year ended December 31, 2021, Chembio issued and sold pursuant to the ATM Agreement a total of 9,709,328 shares of common stock at a volume-weighted average price of $4.20 per share for gross proceeds of $40.8 million and net proceeds, after giving effect to placement fees and other transaction costs, of $38.8 million. Additional shares of common stock may be issued and sold pursuant to the ATM Agreement for gross proceeds of up to $19.2 million.

(b) ***Preferred Stock***

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

(c) ***Options, Restricted Stock, and Restricted Stock Units***

The Board of Directors or its Compensation Committee may authorize the Company's issuance of options, restricted stock, restricted stock units and other equity awards to officers, employees, directors, consultants and other service providers pursuant to the Company's 2019 Omnibus Incentive Plan or otherwise.

NOTE 10 — EQUITY INCENTIVE PLANS:

Effective June 3, 2008, Chembio's stockholders voted to approve the 2008 Stock Incentive Plan (the "2008 Plan"), with 625,000 shares of common stock available to be issued. At the Annual Stockholder Meeting on September 22, 2011 Chembio's stockholders voted to approve an increase to the shares of common stock issuable under the 2008 Plan by 125,000 to 750,000. Under the terms of the 2008 Plan, which expired during 2018, the Board or its Compensation Committee had the discretion to select the persons to whom awards were to be granted. Awards could be stock options, restricted stock and/or restricted stock units (collectively, "Equity Award Units"). The awards became vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through December 31, 2021, there were 750,000 options expired, forfeited or exercised, and at December 31, 2021, 0 options were outstanding and no Equity Award Units were available to be issued under the 2008 Plan.

Effective June 19, 2014, Chembio's stockholders voted to approve the 2014 Stock Incentive Plan (the "2014 Plan"), with 800,000 shares of common stock available to be issued. Under the terms of the 2014 Plan, the Board or its Compensation Committee has the discretion to select the persons to whom awards are to be granted. Awards can be in the form of Equity Award Units. The awards vest at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through December 31, 2021, there were 602,064 Equity Award Units expired, forfeited or exercised. At December 31, 2021, 176,875 Equity Award Units were outstanding and, 21,061 shares were not issued. All shares that expired, forfeited or were not issued rolled over into the 2019 Plan. No Equity Award Units remain available to be issued under the 2014 Plan.

Effective June 18, 2019, Chembio's stockholders voted to approve the 2019 Omnibus Incentive Plan (the "2019 Plan"), with 2,400,000 shares of common stock available to be issued. At the Annual Stockholder Meeting on June 25, 2021, Chembio's stockholders voted to approve an increase to the shares of common stock issuable under the SIP by 2,400,000 to 4,800,000. In addition, shares of common stock underlying any outstanding award granted under the 2019 Plan that, following the effective date of the 2019 Plan, expire, or are terminated, surrendered or forfeited for any reason without issuance of such shares, shall be available for the grant of new awards under the 2019 Plan. Under the terms of the 2019 Plan, the Board or its Compensation Committee has the discretion to select the persons to whom awards are to be granted. Awards can be in the form of options, stock appreciation rights, restricted stock, restricted stock units, performance stock units or other stock-based awards under the 2019 Plan (collectively, "2019 Equity Units"). The 2019 Equity Units become vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through December 31, 2021, 790,538 2019 Equity Units have been cancelled or forfeited. At December 31, 2021, 1,973,096 2019 Equity Units were outstanding, and 3,386,393 2019 Equity Units were available to be awarded.

The Company's results for the years ended December 31, 2021 and 2020 include stock-based compensation expense totaling $2,034,247 and $1,098,698, respectively. Such amounts have been included in the Consolidated Statements of Operations within cost of product sales ($174,537 and $6,300, respectively), research and development ($494,235 and $386,016, respectively) and selling, general and administrative expenses ($1,365,475 and $706,382, respectively).

The weighted-average assumptions made in calculating the fair values of options are as follows for the respective years ended December 31:

	2021	2020
Expected term (in years)	**5.10**	6.29
Expected volatility	**78.95%**	46.21%
Expected dividend yield	**0**	0
Risk-free interest rate	**0.85%**	1.30%

The following table provides stock option activity for the years ended December 31, 2021:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2020	974,778	$ 4.12	5.19 years	$ 1,520,910
Granted	1,006,541	$ 4.54	7.85 years	-
Exercised	36,252	$ 2.36		101,139
Forfeited	260,570	$ 4.32		-
Expired/cancelled	84,125	8.23		
Outstanding at December 31, 2021	**1,600,372**	**$ 4.18**	**6.59 years**	**$ -**
Exercisable at December 31, 2021	**435,794**	**$ 4.38**	**2.71 years**	**$ -**

