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, 2020
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 11, 2021, the registrant had 20,182,357 shares of common stock outstanding.

Documents Incorporated By Reference

Portions of the registrant's proxy statement for its 2020 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 inthis report without ® and ™ symbols, and that practice does not mean that we will not assert, to the fullest extent under applicable law, our rights to the trademarks.

FORWARD-LOOKING STATEMENTS AND STATISTICAL ESTIMATES

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

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

Forward-looking statements and statistical estimates inherently involve risks and uncertainties that could cause actual results to differ materially from those predicted or expressed in this report. These risks and uncertainties include those described in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as filed with the Securities and Exchange Commission on March X, 2020, in Part II, Item 1A. "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020, as filed with the Securities and Exchange Commission on May 4, 2020, in Part II, Item 1A. "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020, as filed with the Securities and Exchange Commission on August 7, 2020, and in Part II, Item 1A, . "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, as filed with the Securities and Exchange Commission on November 5, 2020, and in Part II, Item 1A, "Risk Factors," of this report. You should interpret many of the risks identified in these reports as being heightened as a result of the ongoing and numerous adverse impacts of the COVID-19 pandemic. Investors are cautioned not to place undue reliance on any forward-looking statements or statistical estimates, which speak only as of the date they are made. We undertake no obligation to update any forward-looking statement or statistical estimate, whether as a result of new information, future events or otherwise.

PART I

ITEM 1. BUSINESS

Overview

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

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

- *Enhanced sensitivity and specificity:* This is achieved via our patented approach to separating the sample path from the buffer path, together with other patented and proprietary strategies, than traditional lateral flow tests. It also delivers lower levels of detection.

- *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.

- *Quantitative 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. For example, in June 2020 we received FDA clearance of our 510(k) submission for the DPP Zika IgM System, which consists of an antibody test for Zika IgM and a DPP Micro Reader and which had previously received an FDA Emergency Use Authorization or EUA. In October 2020 the DPP HIV-Syphilis System, an antibody test system for the human immunodeficiency virus or HIV and Treponema pallidum bacteria (the causative agent of syphilis), received FDA approval for a Premarket Approval, or PMA, application.

In February 2020 we began the process of shifting 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:* We initially refocused our business strategy on the development and commercialization of the DPP COVID-19 IgM/IgG System, which consisted of a new serological test for COVID-19 and a DPP Micro Reader that could provide separate numerical readings for both IgM and IgG levels of antibodies to the virus. We acquired three regulatory approvals of the DPP COVID-19 IgM/IgG system in our targeted global testing market: an EUA, granted by the FDA in April 2020; an approval for emergency use issued by Brazil's Agência Nacional de Vigilância Sanitária, or ANVISA, in April 2020, and a CE Marking for the European Union obtained in early May 2020. In June 2020 the FDA revoked the EUA for the DPP COVID-19 IgM/IgG system. In September 2020 we submitted to the FDA an EUA application for the DPP SARS-CoV-2 IgM/IgG System, a new rapid antibody test system that detected COVID-19 antibodies using a different methodology that was consistent with updated FDA guidance, but in December 2020 the FDA notified us that it was declining to review the new system based on the FDA's then-effective prioritization guidance, under which review of the system was not a priority because, for example, the FDA determined that authorization of the tests would have relatively limited impact on testing accessibility or testing capacity.

- *COVID-19 antigen test system:* In July 2020 we received a $628,071 grant, the First BARDA Grant, from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, Division of Research Innovation and Ventures, or BARDA, to assist us in developing, submitting and obtaining an EUA application for a COVID-19 point-of-care antigen system using DPP technology. 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 December 2020 we received a $12.7 million grant from BARDA, in part to support preparation, submission, and approval 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.

- *COVID-19 and Influenza respiratory antigen panel test system:* BARDA's $12.7 million grant in December 2020 also supported our development, submission and receipt of an EUA for a rapid, multiplex respiratory antigen panel point-of-care test system using DPP technology. We are currently seeking to develop and conduct 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, in approximately 20 minutes. 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 is expected to provide results in approximately 20 minutes and to be run on the DPP Micro Reader.

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, non-governmental 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 2020, as total revenues were $32.5 million, a decrease of 5.8% from 2019, and net product sales were $24.8 million, a decrease of 14.1% from 2019. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Consolidated Results of Operations."

In 2020 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, including by eliminating positions that were no longer aligned with our strategy. Our cash and cash equivalents totaled $23.1 million at December 31, 2020, compared to $18.3 million at December 31, 2019.

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; and (3) that present opportunities regionally, demographically or clinically. We are 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, SURE CHECK, STAT-PAK and DPP. We will focus on internally developed products and pursue external opportunities to license novel technologies and products with the intent of leveraging our growing commercial infrastructure.

We currently are targeting rapid diagnostic test solutions for infectious diseases: respiratory diseases, sexually transmitted diseases, gastroenterology and insect-vector diseases. The market for rapid diagnostic infectious disease tests is being 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.

Products

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

Much of 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:* This is achieved via our patented approach to separating the sample path from the buffer path, together with other patented and proprietary strategies, than traditional lateral flow tests. It also delivers lower levels of detection.

- *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.

- *Quantitative 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.

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

Beginning in February 2020 we refocused our business strategy on the development and commercialization of a COVID-19 antibody test system based on DPP technology. We initially developed the DPP COVID-19 IgM/IgG System, which consisted of a new serological test for COVID-19 and a DPP Micro Reader that could provide separate numerical readings for both IgM and IgG levels of antibodies to the CORONA-19 virus. We acquired three regulatory approvals of the DPP COVID-19 IgM/IgG System in our targeted global testing market: an EUA, granted by the FDA in April 2020; an approval for emergency use issued by Brazil's Agência Nacional de Vigilância Sanitária, or ANVISA, in April 2020, and a CE Marking for the European Union obtained in early May 2020. In June 2020, however, the FDA revoked the EUA for the DPP COVID-19 IgM/IgG System.

In the second quarter of 2020 we began shipping the DPP COVID-19 IgM/IgG System to fulfill a $4 million purchase order from Bio-Manguinhos, a long-standing customer that is a subsidiary of the foundation responsible for the development and production of vaccines, diagnostics and biopharmaceuticals for Brazil's national public health system.

In September 2020 we submitted to the FDA an EUA application for the DPP SARS-CoV-2 IgM/IgG System, a new rapid antibody test system that detected COVID-19 antibodies using a different methodology that was consistent with updated FDA guidance. In December 2020 the FDA notified us that it was declining to review the DPP SARS-CoV- 2 IgM/IgG System based on the FDA's then-effective prioritization guidance. Under this guidance, review of the system was not a priority for the FDA because, for example, the FDA determined that authorization of the tests would have relatively limited impact on testing accessibility or testing capacity. 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 IgM/IgG System to be prioritized for review. We are continuing to evaluate whether to commit further resources to the testing and development that would be required in order to seek to submit a new EUA application for a COVID-19 antibody test system.

In January 2021 we announced the CE mark for 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 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.

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.

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.

We are currently seeking to develop and conduct 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, in approximately 20 minutes. 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 is expected to provide results in approximately 20 minutes and to be run on the DPP Micro Reader.

To enhance our offered product line quickly, we signed an in-licensing agreement to distribute a visual-read, point- of-care, EUA-approved respiratory panel for the detection of SARS-CoV-2 antigens, Influenza A and Influenza B. This offering is scheduled to launch in March 2021.

Legacy 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 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		✓
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 rapid diagnostic infectious disease tests;
- our increased market penetration in existing markets and channels, including in the United States, Latin America, 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 a 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. HIV and syphilis continue to be major global public health issues. According to WHO estimates:

- HIV has claimed more than 35 million lives, including 770,000 in 2018. Approximately 37.9 million people were living with HIV at the end of 2018, and 1.7 million were newly infected during 2018.
- 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, Malaysia and Mexico. We are pursuing a CLIA waiver for the DPP HIV-Syphilis tests 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 rapid diagnostic insect-vector 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 diagnostic tests for infectious diseases such as burkholderia, chikungunya, lassa, leptospirosis, Marburg, rickettsia and Zika.

Since 2015 we have received over $14.2 million of funding from some of the world's leading health organizations, which has helped us accelerate the expansion of our pipeline of infectious disease tests. Our collaborators have included Bill & Melinda Gates Foundation, The Paul G. Allen Family Foundation, 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	✓	✓	✓	✓	

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 2020, 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. Our goal is to delight our global customers through all facets of our commercial interactions.

Automation of U.S. Manufacturing

We are automating our U.S. manufacturing processes and expanding our manufacturing capacity. Over the past two 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 has 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, Chembio's new and expanded product portfolio will emphasize high value added tests with strong margins, selling in 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 rapid diagnostic 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.

Employees

As of December 31, 2020, we had 355 full-time equivalent employees, of whom 39 were in administration, 262 were in manufacturing, 32 were in research and development, and 22 were in sales and marketing and customer service. Of these employees, approximately 320 were located in the United States, 0 were located in Malaysia, 19 were located in Germany and 16 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.

In January 2021, Chembio announced a restructuting plan in the US and reduced its workforce by approximately 9%, as further discussed on Note 16 - Subsequent Events.

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 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 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 rapid diagnostic 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.

21st Century Cures Act

The 21st Century Cures Act, enacted in December 2016, contains several sections specific to medical device innovations. We believe that implementation of the 21st Century Cures Act may have a positive impact on its businesses by facilitating innovation and/or reducing the regulatory burden imposed on medical device manufacturers.

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.

Environmental Laws

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

- the refocus of our business strategy to respond to COVID-19, including the successful development and market acceptance of the DPP SARS-CoV-2 IgM/IgG System, the DPP SARS CoV 2 Antigen System and the DPP Respiratory Antigen Panel, which we refer to as the COVID-19 Diagnostic Test Systems;
- our allocation of substantially all of our resources to the development and production of COVID-19 Diagnostic Test Systems;
- the effects of existing or future shareholder litigation;
- our competitors developing more effective or successful products;
- the ability of our products to compete with the new or existing products of our competitors;
- the negative impact of healthcare industry consolidation on our future revenues and operating results;
- our ability to retain key employees and attract additional qualified personnel;
- third-party reimbursement policies; and
- the vulnerability of our business to cyber-attacks.

Risks Related to Our Products

- 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, particularly the COVID-19 Diagnostic Test Systems;
- 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 incurrence of losses in recent years and uncertainty about our future profitability;
- the fluctuation of our financial results;
- our compliance with the terms of our Credit Agreement and Guaranty;
- our ability to generate sufficient cash to service our debt;
- increased interest expenses due to changes in LIBOR;
- the negative impact of changes in foreign currency exchange rates on our operating results; and
- basing our estimates or judgments 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 Third Party Collaborators

- 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, particularly the COVID-19 Diagnostic Test Systems;
- the impact of governmental export controls on our ability to compete in international markets;
- our ability to comply with FDA and other regulatory requirements, particularly with respect to the COVID-19 Diagnostic Test Systems;
- our ability to respond to changes in regulatory requirements;
- the effect of FDA regulation of laboratory-developed tests and genetic testing on demand for our products;
- disruptions at the FDA and other 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 effect of future issuances of Common Stock on the price of our Common Stock and our ability to raise funds in new equity offerings;
- the control management and larger stockholders exercise over us; and
- the depression of the market price of our common stock due to sale by existing stockholders, executive officers or directors.

General Risk Factors

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

RISK FACTORS

Risks Related to Our Business and Our Industry

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

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

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

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

We are allocating substantially all of our resources to the development and production of COVID-19 Test Systems for the foreseeable future, 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.

We are committing substantially all of our financial and personnel resources to the development, manufacturing and commercialization of COVID-19 Diagnostic Test Systems. This resource allocation may negatively impact our legacy product portfolio, as we expect to spend limited funds and time on updating pre-existing products and regulatory approvals or on completing products that were in development prior to our strategic decision to focus on COVID-19 Diagnostic Test Systems. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could dissipate; there is no guarantee that current or anticipated demand will continue, or if demand does continue, that we will be able to produce in quantities to meet the demand. We intend to reestablish our legacy business in the future, 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.

Our near-term success is highly dependent on the success of the COVID-19 Diagnostic Test Systems, and we cannot be certain that we will succeed in developing one or more of those systems or that, if we do, they will attain market acceptance or be successfully commercialized in the United States or elsewhere.

We do not currently have an Emergency Use Authorization, or EUA, from the U.S. Food and Drug Administration, or FDA, for any of the COVID-19 Diagnostic Test Systems, and we do not currently have an application pending for any such EUA. Moreover, market and regulatory requirements continue to change at a rapid pace. The FDA has declined to review certain of our COVID-19 Diagnostic Test Systems based on then-effective prioritization guidance, which is subject to change. There can be no assurance that, if we are to make a submission of any future EUA application, we will meet the requirements of the prioritization guidance in effect at the time of the submission or otherwise be successful in obtaining an EUA that would permit us to offer and sell any COVID-19 Diagnostic Test System in the United States.

Even if we are able to obtain an EUA for any of the COVID-19 Diagnostic Test Systems, including our revised DPP SARS-CoV-2 IgM/IgG System and DPP SARS-CoV-2 Antigen System that product may not gain broad market acceptance among physicians, healthcare payers, patients, and the medical community. We have conducted our own research into the markets for our product candidates, including the COVID-19 Diagnostic Test Systems; however, 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. If we are unable to match the technological changes in the needs of our customers the demand for our products will be reduced. 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 FDA in our product labeling;
- cost-effectiveness of our products relative to competing products;
- convenience and ease of administration;
- potential advantages of alternative treatment methods;
- availability of reimbursement for our products from government or other healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect virtually all of our product revenues for the foreseeable future to be generated from sales of our current products and COVID-19 Diagnostic Test Systems in particular, the failure of these products to find market acceptance would substantially harm our business and would adversely affect our revenue. If the COVID-19 Diagnostic Test Systems are not as successfully commercialized as expected, we may not be able to generate sufficient revenue to become profitable. Any failure of either of the COVID-19 Diagnostic Test Systems to be successfully commercialized in the United States may have a material adverse effect on our business, operating result financial condition and cash flows, and could result in a substantial decline in the price of our common stock.

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, 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 announced their intention to offer new products, services and technologies that could be used in substitution for the COVID-19 Diagnostic Test Systems. Many of those competitors are significantly larger, and have substantially greater financial, engineering and other resources, than us. In addition, our competitors may have or may develop products or technologies that currently or in the future will enable them to produce competitive products with greater capabilities or at lower costs than ours. If we are unable to compete effectively, we may fail to meet our strategic objectives, and our business, financial condition and operating results could be harmed. In addition, the production of an efficacious vaccine or other treatment for COVID-19 may reduce the demand for 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 COVID-19 Diagnostic Test Systems.

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

We may incur additional costs in connection with the defense or settlement of existing and any future shareholder litigation, including four shareholder lawsuits to date that have been brought against us. See Part I, Item 3. “Legal Proceedings” below for additional information regarding these 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.

We expect competition to with respect to testing solutions for COVID-19 to continue to increase and our success will depend on widespread 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, and, as a result, may be able to respond more quickly to new or changing regulatory requirements, new or emerging technologies, and changes in customer requirements. Our products may not compete favorably, and we may not be successful in the face of increasing competition from new products and technologies introduced 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 affect our suppliers and employees, and cause disruptions in current and future plans for operations and expansion.

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

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

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

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 more traditional 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.

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

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

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

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

We may not generate the expected benefits of our acquisitions of opTricon GmbH or Orangelife Comercio e Industria Ltda. and the ongoing integration of the acquisitions could disrupt our ongoing business, distract our management and increase our expenses.

We acquired opTricon GmbH, or opTricon, and Orangelife Comercio e Industria Ltda., or Orangelife, in November 2018 and November 2019, respectively, with the expectation that the acquisition will result in various benefits, including securing global commercial rights and reducing cost of goods. Achieving the anticipated benefits of either acquisition is subject to a number of uncertainties, including whether our business and the businesses of opTricon or Orangelife can be integrated in an efficient and effective manner. We cannot assure you that we will be able to accurately forecast the performance or ultimate impact of either the opTricon acquisition or the Orangelife acquisition.

The integration processes may take longer than anticipated and result in the loss of valuable employees, the incurrence of additional and unforeseen expenses, the disruption of our ongoing business, processes and systems, or inconsistencies in standards, controls, procedures, practices, policies and compensation arrangements, any of which could adversely affect our ability to achieve the anticipated benefits of the acquisitions. There may be increased risk due to integrating financial reporting and internal control systems. The integration processes are subject to a number of uncertainties, and no assurance can be given that the anticipated benefits, expense savings and synergies will be realized or, if realized, the timing of their realization. Failure to achieve these anticipated benefits could result in increased costs or decreases in the amount of expected revenues and could adversely affect our future business, financial condition, operating results and prospects.

We have incurred and will continue to incur non-recurring expenses in connection with the opTricon acquisition and the Orangelife acquisition, including legal, accounting and other expenses. Additional unanticipated costs may be incurred following consummation of the opTricon acquisition or the Orangelife acquisition in the course of the integration of the respective businesses into our business. We cannot be certain that the realization of efficiencies related to the integration of the two businesses will offset the transaction and integration costs in the near term, or at all, or any losses from undiscovered liabilities not covered by an indemnification from the sellers of opTricon or Orangelife.

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 WHO, CDC, the U.S. Agency for International Development, foreign governments and their agencies, non-governmental organizations, and HIV service organizations. If we are unsuccessful in our efforts to participate in these programs, our operating results could be materially harmed.

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

Developing testing guidelines could negatively affect sales of our products.

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

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

We have received funding under grant award programs funded by governmental agencies such as NIDA and BARDA. To fund a portion of our future research and development programs, we may apply for additional grant funding from these or similar governmental agencies. However, funding by these governmental agencies may be significantly reduced or eliminated in the future for a number of reasons. For example, some programs are subject to a yearly appropriations process in Congress. In addition, 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. Therefore, we cannot assure you that we will receive any future grant funding from any government agencies, or, that if received, we will receive the full amount of the particular grant award. Any such reductions could delay the development of our product candidates and the introduction of new products.

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

We may be subject to cyber-attacks whereby computer hackers may attempt to access our computer systems or our third party IT service provider's systems and, if successful, misappropriate personal or confidential information, particularly if we gain recognition in our industry. 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 provider, revenue and expense accounting, consumer call support, online business, 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 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.

Our management and larger stockholders exercise significant control over us.

As of December 31, 2020, 2% of our outstanding common stock was beneficially owned by our executive officers, directors and 5% stockholders including three large investors that beneficially own 18%, of our outstanding common stock. For the foreseeable future, and assuming these ownership percentages continue to apply, to the extent that these parties vote similarly, they may be able to exercise significant control over many matters requiring approval by the board of directors or our stockholders. As a result, they may be able to:

- control the composition of our board of directors;
- control our management and policies;
- determine the outcome of significant corporate transactions, including changes in control that may be beneficial to stockholders; and,
- act in each of their own interests, which may conflict with or differ from the interests of each other or the interests of the other stockholders.

Risks Related to Our Products

Our COVID-19 Diagnostic Test Systems may not gain wide industry acceptance, and industry adoption of alternative technology could negatively impact our ability to compete successfully.

Of the 171 manufacturers and commercial laboratories to receive an EUA for COVID-19 diagnostics as of July 31, 2020, 35 were for serology tests, 134 were for molecular tests, and 2 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 which may impact the ability of the COVID-19 Diagnostic Test Systems to adequately detect COVID-19 or SARS-CoV-2 antigens 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. 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 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 increase manufacturing production capacity through the implementation of additional customized manufacturing automation equipment.