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

	Stock Options Outstanding				Stock Options Exercisable		
Range of Exercise Prices	Shares Outstanding	Average Remaining Contract Life (Year)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Shares Exercisable	Weighted Average Exercise Price	Aggregate Intrinsic Value
1 to 2.79999	571,209	5.35	$ 2.36	$ -	248,372	$ 2.36	$ -
2.8 to 4.59999	29,410	9.43	3.05	-	-	-	-
4.6 to 6.39999	827,217	8.62	4.82	-	24,922	5.54	-
6.4 to 8.19999	172,536	0.47	7.34	-	162,500	7.29	-
Total	1,600,372	6.59	$ 4.18	$ -	435,794	$ 4.38	$ -

As of December 31, 2021, there was $2,129,141 of net unrecognized compensation cost related to stock options that are not vested, which is expected to be recognized over a weighted average period of approximately 2.55 years. The total fair value of shares vested during the year ended December 31, 2021, was $348,727.

The following table summarizes information about restricted stock and restricted stock units outstanding as of December 31, 2021:

	Number of Shares & Units	Weighted Average Grant Date Fair Value
Unvested at December 31, 2020	603,531	$ 3.08
Granted	404,852	4.25
Vested	176,906	4.12
Forfeited/expired/cancelled	126,152	3.01
Unvested at December 31, 2021	**705,325**	**3.34**

As of December 31, 2021, there was $1,474,042 of net unrecognized compensation cost related to restricted stock and restricted stock units that are not vested, which is expected to be recognized over a weighted average period of approximately 1.9 years. Stock based compensation cost related to restricted stock and restricted stock units recognized during the years ended December 31, 2021 and 2020 was $1,160,953 and $617,919, respectively.

NOTE 11 — GEOGRAPHIC INFORMATION AND ECONOMIC DEPENDENCY:

The Company produces only one group of similar products known collectively as "rapid medical tests" and operates under one segment, as a single reporting unit. Product revenue by geographic area are as follows:

	Year Ending December 31,	
	2021	2020
Africa	**$ 5,562,787**	$ 4,890,370
Asia	**664,579**	824,488
Europe & Middle East	**4,067,682**	5,274,927
Latin America	**18,418,983**	9,841,772
United States	**6,023,413**	3,935,592
	$ 34,737,444	$ 24,767,149

Property, plant and equipment, net by geographic area are as follows:

	2021	2020
Asia	**$ 86,041**	$ 326,267
Europe & Middle East	**113,883**	147,692
Latin America	**36,224**	14,719
United States	**8,320,625**	8,199,725
	$ 8,556,773	$ 8,688,403

Effective May 2021, the Company discontinued its operations in Malaysia. Impairment charges recorded for the Malaysian property, plant and equipment for the year ended December 31, 2021 and 2020 were $0.1 and $0 millions, respectively.

NOTE 12 — COMMITMENTS, CONTINGENCIES AND CONCENTRATIONS:

a) Employment Contracts:

The Company has multi-year contracts with two key employees. The contracts call for salaries presently aggregating $843,000 per year, and they expire in December 2022 and December 2025. The following table is a schedule of future minimum salary commitments:

2022	$ 843,000
2023	383,000
2024	383,000
2025	383,000

b) Benefit Plan:

The Company has a 401(k) plan established for its employees whereby it matches 40% of the first 5% (or 2% of salary) that an employee contributes to the plan. Matching contribution expenses totaled $138,513 and $87,377 for the years ended December 31, 2021 and 2020, respectively.

c) 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:

	Year Ended December 31, 2021	Year Ended December 31, 2020
Operating lease expense	**$ 1,625,280**	$ 1,669,105
Finance lease cost		
Amortization of right-of-use assets	**$ 66,872**	$ 58,414
Interest on lease liabilities	**20,077**	19,986
Total finance lease expense	**$ 86,949**	$ 78,400

Supplemental cash flow and other information related to leases were as follows:

	Year Ended December 31, 2021	Year Ended December 31, 2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	**$ 1,404,532**	$ 1,139,944
Operating cash flows for finance leases	**20,077**	19,987
Financing cash flows for finance leases	**61,867**	51,166
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	**$ -**	$ -
Finance leases	**25,609**	69,528

Supplemental balance sheet information related to leases was as follows:

	December 31, 2021	December 31, 2020
Finance Leases		
Finance lease right of use asset	**$ 340,762**	$ 315,154
Accumulated depreciation	**(148,892)**	(82,020)
Finance lease right of use asset, net	**$ 191,870**	$ 233,134
Current portion of finance lease liability	**68,176**	58,877
Finance lease liability	**139,678**	185,239
Total finance lease liabilities	**$ 207,854**	$ 244,116
Weighted Average Remaining Lease Term		
Operating leases	**7.5 years**	9.0 years
Finance leases	**2.9 years**	3.7 years
Weighted Average Discount Rate		
Operating leases	**8.08%**	8.58%
Finance leases	**8.76%**	8.18%