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 accomplish this consists of the implementation of 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. Our business, financial condition and results of operations could be harmed if we are unable to timely obtain automation equipment that meets our requirements or if there are significant increases in the costs of equipment.

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

Some of our products may require lengthy and unpredictable sales cycles, which makes it more difficult to accurately forecast revenues in a given period and may cause revenues and operating results to vary from period to period. Our products may involve sales to large public and private institutions which may require many levels of approval and may be dependent on economic or political conditions and the availability of grants or 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.

Customer concentration creates risks for our business.

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

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

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

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

Financial, Economic and Financing Risks

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

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

If we are unable to increase our revenues and manage our expenses in accordance with our operating plan, our operating results would be harmed and we may not be able to generate the cash flow needed to fund the investments in our production capacity and other activities, 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.
- We could raise additional funds through public or private financings, strategic relationships, or other arrangements, to the extent funding would be available to us on acceptable terms or at all. If we succeed in raising additional funds through the issuance of equity or convertible securities, then the issuance could result in substantial dilution to existing stockholders. Furthermore, the holders of these new securities or debt may have rights, preferences and privileges senior to those of the holders of our Common Stock.

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

Our financial results may fluctuate.

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

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

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

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

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

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

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

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

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

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

Loans under the Credit Agreement and Guaranty bear interest at a rate per annum equal to the sum of (a) the greater of the one-month London Interbank Offered Rate, or LIBOR, and 2.5% plus (b) 8.75%. At any time at which an event of default has occurred and is continuing, the interest rate will increase by 4.0%. Accrued interest is payable on a monthly basis. On July 27, 2017, the U.K. Financial Conduct Authority announced that it will no longer require banks to submit rates for the calculation of LIBOR after 2021. On November 30, 2020, ICE Benchmark Administration, or IBA, the administrator of LIBOR, with the support of the United States Federal Reserve and the United Kingdom's Financial Conduct Authority, announced plans to consult on ceasing publication of USD LIBOR on December 31, 2021 for only the one week and two month USD LIBOR tenors, and on June 30, 2023 for all other USD LIBOR tenors. While this announcement extends the transition period to June 2023, the United States Federal Reserve concurrently issued a statement advising banks to stop new USD LIBOR issuances by the end of 2021. In light of these recent announcements, the future of LIBOR at this time is uncertain and any changes in the methods by which LIBOR is determined or regulatory activity related to LIBOR's phaseout could cause LIBOR to perform differently than in the past or cease to exist.

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

Pursuant to the Credit Agreement and Guaranty, if LIBOR becomes unavailable in the future, the Administrative Agent and Borrower (as such terms are defined in the Credit Agreement and Guaranty) may select an alternative benchmark rate, which may include SOFR. 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 Chembio Diagnostics Malaysia, opTricon and Orangelife, one of our 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. Our expectation is that the Chembio Diagnostics Malaysia, opTricon and Orangelife businesses will continue to grow and, consequently, our exposure to foreign currency exchange rates may grow as well.

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 which includes extensive product performance evaluations including five active collaborations and manufacturer's quality systems, as well as price and delivery. In Brazil, where we operate our subsidiary Orangelife and 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, and is its 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.

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.

Changes in interpretation or application of U.S. Generally Accepted Accounting Principles may adversely affect our operating results.

We prepare our financial statements to conform to U.S. generally accepted accounting principles. These principles are subject to interpretation by the Financial Accounting Standards Board, the American Institute of Certified Public Accountants, the Public Company Accounting Oversight Board, the Securities and Exchange Commission and various other regulatory or accounting bodies. A change in interpretations of, or our application of, these principles can have a significant effect on our reported results and may even affect our reporting of transactions completed before a change is announced. Additionally, as we are required to adopt new accounting standards, our methods of accounting for certain items may change, which could cause our results of operations to fluctuate from period to period. For example, upon adoption of Accounting Standards Codification ("ASC") 606 Revenue from Contracts with Customers of the Financial Accounting Standards Board ("FASB"), we now recognize revenue upon transfer of control, which is generally at time of delivery. Under the previous accounting guidance, we recognized revenue upon acceptance when and if we had production responsibilities. If circumstances change over time or interpretation of the revenue recognition rules change, we could be required to adjust the timing of recognizing revenue and our financial results could suffer.

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 (i) revenue recognition, including uncertainties related to variable consideration and milestones; (ii) stock-based compensation; (iii) allowance for uncollectible accounts receivable; (iv) inventory reserves and obsolescence; (v) customer sales returns and allowances; (vi) contingencies; and (vii) income taxes, (viii) goodwill and intangibles, (ix) business acquisition, and (x) research and development costs.

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

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

Risks Related to Intellectual Property

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

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

As appropriate, we intend to file patent applications and obtain patent protection for our proprietary technology. These patent applications and patents will cover, as applicable, compositions of matter for our products, methods of making those products, methods of using those products and apparatuses relating to the use or manufacture of those products. However, there have been changes to the patent laws and proposed changes to the rules of the U.S. Patent and Trademark Office, which may impact our ability to protect our technology and enforce our intellectual property rights. For example, in 2011, the 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 Third Party Collaborators

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 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 antigens, nitrocellulose or other critical components used in our products would require additional development work and 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.

We may work with strategic collaborators to assist in developing and commercializing our products, which could limit rights we receive from the collaborations and exposes us to other risks outside our control.

Some business opportunities that require a technology controlled by a third party, a significant level of investment for development and commercialization or a distribution network beyond our existing sales force may necessitate involving one or more strategic collaborators. As part of our strategy for development and commercialization of our products, we may enter into arrangements with distributors or other third-parties. Relying on such collaborative relationships could be risky to our business for a number of reasons, including: (i) we may be required to transfer material rights to such strategic collaborators, licensees and others; (ii) our collaborators may not obtain regulatory approvals necessary to continue the collaborations in a timely manner; (iii) our collaborators may decide to terminate our collaborative arrangement or become insolvent; (iv) our collaborators may develop technologies or components competitive with our products; (v) disagreements with collaborators could result in the termination of the relationship or litigation; and (vi) we may not be able to agree to future collaborative arrangements, or renewals of existing collaborative agreements, on acceptable terms or at all.

We expect our collaborators will have an economic motivation to succeed in performing their contractual responsibilities under our agreements, there is no assurance that they will do so. Due to our reliance on strategic agreements, it can make it difficult to accurately forecast our future revenues and operating results.

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.

By relying on distributors or third-parties to market and sell our products could negatively impact our business for various reasons, including: (i) we may not be able to find suitable distributors for our products on satisfactory terms, or at all; (ii) agreements with distributors may prematurely terminate or may result in litigation between the parties; (iii) our distributors or other customers may not fulfill their contractual obligations and distribute our products in the manner or at the levels we expect; (iv) our distributors may prioritize their own private label products that compete with our products; (v) Our existing distributor relationships or contracts may preclude or limit us from entering into arrangements with other distributors; and (vi) 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 increases our risk and liability.

We are currently receiving funding from the U.S. government related to DPP Zika, and our growth strategy targets 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, International Organization for Standards 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 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 U.S. Food and Drug Administration, or 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 does 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 United States 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 United States 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 U.S. by the U.S. Food and Drug Administration or 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 continued development of vaccines for COVID-19 and changes in the FDA's prioritization guidance.

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 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 FDA 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 QSRs and FDA regulatory requirements in the United States and other applicable regulations worldwide, including but not limited to 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 and in June 2020 we received notice from the FDA that the EUA for the DPP COVID-19 IgM/IgG System had been revoked. 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, the QSR and ISO requirements, 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 and genetic testing.

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.

However, the FDA has announced that it would begin regulating LDTs, and in October 2014 the FDA issued proposed guidance on the regulation of LDTs for public comment. But, on November 18, 2016, the FDA announced that it would not finalize the proposed guidance prior to the end of the Obama administration. On January 13, 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 Trump 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 genetic or 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 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 FDA’s ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA’s ability to perform routine functions. Average review times at the agency 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 March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. 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 several government regulations, compliance with which could increase our costs and affect our operations.

In addition to the FDA regulations previously described, laws and regulations in some states may restrict our ability to sell products in those states.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We will continue to try to increase revenue derived from international sales of our products. 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: (i) uncertainty in the application of foreign laws and the interpretation of contracts with foreign parties; (ii) cultural and political differences that favor local competitors or make it difficult to effectively market, sell and gain acceptance of our products; (iii) exchange rates, currency fluctuations, tariffs and other barriers, extended payment terms and dependence on international distributors or representatives; (iv) trade protection measures, trade sanctions and import/export licensing requirements; (v) our inability to obtain or maintain regulatory approvals or registrations for our products; (vi) Economic conditions, political instability, the absence of available funding sources, terrorism, civil unrest, war and natural disasters in foreign countries; (vii) Reduced protection for, or enforcement of, our patents and other intellectual property rights in foreign countries; (viii) our inability to identify international distributors and negotiate acceptable terms for distribution agreements; and (ix) 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 has limited liquidity, and investors may not be able to sell as much stock as they want at prevailing market prices or at all.

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

The price of our Common Stock could continue to be volatile.

The price of our Common Stock has been volatile, subject to rapid and substantial decreases in stock price, and may be volatile in the future. By way of example, on February 10, 2021, the price of our Common Stock closed at $7.92 per share while on February 17, 2021, our stock price closed at $6.94 per share with no discernable announcements or developments by us or third parties. On February 12, 2021, the intra-day sales price of our Common Stock fluctuated between a reported low sale price of $6.96 and a reported high sales price of $7.45. The following factors, among others, could have a significant impact on the market for our Common Stock: (1) the performance of our business; (2) clinical results with respect to our products or those of our competitors; (3) the gain or loss of significant contracts and availability of funding for the purchase of our products; (4) actions undertaken by the Congress or the Presidential Administration; (5) changes in our relations with our key customers, distributors or suppliers; (6) developments in patent or other proprietary rights; (7) litigation or threatened litigation; (8) general market and economic conditions; (9) the relatively low trading volume for our Common Stock; (10) changes in competition; (11) complaints or concerns about the performance or safety of our products and publicity about those issues, including publicity expressed through social media or otherwise over the internet; (12) failure to achieve, or changes in, financial estimates by securities analysts and comments or opinions about us by securities analysts or major stockholders; (13) announcement of regulatory or enforcement actions by the FDA or other agencies against us, our products or our customers; (14) changes in our operating results; (15) terrorist attacks, civil unrest, war and national disasters; and (16) other factors unrelated to our operating performance or prospects.