Maturities of lease liabilities as of December 31 were as follows:

	December 31, 2021		December 31, 2020	
	Operating Leases	Finance Leases	Operating Leases	Finance Leases
2022	**$ 1,447,249**	**$ 83,624**	$ 1,209,787	$ 76,904
2023	**1,221,017**	**83,624**	1,057,757	76,904
2024	**1,018,875**	**55,856**	1,026,272	76,904
2025	**1,049,442**	**12,471**	1,018,875	49,136
2026	**1,080,925**	**1,680**	1,049,442	5,755
Thereafter	**3,643,520**	-	4,724,445	-
Total lease payments	**$ 9,461,028**	**$ 237,255**	$ 10,086,578	$ 285,603
Less: imputed interest	**(2,598,583)**	**(29,401)**	(3,116,975)	(41,487)
Total	**$ 6,862,445**	**$ 207,854**	$ 6,969,603	$ 244,116

d) Economic Dependency:

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

	For The Years Ended				Accounts Receivable	
	December 31, 2021		December 31, 2020		December 31, 2021	December 31, 2020
	Net Product Sales	% of Net Product Sales	Net Product Sales	% of Net Product Sales		
Customer 1	**$ 17,576,641**	**51%**	$ 6,224,737	25%	**$ 7,672,845**	$ 522,218
Customer 2	*****	*****	2,955,312	12%	*****	1,987
Customer 3	**3,606,552**	**10%**	*	*	**1,433,305**	*

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

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

	For The Years Ended				Accounts Payable	
	December 31, 2021		December 31, 2020		December 31, 2021	December 31, 2020
	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	**$ 3,163,285**	**16%**	$ 2,222,182	13%	**$ 1,361,383**	$ 222,588
Vendor 2	**$ 2,031,795**	**10%**	$ *	*	**$ 353,097**	$ *

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

The Company purchases materials pursuant to intellectual property rights agreements that are important components in its products. Management believes that other suppliers could provide similar materials on comparable terms. A change in suppliers, however, could cause a delay in manufacturing and a possible loss of sales, which could adversely affect operating results.

e) Litigation:

SEC Investigation

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

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

Legal Proceedings

Stockholder Litigation

Putative Stockholder Securities Class-Action Litigation

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

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

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

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

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

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

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

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

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

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

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

Putative Stockholder Derivative Litigation

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

The Wong complaint requests a declaration that the individual defendants have breached or aided and abetted the breach of their fiduciary duties to Chembio, an award of damages to us, restitution, and an award of the plaintiff's costs and disbursements in the action, including reasonable attorneys' and experts' fees, costs and expenses, and improvements to Chembio's corporate governance and internal procedures regarding compliance with laws. Pursuant to a stipulation by which the individual defendants named in the Wong complaint agreed to waive service of process, the Court ordered that the time for defendants to answer or otherwise respond to the complaint be extended to November 19, 2020. The parties subsequently entered into a stipulation for a stay of proceedings in the action relating to the Wong complaint pending final disposition of motions to dismiss the pending putative class-action litigation, subject to certain conditions. The Court entered an order granting the requested stay on November 3, 2020. At this stage of the litigation, the Company is not able to predict the probability of a favorable or unfavorable outcome.

Employee Litigation

On March 19, 2021, John J. Sperzel III, Chembio's former chief executive officer, filed a fifteen-count complaint in the United States District Court for the Eastern District of New York. The complaint was filed following the dismissal of an action previously filed by Mr. Sperzel in the United States District Court in Maine, which was dismissed for lack of personal jurisdiction over Chembio. In summary, the complaint filed in the Eastern District of New York alleges that Chembio wrongfully refused to allow Mr. Sperzel to exercise certain options to purchase, for an aggregate exercise price of $943,126, a total of 266,666 shares of common stock that were allegedly vested as of the date of his separation from Chembio, on January 3, 2020. The complaint alleges that under the terms of the applicable stock incentive plans, Mr. Sperzel had thirty days after the date on which he ceased to qualify as an "Eligible Person" under the plans within which to exercise the options, and asserts that by reason of his alleged continued service to us, he remained an "Eligible Person" and ostensibly retained the right to exercise the options. The Compensation Committee of the Board determined that the options expired on February 3, 2020, thirty days after Mr. Sperzel's separation from Chembio, and that a purported attempt by Mr. Sperzel to exercise the options after that date was not valid.

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

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

Other

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

NOTE 13 — LONG-TERM DEBT:

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

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 December 31, 2021 the interest rate was 11.25%.

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

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

As of December 31, 2021, the loan balance, net of unamortized discounts and debt issuance costs, was $18.8 million, and Chembio was in compliance with its loan covenants.