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

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

Our Common Stock may become the target of a “short squeeze.”

In the past several weeks prior to the filing of this Annual Report on Form 10-K, securities of certain companies have increasingly experienced significant and extreme volatility in stock price due to short sellers of shares of common stock, known as a “short squeeze.” Short squeezes have caused extreme volatility in those companies and in the market and have led to the price per share of those companies to trade at a significantly inflated rate that is disconnected from the underlying value of the company. Sharp rises in a company’s stock price may force traders in a short position to buy the stock to avoid even greater losses. Many investors who have purchased shares in those companies at an inflated rate face the risk of losing a significant portion of their original investment as the price per share has declined steadily as interest in those stocks have abated. There can be no assurance that we will not, in the future be, a target of a short squeeze, and you may lose a significant portion or all of your investment if you purchase our shares at a rate that is significantly disconnected from our underlying value.

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

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

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

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

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

We do not intend to pay cash dividends on our Common Stock.

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

General Risk Factors

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

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

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

Developments related to the U.K.'s referendum on membership in the E.U. could adversely affect us.

On June 23, 2016, the United Kingdom voted in favor of leaving the European Union, or E.U. On January 24, 2020, the U.K. and the E.U. entered into a withdrawal agreement pursuant to which the U.K. formally left the E.U. on January 31, 2020,In December 2020, the U.K. and E.U. agreed on a trade and cooperation that will provisionally apply after the end of the transition period until it is ratified by the parties to the agreement. On December 31, 2020, the U.K. passed legislation giving effect to the trade and cooperation agreement. The E.U. is expected to formally adopt the agreement in early 2021. The trade and cooperation agreement covers the general objectives and framework of the relationship between the U.K. and the E.U., including as it relates to trade, transport, visas, judicial, law enforcement and security matters. Notably, under the trade and cooperation agreement, U.K. goods no longer benefit from the free movement of goods, and there is no longer the free movement of people between the U.K. and the E.U.

Such a withdrawal from the E.U. is unprecedented, and it is unclear how the changes to U.K.'s access to the European single market for goods, capital, services and labor within the E.U., or the European single market, and the wider commercial, legal and regulatory environment, will impact our U.K. operations. We may also face new regulatory costs and challenges that could have an adverse effect on our operations and development programs. For example, because the regulatory framework for pharmaceutical products in the U.K. covering quality, safety and efficacy of pharmaceutical products, clinical studies, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from E.U. directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the U.K. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the U.K. and/or E.U. for our product or gene therapy product candidate, which could significantly harm our business.

Given the lack of comparable precedent, it is unclear what financial, trade and legal implications the withdrawal of the United Kingdom from the E.U. will have and how such withdrawal may affect us.

Legislative and other regulatory changes could have an effect on our business.

Changes in regulatory or economic conditions or in the laws and policies governing foreign trade, taxes, manufacturing, and development in the United States could impact our business. Economic and regulatory changes could also affect foreign currency exchange rates which, in turn, could affect our reported financial results and our competitiveness on a worldwide basis.

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, 2021.

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.

On February 5, 2019, we also entered into an agreement to sublet the space at Holbrook, New York. The sublease has a term that (a) commenced on the date we vacate the premises and (b) terminate on April 29, 2020. The sublessee has paid us 50% of our rent and additional rent payments, which will total approximately $100,000 per year during the term of the sublease. The sublease ran conterminously with the base lease in Holbrook, for which the Company was primarily responsible until the end of the lease term in April 2020.

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. 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 March 1, 2021, there were 115 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, 2020, we issued unregistered securities in connection with the acquisition of Orangelife. See Note 3 - Acquisitions, for further discussion.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the year ended December 31, 2020.

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

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

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

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

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

In 2020 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, including by eliminating positions that were no longer aligned with our strategy.

Consolidated Results of Operations

The results of operations for the years ended December 31, 2020 and 2019 were as follows:

	Year Ended December 31, (in thousands)			
	2020		2019	
TOTAL REVENUES	$ 32,470	100%	$ 34,464	100%
COSTS AND EXPENSES:				
Cost of product sales	23,874	74%	22,394	65%
Research and development expenses	9,509	29%	8,538	25%
Selling, general and administrative expenses	21,038	65%	16,139	47%
Severance and related costs	1,122	3%	—	0%
Acquisition costs	63	0%	721	2%
	55,606	171%	47,792	139%
LOSS FROM OPERATIONS	(23,136)	(71)%	(13,328)	(39)%
OTHER (EXPENSE) / INCOME	(2,842)	(9)%	(847)	(2)%
LOSS BEFORE INCOME TAX BENEFIT	(25,978)	(80)%	(14,175)	(41)%
Income tax benefit	457	1%	500	1%
NET LOSS	$ (25,521)	(79)%	$ (13,675)	(40)%

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during 2020 were $32.5 million, a decrease of $2.0 million, or 5.8%, compared to 2019. The decrease in total revenues reflected a $4.1 million, or 14%, decrease in net product sales, which was principally comprised of (a) lower sales in Africa, Latin America, and the United States associated with diminished funding and the closure of clinics for HIV testing due to the COVID-19 pandemic, offset in part by (b) The Company's success in achieving regulatory approvals for and selling the COVID-19 IgM/IgG Systems in Latin America and gains in Europe associated with our long term agreement with UNICEF for our DPP Zika IgM/IgG and DPP ZCD IgM/IgG multiplex tests and Micro Readers. The decrease in net product sales was offset in part by a $2.2 million, or 31.9%, increase in research and development and grant revenues relating to new government grants for the development, and submission for U.S. regulatory approval, of DPP SARS-CoV-2 Antigen and DPP Respiratory Panel test systems.

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 $5.6 million, or 86.2% compared to 2019. The following schedule calculates gross product margin:

	For the years ended December 31		Favorable/	
	2020	2019	(unfavorable)	% Change
	(in thousands)			
Net product sales	$ 24,767	$ 28,845	$ (4,078)	(14.1)%
Less: Cost of product sales	(23,874)	(22,394)	(1,480)	6.6%
Gross product margin	$ 893	$ 6,451	$ (5,558)	(86.2)%
Gross product margin %	3.6%	22.4%		

In 2020 we invested in developing and offering products to address the COVID-19 pandemic, which we expect will 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 (see Q1'21 Restructuring Charge). The $5.6 million decrease in gross product margin was comprised of (a) $4.7 million from unfavorable product margins and (b) $0.9 million from unfavorable product sales volume as described under "—Total Revenues" above. The $4.6 million decrease from unfavorable product margins principally reflected the following:

- We incurred the cost of product sales for COVID-19 IgM/IgG Systems that were returned by customers following the Revocation.
- The Revocation precluded planned sales of COVID-19 IgM/IgG Systems to customers in the United States in the last three quarters of 2020 and resulted in the deferral ,of certain customer opportunities for sales of COVID-19 IgM/IgG Systems outside the United States, which negatively impacted our sales mix as we experienced (a) significantly lower sales in the United States, where we have our highest average selling prices, and (b) outside the United States, a higher mix of sales in geographic regions with lower average selling prices.
- We experienced operational inefficiencies, including those triggered by the Revocation and activities related to qualifying automated lines for production of certain products, which resulted in increased cost of product sales as we substantially shifted our production from COVID-19 products back to legacy products.

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/	
	2020	2019	(unfavorable)	% Change
	(in thousands)			
Clinical and regulatory affairs	$ 1,061	$ 1,516	$ 455	30.0%
Other research and development	8,448	7,022	(1,426)	(20.3)%
Total research and development	$ 9,509	$ 8,538	$ (971)	(11.4)%

The decrease in clinical and regulatory affairs costs for 2020 as compared to 2019 was primarily associated with reduced clinical trial costs following the FDA's granting of premarket approval for the DPP HIV-Syphilis test during 2020, offset in part by expenditures related to the DPP SARS-CoV-2 Systems. The increase in other research and development costs was primarily related to costs associated with the development of the DPP SARS-CoV-2 Systems.

Selling, General and Administrative Expense

Selling, general and administrative expenses include administrative expenses, sales and marketing costs (including commissions), and other corporate items. The $4.9 million, or 30%, increase in selling, general and administrative expenses for 2020 as compared to 2019 primarily reflected legal costs arising subsequent to the Revocation, costs from expanding our U.S. commercial organization, a full year of our Brazilian facility (which was acquired during the fourth quarter of 2019), and facility costs related to the COVID-19 pandemic, offset in part by cost savings from retrenching our Malaysia facility and other restructuring actions taken during the first quarter of 2020.

Severance, Restructuring and other related costs

During the year ended December 31, 2020, the Company recognized $0.7 million in net severance expenses related to the departure of Chembio's former chief executive officer and the elimination of certain positions as part of its multi-faceted expense reduction program to reduce operating expenses. The Company undertook actions to adjust the size and composition of the organization, including by removing positions that were non-essential in light of its new business strategy, and to remove other expenses, all of which the Company expects will provide savings throughout, and after, 2020.

In light of market dynamics, the Company retrenched its Malaysian operations, including the termination of employment of its Malaysian workforce. The Company will maintain its Malaysian subsidiary and sustain the product registrations that were obtained throughout southeast Asia, with the benefit of having that entity and the WHO prequalification certified facility.

Based on these activities, the Company took restructuring actions totaling $0.4 million to realign and resize its production capacity and cost structure. All expenses have been paid as of December 31, 2020.

Acquisition Costs

Acquisition costs include legal, due diligence, audit, and related costs associated with acquisitions. The $0.7 million decrease in acquisition costs for 2020 as compared to 2019 reflected the fact that we completed acquisitions in 2019 but not 2020.

Other (Expense) / Income

Other (expense) / income was principally comprised of interest expense net of interest income. Interest expense increased by $2.0 million for 2020 as compared to 2019, due to the interest paid on the term loan debt we incurred in September 2019.

Income Tax Benefit

For 2020 we recognized a tax benefit of $0.4 million primarily attributable to the loss generated by Chembio Diagnostics Germany. As of December 31, 2020 and 2019, the Company recorded a full valuation allowance against its net deferred tax assets.

Liquidity and Capital Resources

During the year ended December 31, 2020, we funded our business operations, including capital expenditures and working capital requirements, principally from a public offering of common stock, which generated proceeds of $28.4 million (net of expenses), and from cash and cash equivalents. Our operations used $18.9 million of cash. As of December 31, 2020, we had outstanding indebtedness of $20 million (carrying amount of $18.2 million) pursuant to the Credit Agreement described under "—Sources of Funds—Credit Agreement" below.

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

Sources of Funds

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

- Principal Amount. The Credit Agreement provides for a $20,000,000 senior secured term loan credit facility, which was drawn in full on September 4, 2019. Under the terms of the Credit Agreement, we may use the proceeds for general working capital purposes and other permitted corporate purposes, to refinance certain of our existing indebtedness and to pay fees, costs and expenses incurred in connection with the Credit Agreement.

- 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.

- 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 10% through September 3, 2020, 8% from September 4, 2020 through September 3, 2021, and 4% from September 4, 2021 through September 3, 2022. No premium will be due with respect to any prepayment made on or after September 4, 2022.

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

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

- Representations and Warranties; Financial and Other Covenants. In the Credit Agreement we made customary representations and warranties as well as customary affirmative and negative covenants, including covenants limiting additional indebtedness, liens, guaranties, mergers and acquisitions, substantial asset sales, investments and loans, sale and leasebacks, transactions with affiliates, and fundamental changes. The Credit Agreement also contains financial covenants requiring that we maintain aggregate unrestricted cash of not less than $3,000,000 at all times and we achieve specified minimum rolling four-quarter ("last twelve month") total revenue amounts as of September 30, 2019 and the last day of each calendar quarter thereafter. The minimum total revenue amounts, which range from $32.0 million to $50.1 million, were developed for purposes of the Credit Agreement and do not reflect the internal estimates and plans used by our management and board of directors to understand and evaluate our operating performance, to establish budgets, and to establish operational goals for managing our business. We therefore do not believe that the covenant requirements provide useful information to investors or others in enhancing an understanding of our future prospects.

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

We were in compliance with the cash balance and revenue financial covenants as of December 31, 2020.

Equity and Equity-Related Securities. We raised additional capital from an underwritten public offering of common stock in 2020 in the amount of $28.4 million (net of expenses).

Research and Development Awards. We routinely seek research and development programs that may be awarded by government, non-governmental organizations, and non-profit entities, including private foundations. Since 2015 we have received over $14.2 million of funding from some of the world's leading health organizations, which has helped us accelerate the expansion of our pipeline of infectious disease tests. Our collaborators have included Bill & Melinda Gates Foundation, The Paul G. Allen Family Foundation, FIOCRUZ and FIND, as well as U.S. government agencies such as Centers for Disease Control and Prevention, Biomedical Advanced Research and Development Authority or BARDA, and the U.S. Department of Agriculture. See "Item 1. Business—Products" above. During the year ended December 31, 2020, we recognized grant revenue totaling $2 million from government, non-governmental organizations, and non-profit entities.

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

	December 31, 2020
	(in thousands)
Cash and cash equivalents	$ 23,066
Accounts receivable, net	3,377
Inventories, net	12,516
Prepaid expenses and other current assets	779
Total current assets	39,738
Less: Total current liabilities	12,351
Working capital	$ 27,387

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

Our cash and cash equivalents at December 31, 2020, which included a restricted amount of $1.0 million, were held for working capital purposes. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends. We have not entered into, and do not expect to enter into, investments for trading or speculative purposes. Our accounts receivable and inventory balances fluctuate from period to period, which affects our cash flow from operating activities. Fluctuations vary depending on cash collections, client mix, raw material lead times, the mix of vendor terms, and the timing of shipment of our products and the invoicing of our research and development activities.

Uses of Funds

Cash Flow Used in Operating Activities. Our operations used $18.9 million of cash during the year ended December 31, 2020, primarily due to the net loss adjusted for non-cash items of $7.3 million and a $6.5 million increase in inventory related to supply chain timelines, including materials for COVID-19 systems that were ordered but could not be cancelled following the Revocation. Those uses of cash were offset in part by a $3.9 million increase in accounts payable and other accrued liabilities, a $1.5 million increase in deferred revenue, and a $0.3 million reduction in accounts receivable.

Capital Expenditures. Our capital expenditures totaled $4.2 million in 2020, of which $4.0 million related to investments in automated manufacturing equipment, facilities, and other fixed assets.

We have capital purchase obligations of $1.3 million related to additional automated manufacturing equipment with payments expected to come due during 2021 based on vendor performance milestones.

Effects of Inflation

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

Q1'21 Restructuring Charge

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

Costs associated with the 2021 Plan are primarily related to Severance and Legal costs. Severance payouts are expected to be substantially completed by the end of the six months ending June 30, 2021. Under the 2021 Plan, the Company expects to incur pre-tax charges between approximately $0.1 million and $0.2 million.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K under the Securities Exchange Act of 1934.

Significant Accounting Policies and Critical Accounting Estimates

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).

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 cumulative 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.

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 judgement and estimates in recognizing revenue for relevant contracts.

Stock-Based Compensation

We recognize the fair value of equity-based awards as compensation expense in our consolidated statement of operations. The fair value of restricted stock and restricted stock unit awards are their fair value on the date of grant. The fair value of our stock option awards was estimated using a Black-Scholes option valuation model. This valuation model's computations incorporate subjective assumptions, such as the expected stock price volatility and the estimated life of each award. The fair value of equity-based awards, after considering the effect of expected forfeitures, is then amortized, generally on a straight-line basis, over the related vesting period of the option.

Research and Development Costs

Research and development activities consist primarily of new product development, continuing engineering for existing products, and regulatory and clinical trial costs. Costs related to research and development efforts on existing or potential products are expensed/accrued as incurred.

Inventories

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. The Company also writes off, in the applicable period, the costs related to expired inventory. Costs of purchased inventories are recorded using weighted-average costing.

Accounts Receivable

Our policy is to review our accounts receivable on a periodic basis, no less frequently than monthly. On a quarterly basis an analysis is made of the adequacy of our allowance for doubtful accounts and adjustments are made accordingly. The allowance was approximately 0.6% of accounts receivable as of December 31, 2020.

Goodwill and Indefinite-lived Intangible Assets

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.

Indefinite-lived intangible assets are tested for impairment annually during the first fiscal quarter of the year, and when events or changes in circumstances indicate the assets might be impaired. Impairment is indicated when the carrying value of the intangible asset exceeds its fair value.

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, 2020 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 Interim 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, 2020. 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, 2020 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, 2020. 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, 2020.

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 Comapny's Chief Excutive 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 liminations 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.
3.2	Amended and Restated Bylaws, of Chembio Diagnostics, Inc.
4.1	Warrant to Purchase Common Stock dated as of September 3, 2019, issued by Chembio Diagnostics, Inc. to Perceptive Credit Holdings II, LP
4.2	Description of Securities
10.1(a)*	2008 Stock Incentive Plan, as amended
10.1(b)*	Form of Option for 2008 Stock Incentive Plan
10.2(a)*	2014 Stock Incentive Plan
10.2(b)*	Form of Option for 2014 Stock Incentive Plan
10.3	2019 Omnibus Incentive Plan
10.4*	Restated Annual Incentive Bonus Plan of Chembio Diagnostics, Inc., adopted as of March 15, 2019
10.5*	Outside Director Compensation Policy of Chembio Diagnostics, Inc.
10.6*‡	Employment Agreement, dated as of March 4, 2020 and effective as of March 16, 2020, between Chembio Diagnostics, Inc. and Richard L. Eberly
10.7(a)*	Employment Agreement dated March 5, 2016 between Chembio Diagnostics, Inc. and Javan Esfandiari
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
10.8(a)*	Employment Agreement dated December 18, 2017 between Chembio Diagnostics, Inc. and Neil A. Goldman
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
10.9*	Offer Letter dated October 19, 2016 between Worldwide Workplace Ireland and Robert Passas, with respect to employment by Chembio Diagnostics Systems, Inc.
10.10(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
10.10(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
10.11	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
10.12	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.
10.13†	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
10.14*‡	Letter agreement dated June 15, 2020 between Chembio Diagnostics, Inc. and Gail S. Page
10.15*	Amendment No. 1, dated June 30, 2020, to the letter agreement dated June 15, 2020 between Chembio Diagnostics, Inc. and Gail S. Page
14.1	Ethics Policy
21.1	List of Subsidiaries of Chembio Diagnostics, Inc.
22.1	Consent of EY, Independent Registered Public Accounting Firm
23.1	Consent of BDO USA, LLP, 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
104	Cover Page Interactive Data File (embedded within the Inline XBRL 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.

‡ Certain sensitive personally identifiable information in this exhibit was omitted by means of redacting a portion of the text and replacing it with [***].