NOTE 14 — IMPAIRMENT, RESTRUCTURING, SEVERANCE AND RELATED COSTS:

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

In light of the uncertainty of the timing and any receipt of those regulatory approvals, the timing of progress on and results of clinical trial programs, and the timing and any receipt of product orders from the commercialization of the COVID-19 Diagnostic Test Systems and other diagnostic test systems both within and outside the United States, during the second quarter of 2021, the Company engaged the services of an independent financial advisory firm (the "Financial Advisor"). The Financial Advisor worked with management to develop a forecast model to assess the amount and timing of the Company's liquidity needs, assuming various business cases, and together with legal counsel advised the Company regarding alternative approaches to enhancing its liquidity position, participating in discussions with the Lender, and related matters. During the year ended December 31, 2021 and 2020, the Company incurred $1.1 and $0.4 million, respectively, related to these restructuring matters.

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

The table below represents the total costs by category:

	For the year ended December 31, 2021	For the year ended December 31, 2020
Severance	**$ 83,087**	$ 723,118
Restructuring costs	**1,083,951**	399,192
Impairment	**5,880,741**	-
	$ 7,047,779	$ 1,122,310

Impairment details are as follows:

	For the year ended December 31, 2021
Goodwill	$ 2,567,753
Intellectual Property	1,090,472
Developed Technology	1,115,819
Customer Contracts	776,683
Trademarks	67,157
Fixed Asset	152,109
ROU Lease Asset	110,748
Total	**$ 5,880,741**

NOTE 15 — SUBSEQUENT EVENTS:

On February 17, 2022, Chembio Diagnostics GmbH, our German subsidiary formed under the laws of the Federal Republic of Germany, has filed a petition for insolvency in the Charlottenburg District Court ("Amtsgericht Charlottenburg") in Berlin, Germany in compliance with German insolvency law. A provisional insolvency administrator ("Administrator") has been appointed to manage cash disbursements and general affairs of the business. We expect to provide certain support and liquidity for the subsidiary to continue operations until such time a viable business strategy has been determined and agreed to with the Administrator.

Exhibit 21.1

CHEMBIO DIAGNOSTICS, INC.

Subsidiaries of the Registrant

Name of Subsidiary	Jurisdiction of Incorporation
Chembio Diagnostic Systems Inc.	Delaware
Chembio Diagnostics Brazil LLC	Delaware
Chembio Diagnostics Brazil Ltda.	Brazil
Chembio Diagnostics Malaysia Sdn. Bhd.	Malaysia
Chembio Diagnostics Germany Holdings GmbH	Germany
Chembio Diagnostics GmbH	Germany

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statement (Form S-3 No. 333-254261) of Chembio Diagnostics, Inc.,

2. Registration Statement (Form S-8 No. 333-151785) pertaining to the 2008 Stock Incentive Plan of Chembio Diagnostics, Inc.,

3. Registration Statement (Form S-8 No. 333-203633) pertaining to the 2014 Stock Incentive Plan and an employment agreement of Chembio Diagnostics, Inc.,

4. Registration Statement (Form S-8 No. 333-254240) pertaining to the 2019 Omnibus Incentive Plan and an employment agreement of Chembio Diagnostics, Inc., and

5. Registration Statement (Form S-8 No. 333-262199) pertaining to an employment agreement of Chembio Diagnostics, Inc.;

of our report dated March 3, 2022, with respect to the consolidated financial statements of Chembio Diagnostics, Inc, included in this Annual Report (Form 10-K) of Chembio Diagnostics, Inc. for the year ended December 31, 2021.

/s/ Ernst & Young, LLP

Jericho, New York
March 3, 2022

Exhibit 31.1

CERTIFICATION

I, Richard L. Eberly, certify that:

1. I have reviewed this Form 10-K 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(s) 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 13a15(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(s) 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 control over financial reporting.

Date: March 3, 2022

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

Exhibit 31.2

CERTIFICATION

I, Lawrence J. Steenvoorden, certify that:

1. I have reviewed this Form 10-K 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(s) 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 13a15(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(s) 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 control over financial reporting.

Date: March 3, 2022

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

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K (the "Report") of Chembio Diagnostics, Inc. (the "Company") for the year ended December 31, 2021, each of the undersigned Richard L. Eberly, the President & Chief Executive Officer of the Company, and Lawrence J. Steenvoorden, the Executive Vice President & Chief Financial Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of the undersigneds' knowledge and belief:

(1) This Form 10-K for the year ended December 31, 2021 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 this Form 10-K for the year ended December 31, 2021 fairly presents, in all material respects, the financial condition and results of operations of Chembio Diagnostics, Inc. for the periods presented therein.

Dated: March 3, 2022

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

Dated: March 3, 2022

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