** 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 11, 2021 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 11, 2021
/s/ Neil A. Goldman Neil A. Goldman	Executive Vice President and Chief Financial Officer (Principal Financial & Accounting Officer)	March 11, 2021
/s/ Katherine L. Davis Katherine L. Davis	Chair of the Board	March 11, 2021
/s/ David W. K. Acheson David W. K. Acheson	Director	March 11, 2021
/s/ David W. Bespalko David W. Bespalko	Director	March 11, 2021
/s/ Mary Lake Polan Mary Lake Polan	Director	March 11, 2021
/s/ John G. Potthoff John G. Potthoff	Director	March 11, 2021

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, 2020, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for the year ended December 31, 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, 2020, and the results of its operations and its cash flows for the year ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

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 audit. 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 audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates 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 matter 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 matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Revenue Recognition – Variable Consideration

Description of the Matter

For the year ended December 31, 2020, the Company recognized $24.8 million of net product revenue. As discussed in Note 2 to the consolidated financial statements, variable consideration, which includes the effect of estimated future returns, is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenues recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

Auditing the Company's measurement of variable consideration related to future returns was especially complex and involved a higher degree of subjectivity due to the significant estimation uncertainty. The estimation of variable consideration was dependent upon significant assumptions such as the probability of future returns and the likelihood of changes in approval by regulatory agencies. Changes in management's significant assumptions can have a material effect on the amount and timing of revenue recognized.

How We Addressed the Matter in Our Audit

To test the estimation of variable consideration, our audit procedures included, among others, the evaluation of the completeness of the underlying data used in management's calculation and testing the significant assumptions described above. For example, these procedures included evaluating the likelihood of changes in regulatory approval, inspection of Company's correspondences with the third parties and regulatory agencies, and corroborating inquiries of the Company's operational personnel in order to support management's assumptions. We also tested subsequent cash collection for products shipped to third party customers and performed a lookback analysis comparing actual product returns to the reserve established by management.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2020.
Jericho, New York
March 11, 2021

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Chembio Diagnostics, Inc.
Hauppauge, New York

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Chembio Diagnostics, Inc. (the "Company") and subsidiaries as of December 31, 2019, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows the year then ended, 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 and subsidiaries at December 31, 2019, and the results of their operations and their cash flows for the year ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

On January 1, 2019, the Company changed its method of accounting for leases due to the adoption of Accounting Standards Codification Topic 842, Leases. The effects of the adoption are described in Note 3 to the consolidated financial statements.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. 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 consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ BDO USA, LLP

We served as the Company's auditor from 2011 to 2019.

Melville, NY
March 13, 2020

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

	December 31,	
	2020	2019
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 23,066,301**	$ 18,271,352
Accounts receivable, net of allowance for doubtful accounts of $296,793 and $62,000 at December 31, 2020 and 2019, respectively	**3,377,387**	3,661,325
Inventories, net	**12,516,402**	9,598,030
Prepaid expenses and other current assets	**778,683**	693,013
TOTAL CURRENT ASSETS	**39,738,773**	32,223,720
FIXED ASSETS:		
Property, plant and equipment, net	**8,688,403**	5,933,569
Finance lease right-of-use assets, net	**233,134**	210,350
OTHER ASSETS:		
Operating right-of-use assets, net	**6,112,632**	7,030,744
Intangible assets, net	**3,645,986**	3,914,352
Goodwill	**5,963,744**	5,872,690
Deposits and other assets	**509,342**	543,539
TOTAL ASSETS	**$ 64,892,014**	$ 55,728,964
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 10,042,790**	$ 5,526,243
Deferred revenue	**1,606,997**	125,000
Notes Payable	**-**	180,249
Operating lease liabilities	**642,460**	568,294
Finance lease liabilities	**58,877**	41,894
TOTAL CURRENT LIABILITIES	**12,351,124**	6,441,680
OTHER LIABILITIES:		
Long-term operating lease liabilities	**6,327,143**	6,969,603
Long-term finance lease liabilities	**185,239**	171,953
Long-term debt, less current portion, net	**18,182,158**	17,644,149
Deferred tax liability	**69,941**	466,326
TOTAL LIABILITIES	**37,115,605**	31,693,711
COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding	**-**	-
Common stock - $0.01 par value; 100,000,000 shares authorized, 20,223,498 and 17,733,617 shares issued and outstanding at December 31, 2020 and 2019, respectively	**202,235**	177,335
Additional paid-in capital	**124,961,514**	95,433,077
Accumulated deficit	**(97,106,331)**	(71,585,003)
Treasury stock – 41,141 and 0 shares at cost, at December 31, 2020 and 2019, respectively	**(190,093)**	-
Accumulated other comprehensive income	(90,916)	9,844
TOTAL STOCKHOLDERS' EQUITY	**27,776,409**	24,035,253
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 64,892,014**	$ 55,728,964

See accompanying notes to consolidated financial statements

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

	December 31,	
	2020	2019
REVENUES:		
Product revenue	**$ 24,767,149**	$ 28,844,997
R&D revenue	**4,851,562**	4,025,538
Government grant income	**2,018,924**	654,744
License and royalty revenue	**832,562**	938,753
TOTAL REVENUES	**32,470,197**	34,464,032
COSTS AND EXPENSES:		
Cost of product sales	**23,874,487**	22,394,317
Research and development expenses	**9,508,494**	8,538,416
Selling, general and administrative expenses	**21,037,701**	16,138,424
Severance and related costs	**1,122,310**	-
Acquisition costs	**63,497**	721,465
	55,606,489	47,792,622
LOSS FROM OPERATIONS	**(23,136,292)**	(13,328,590)
OTHER (EXPENSE) INCOME:		
Interest expense, net	**(2,841,830)**	(846,831)
LOSS BEFORE INCOME TAX BENEFIT	**(25,978,122)**	(14,175,421)
Income tax benefit	**456,794**	500,292
NET LOSS	**$ (25,521,328)**	$ (13,675,129)
Basic and diluted loss per share	**$ (1.34)**	$ (0.81)
Weighted average number of shares outstanding, basic and diluted	**19,085,691**	16,954,142

See accompanying notes to consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
FOR THE YEARS ENDED

	December 31,	
	2020	2019
Net loss	**$ (25,521,328)**	$ (13,675,129)
Other comprehensive loss:		
Foreign currency translation adjustments	**(100,760)**	(102,352)
COMPREHENSIVE LOSS	**$ (25,622,088)**	$ (13,777,481)

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, 2020 AND 2019

	Common Stock		Additional Paid-in-Capital	Treasury Stock		Accumulated Deficit	AOCI	Total
	Shares	Amount	Amount	Shares	Amount	Amount	Amount	Amount
Balance at December 31, 2018	**17,166,459**	**$ 171,664**	**$ 90,953,788**	**-**	**$ -**	**$ (57,909,874)**	**$ 112,196**	**$ 33,327,774**
Common Stock:								
Restricted stock issued	**381,908**	**3,819**	**(128,081)**	-	-	-	-	**(124,262)**
Restricted stock compensation	-	-	**1,394,812**	-	-	-	-	**1,394,812**
Issuance of common stock for business acquired	**153,707**	**1,537**	**441,754**	-	-	-	-	**443,291**
Options:								
Exercised	**31,543**	**315**	**32,171**	-	-	-	-	**32,486**
Stock option compensation	-	-	**261,088**	-	-	-	-	**261,088**
Warrants and Other:								
Warrant on Term Debt	-	-	**1,196,093**	-	-	-	-	**1,196,093**
Contingent Earnout for business acquired	-	-	**1,281,452**	-	-	-	-	**1,281,452**
Comprehensive loss	-	-	-	-	-	-	**(102,352)**	**(102,352)**
Net loss	-	-	-	-	-	**(13,675,129)**	-	**(13,675,129)**
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**
Warrants exercised	**253,161**	**2,532**	**(2,532)**	-	-	-	-	-
Treasury stock	-	-	**190,093**	**(41,141)**	**(190,093)**	-	-	-
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**

See accompanying notes to consolidated financial statements

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

	December 31, 2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	**$ 34,736,133**	$ 37,930,172
Cash paid to suppliers and employees	**(50,238,409)**	(45,655,562)
Cash paid for operating leases	**(1,139,944)**	(632,952)
Cash paid for finance leases	**(19,987)**	(7,892)
Interest and taxes, net	**(2,225,031)**	(689,272)
Net cash used in operating activities	**(18,887,238)**	(9,055,506)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of businesses, net of cash acquired	**-**	(100,000)
Acquisition of and deposits on fixed assets	**(3,961,369)**	(3,502,540)
Patent Application Costs	**(205,493)**	(297,006)
Working capital adjustment related to business combination	**-**	145,760
Net cash used in investing activities	**(4,166,862)**	(3,753,786)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock, net	**28,436,740**	-
Proceeds from option exercises	**-**	32,486
Principal payments for finance leases	**(51,166)**	(19,875)
Payments on debt issuance costs	**-**	(186,313)
Payments on note payable	**(180,249)**	(181,822)
Proceeds from issuance of long-term debt, net	**-**	18,850,000
Stimulus package loan	**2,978,315**	-
Payment of stimulus package loan	**(2,978,315)**	-
Payments of tax withholdings on stock award	**(441,723)**	-
Net cash provided by financing activities	**27,763,602**	18,494,476
Effect of exchange rate changes on cash	**85,447**	61,617
INCREASE IN CASH AND CASH EQUIVALENTS	**4,794,949**	5,746,801
Cash and cash equivalents - beginning of the period	**18,271,352**	12,524,551
Cash and cash equivalents - end of the period	**$ 23,066,301**	$ 18,271,352
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net Loss	**$ (25,521,328)**	$ (13,675,129)
Adjustments:		
Depreciation and amortization	**2,697,126**	1,916,194
Share based compensation	**1,223,171**	1,655,900
Benefit from deferred tax liability	**(396,385)**	(513,715)
Provision for doubtful accounts	**270,193**	20,000
Non-cash inventory changes	**3,543,515**	-
Changes in assets and liabilities, net of effects from acquisitions:		
Accounts receivable	**283,939**	3,764,045
Inventories	**(6,461,887)**	(1,457,612)
Prepaid expenses and other current assets	**(85,670)**	64,355
Deposits and other assets	**34,195**	(90,624)
Accounts payable and accrued liabilities	**4,043,896**	(441,015)
Deferred revenue	**1,481,997**	(297,905)
Net cash used in operating activities	**$ (18,887,238)**	$ (9,055,506)
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	**$ 472,651**	$ 430,000
Issuance of common stock for net assets of business acquired	**–**	443,291
Contingent liability earnout	**1,011,261**	1,225,000

See accompanying notes to consolidated financial statements

NOTE 1 — DESCRIPTION OF BUSINESS:

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

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

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

During 2020, the Company refocused its business strategy on the development and commercialization of the DPP COVID-19 IgM/IgG System, which consists of a new serological test for COVID-19 and a Micro Reader analyzer. In the twelve months ended December 31, 2020, the Company developed, received regulatory approval in the US, Brazil and Europe, and commercialized the DPP COVID-19 IgM/IgG System, which provided numerical readings for both IgM and IgG levels of antibodies to the virus, and began developing its strategy for a portfolio of products both related to and expanding beyond COVID-19. On June 16, 2020, the U.S. FDA Food and Drug Administration (the "FDA") revoked the Company's Emergency Use Authorization ("EUA") for the DPP COVID-19 System in the U.S., and the Company immediately began developing a revised version. The Company submitted an application for EUA to the FDA for its new rapid antibody test system, DPP SARS-CoV-2 IgM/IgG on September 8, 2020 (the "IgM/IgG EUA").

On December 3, 2020, the Company received from the FDA a letter responding to the IgM/IgG EUA. The response letter stated that, given the volume of EUA requests it has received, the FDA was prioritizing review of EUA requests for tests, taking into account a variety of factors such as the public health need for the product and the availability of the product. The response letter further stated that the FDA determined that review of the IgM/IgG EUA request was not a priority because, for example, authorization of the test would have relatively limited impact on testing accessibility or testing capacity, and therefore the FDA declined to review the IgM/IgG EUA request at that time.

On July 6, 2020, the Company received a $628,071 grant from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, Division of Research Innovation and Ventures ("BARDA") to assist the Company in developing a COVID-19 point-of-care antigen system using Chembio's proprietary DPP technology and submitting an application for EUA to the FDA for the system. On October 15, 2020, Chembio submitted the EUA application for the DPP SARS-CoV-2 Antigen test system, which was designed to detect SARS-CoV-2 antigens in only 20 minutes. The DPP SARS-CoV-2 Antigen test system consists of a DPP SARS-CoV-2 Antigen test cartridge, a DPP Micro Reader optical analyzer and a minimally-invasive nasal swab.

On December 2, 2020, the Company received a $12,691,726 grant 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 contract also supports preparation of a submission in pursuit of FDA 510(k) clearance for the Company's rapid DPP SARS-CoV-2 Antigen test system.

The DPP Respiratory Antigen Panel test system is intended 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 or nasopharyngeal swab. It is expected to provide results in approximately 20 minutes and be run on Chembio's DPP Micro Reader analyzer. The system is intended to enable appropriate clinical management of patients with suspected respiratory infections and assist in the containment of COVID-19 cases during the flu season.

In addition to its DPP COVID-19 rapid test products, the Company has a broad portfolio of infectious disease products, which it expects to generate a diminished amount of revenue for the foreseeable future both due to the impact of the global COVID-19 pandemic and while it focuses on the development, manufacture, and commercialization of DPP COVID-19 products. Through Research & Development ("R&D") Services, the Company is developing tests in collaboration with Takeda Pharmaceutical Company Limited.

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.

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

Certain amounts related to other government income in the prior period financial statements have been reclassified to conform to the presentation of the current period financial statements.

(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, accrued expenses and other current liabilities approximate fair value due to the immediate or short-term maturity of these financial instruments. Included in cash and cash equivalents is $14.8 million and $16.0 million as of December 31, 2020 and 2019, 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 $18.2 million) and $20 million (carrying value of $17.6 million) as of December 31, 2020 and 2019, 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, and include restricted cash of $1 million and $0 as of December 31, 2020 and 2019, respectively.

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

(e) ***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. The Company monitors the credit ratings of the financial institutions to mitigate this risk. Concentration of credit risk with respect to trade receivables is principally mitigated by the Company's ability to obtain letters of credit from certain foreign customers and its diverse customer base, both in number of customers and geographic locations.

(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. The Company also writes off, in the applicable period, the costs related to expired inventory. Costs of purchased inventories are recorded using weighted-average costing.

(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. No impairment of long-lived tangible and intangible assets was recorded for the years ended December 31, 2020 and 2019.

(*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.

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. The Company's process for estimating reserves established for these variable consideration components does not differ materially from its historical practices.

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 cumulative 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 often 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.

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, 2019, the Company reported $0.1 million in deferred revenue of which $0.1 million was earned and recognized as R&D, milestone and grant revenue during the year ended December 31, 2020. At December 31, 2020, the Company reported $1.6 in deferred revenue, in which $0.8 million is expected to be recognized during the three months ending March 31, 2021 and the remainder in the next twelve months.

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 $0.4 million for the year ended December 31,2020 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 $1.6 million for the year ended December 31,2020 and was recorded as government grant income..

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

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

There were 603,531 and 545,986 restricted shares awards outstanding as of December 31, 2020 and 2019, respectively, that were not included in the calculation of diluted loss per share for the year ended December 31, 2020 and 2019, because their effect would have been anti-dilutive. There were 974,778 and 642,625 options outstanding as of December 31, 2020 and 2019 respectively, that were not included in the calculation of diluted loss per share for the twelve months ended December 31, 2020 and 2019, 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, non-employee members of the Company's board of directors and non-employee consultants 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.

Using this model, 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 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 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 expected life of the option.

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

(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 and Indefinite-lived Intangible Assets:***

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.

Indefinite-lived intangible assets are tested for impairment annually during the first day of the fiscal fourth quarter of the year, and when events or changes in circumstances indicate the assets might be impaired. Impairment is indicated when the carrying value of the intangible asset exceeds its fair value.

(*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. Foreign transaction gains/losses are immaterial.

(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 non-cancellable 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.

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

Recently Adopted

ASU 2020-10, Codification Improvements

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

ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13")

In June 2016, the FASB issued ASU 2016-13. ASU 2016-13 provides guidance on measurement of credit losses on financial instruments that changes the impairment model for most financial assets and certain other instruments, including trade and other receivables, held-to-maturity debt securities and loans, and that requires entities to use a new, forward-looking "expected loss" model that is expected to generally result in the earlier recognition of allowances for losses. The Company adopted the standard effective January 1, 2020 and has evaluated the effects of this standard and determined that the adoption did not have a material impact on the Company's consolidated financial statements.

ASU 2018-13, Fair Value Measurement - Disclosure Framework (Topic 820) ("ASU 2018-13")

In August 2018, the FASB issued ASU 2018-13. ASU 2018-13 improves the disclosure requirements on fair value measurements. The updated guidance became effective for fiscal years beginning after December 15, 2019 including interim periods within those years. The Company adopted the standard effective January 1, 2020 and has evaluated the effects of this standard and determined that the adoption did not have a material impact on the Company's consolidated financial statements.

ASU 2017-4, Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment ("ASU 2017-4")

In January 2017, the FASB issued ASU 2017-4. ASU 2017-4 simplifies the subsequent measurement of goodwill and eliminates Step 2 from the goodwill impairment test. ASU 2017-4 is effective for annual and interim goodwill tests beginning after December 15, 2019. The Company adopted the standard effective January 1, 2020 and has evaluated the effects of this standard and determined that the adoption did not have a material impact on the Company's consolidated financial statements.

Not Yet 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 will adopt the standard effective January 1, 2021 and has determined that the adoption will 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 will adopt the standard effective January 1, 2021 and has determined that the adoption will not have a material impact on the Company's consolidated financial statements.

ASU 2020-06 - Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity
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 all potential impact of the standard and will disclose the nature and reason for any elections that the Company makes.

NOTE 3 — ACQUISITIONS:

Orangelife

On November 25, 2019, pursuant to a quota purchase agreement, the Company acquired all of the outstanding shares of Orangelife Comercio e Industria Ltda., or Orangelife, a privately-held Brazilian company, which is an original equipment manufacturer of point-of-care tests approved by the Brazilian Health Surveillance Agency (Agência Nacional de Vigilância Sanitária, or ANVISA) for infectious diseases that include HIV, Hepatitis C, Zika, Chikungunya, and Dengue Fever. Orangelife tests are manufactured in its Rio de Janeiro facility, which is ISO-certified and approved by ANVISA to produce Class II/III/IV medical devices. The purchase price includes the following consideration:

- $150,000 in cash and 153,707 shares of common stock.
- Issuance of 316,456 shares of common stock to the founder and former chief executive officer of Orangelife, based on the transfer and approval of registration of certain of the Company's products in Brazil prior to November 25, 2022. All of the shares may be deliverable in the event of change in control of Chembio. The number of shares issued was subject to adjustments based upon Orangelife's working capital at closing. The fair value of the shares on the date of the acquisition was recorded in equity and was valued at $1.2 million.

The purchase consideration is subject to routine post-closing adjustments and has been finalized as of December 31, 2020. The acquisition of Orangelife will allow us to expand our commercial presence by offering our products to the state, private, and pharmacy markets in Brazil, in addition to providing local support to our long time customer Bio-Manguinhos, the subsidiary of the Oswaldo Cruz Foundation (Fiocruz) that oversees development and production of vaccines, diagnostics, and biopharmaceuticals, primarily to meet the demands of Brazil's national public health system. The results of Orangelife's operations have been reflected in the consolidated financial statements since November 25, 2019.

The acquisition was accounted for using the purchase method of accounting. The following table summarizes the allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed on the closing date of November 25, 2019:

	Amount
Net current assets	$ 320,293
Property, plant and equipment and other assets	226,035
Inventory	289,205
Goodwill	986,058
Deferred tax liability	(50,000)
Other intangible assets (estimated useful life):	
Trade name (0.5 years)	5,000
Customer contracts / relationships (5 years)	195,000
Total consideration	$ 1,971,591

The Company calculated the fair value of the property, plant and equipment based on the net book value of Orangelife as that approximates fair value. The estimated fair value of the trade name, customer contracts/relationships and contingent earnouts were based on discounted cash flows using management estimates.

As a result of the consideration paid exceeding the fair value of the net assets acquired, goodwill in the amount of $986,058 was recorded in connection with this acquisition, none of which will be deductible for tax purposes. In addition, the Company recorded $200,000 in intangible assets associated with the addition of Orangelife's trade name and customer base.

The following represents unaudited pro forma operating results for the year ended December 31, 2019 as if the operations of Orangelife had been included in the Company's Consolidated Statements of Operations as of January 1, 2019. This pro forma financial information is unaudited and presented for illustrative purposes only and is not necessarily indicative of the operating results that would have occurred if the acquisition of Orangelife and the other transactions contemplated by this acquisition had been completed as of January 1, 2019, nor is it necessarily indicative of the future operating results of Chembio Diagnostics and Orangelife on a combined and consolidated basis.

	Unaudited Proforma December 31, 2019
Total revenues	$ 35,157,248
Net loss	$ (13,654,001)
Net loss per common share (basic and diluted)	$ (0.80)

NOTE 4 — INVENTORIES:

Net inventories consist of the following at December 31:

	December 31	
	2020	2019
Raw Materials	**$ 5,955,215**	$ 2,901,319
Work in Process	**2,549,516**	793,343
Finished Goods	**4,011,671**	5,903,368
	$ 12,516,402	$ 9,598,030

NOTE 5 — FIXED ASSETS:

Fixed assets consist of the following at December 31:

	December 31	
	2020	2019
Machinery and Equipment	**$ 10,996,869**	$ 7,955,511
Furniture and Fixtures	**25,418**	21,477
Computer Equipment	**446,300**	416,359
Leasehold Improvements	**3,158,074**	3,038,469
Enterprise Business Systems	**2,741,806**	1,830,925
Subtotal:	**17,368,467**	13,262,741
Less: Accumulated Depreciation and Amortization	**(8,680,064)**	(7,329,172)
	$ 8,688,403	$ 5,933,569

Depreciation expense for the 2020 and 2019 years totaled $1,227,860 and $933,558, respectively.

As of December 31, 2020 and 2019, the Company has purchased manufacturing equipment that is not yet in use and therefore has not been depreciated, aggregating $3,011,273 and $1,400,181, respectively.

NOTE 6 — ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:

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

	December 31	
	2020	2019
Accounts Payable - suppliers	**$ 5,727,781**	$ 3,144,098
Accrued Commissions & Royalties	**807,708**	931,760
Accrued Payroll	**277,908**	231,753
Accrued Vacation	**417,238**	410,199
Accrued Bonuses	**1,193,985**	215,000
Accrued Professional Fees	**511,681**	-
Accrued Expenses - Other	**1,106,489**	593,433
	$ 10,042,790	$ 5,526,243

NOTE 7 — REVENUE:

Deferred Revenue

The Company recognizes income from R&D milestones when those milestones are reached and non-milestone contracts and grants when earned. These projects are invoiced after expenses are incurred. Any projects or grants funded in advance are deferred until earned.

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, 2020 and 2019, there were $1,606,997 and $125,000 unearned advanced revenues, respectively.

Disaggregation of Revenue

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

	Exchange Transactions	**Non-Exchange Transactions**	**Total**
Net product sales	**$ 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**

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

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

The following tables disaggregates total revenues for the period ending December 31, 2019:

	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	$ 28,844,997	$ -	$ 28,844,997
R&D revenue	3,321,031	704,507	4,025,538
Government grant income	-	654,744	654,744
License and royalty revenue	938,753	-	938,753
	$ 33,104,781	$ 1,359,251	$ 34,464,032

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

The following tables disaggregates total revenues for the period ending December 31, 2019 by region:

	Total
Africa	$ 7,564,360
Asia	888,800
Europe & Middle East	6,498,995
Latin America	11,808,768
United States	7,703,109
	$ 34,464,032

NOTE 8 — INCOME TAXES:

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

	Year Ending December 31,	
	2020	2019
United States operations	$ (23,384,133)	$ (12,504,780)
International operations	(2,593,989)	(1,670,641)
(Loss) before taxes	$ (25,978,122)	$ (14,175,421)

The (benefit from) provision for income taxes for the years ended December 31, 2020 and 2019 is comprised of the following:

	Year Ending December 31,	
	2020	2019
Current		
Federal	$ (66,906)	$ -
State	6,497	9,790
Foreign	-	3,633
Total current (benefit) provision	(60,409)	13,423
Deferred		
Federal	-	-
State	-	-
Foreign	(396,385)	(513,715)
Total deferred (benefit) provision	(396,385)	(513,715)
Total (benefit) provision	$ (456,794)	$ (500,292)

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

	Year Ending December 31,	
	2020	2019
Federal income tax at statutory rates	**21.00%**	21.00%
State income taxes, net of federal benefit	**(0.02)%**	(0.05)%
Nondeductible expenses	**(0.19)%**	(1.00)%
Foreign rate differential	**0.47%**	0.45%
Change in valuation allowance	**(19.37)%**	(17.51)%
Other	**(0.13)%**	0.64%
Income tax benefit	**1.76%**	3.53%

In January 2018, the FASB released guidance on the accounting for tax on the global intangible low-taxed income ("GILTI") provisions of the Tax Act. The GILTI provisions impose a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations. The guidance allows companies to make an accounting policy election to either (1) account for GILTI as a component of tax expense in the period in which they are subject to the rules (the period cost method), or (ii) account for GILTI in the Company's measurement of deferred taxes (the deferred method). After completing the analysis of the GILTI provisions, the Company elected to account for GILTI using the period cost method.

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 2020 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, 2020, the Company has post-change net operating loss carry-forwards of approximately $27,001,828 which expire between 2021 and 2037 and $35,840,768 which do not expire. In addition, the Company has research and development tax credit carryforwards of approximately $1,696,870 for the year ended December 31, 2020, which expire between 2021 and 2036.

The Company has state net operating loss carryforwards of approximately $3,511,090 which generally expire between 2035 and 2039. The Company has foreign net operating loss carryforwards of approximately $5,598,852 which generally expire between 2025 and 2026.

	2020	2019
Inventory reserves	**$ 461,709**	$ 196,193
Accrued expenses	**130,291**	105,323
Net operating loss carry-forwards	**14,844,798**	10,079,317
Research and development credit	**1,696,870**	1,679,495
Stock-based compensation	**398,900**	581,053
	602,187	-
Lease obligations	**1,583,814**	1,646,584
Depreciation	**-**	44,993
Total deferred tax assets	**19,718,569**	14,332,958
Right-of-use assets	**(1,340,914)**	(1,538,129)
Depreciation	**(254,366)**	-
Intangibles	**(821,363)**	(921,807)
Total deferred tax liabilities	**(2,416,643)**	(2,459,936)
Net deferred tax assets before valuation allowance	**17,301,926**	11,873,022
Less valuation allowances	**(17,371,867)**	(12,339,348)
Net noncurrent deferred tax liabilities	**$ (69,941)**	$ (466,326)

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, 2020 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, 2020, the Company does not have a liability for uncertain tax positions.

The Company files Federal and state income tax returns, Chembio Germany files in Germany, Chembio Brazil files in Brazil and Chembio Malaysia files in Malaysia and has been on tax holiday which expired on December 31, 2018. With few exceptions, tax years for fiscal 2017 through 2020 are open and potentially subject to examination by federal, state and foreign taxing authorities.

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 9 — STOCKHOLDERS' EQUITY:

(a) ***Common Stock***

During 2020, options to purchase 36,000 shares of the Company's common stock were exercised for 5,528 shares of common stock, net of tax withholdings, at an exercise prices of $6.30. During 2019, options to purchase 54,343 shares of the Company's common stock were exercised for 31,543 shares of common stock at an exercise prices ranging from $3.48 to $4.35 in each case by surrendering options or shares of common stock already owned.

In April 2020, the Company closed on an underwritten public offering of 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.

(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.

(d) ***Warrants***

As of December 31, 2020, the Company has no warrants outstanding to purchase shares of common stock as further discussed in Note 14 – Warrants.

NOTE 10 — EQUITY INCENTIVE PLANS:

Effective June 3, 2008, the Company's stockholders voted to approve the 2008 Stock Incentive Plan ("SIP"), with 625,000 shares of common stock available to be issued. At the Annual Stockholder Meeting on September 22, 2011 the Company's stockholders voted to approve an increase to the shares of common stock issuable under the SIP by 125,000 to 750,000. Under the terms of the SIP, which expired during 2018, the Board of Directors 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 ("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, 2020, there were 694,000 options expired, forfeited or exercised, and at December 31, 2020, 56,000 options were outstanding. No Equity Award Units were available to be issued under the SIP.

Effective June 19, 2014, the Company's stockholders voted to approve the 2014 Stock Incentive Plan ("SIP14"), with 800,000 shares of common stock available to be issued. Under the terms of the SIP14, the Board or its Compensation Committee has the discretion to select the persons to whom awards are to be granted. Awards can be in the form of Equity Award Units. The awards become vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through December 31, 2020, there were there were 514,782 options expired, forfeited or exercised. At December 31, 2020, 264,157 options were outstanding and 0 Equity Award Units are available to be issued under the SIP14. Following the approval of the 2019 Plan (defined below), any Equity Award Units outstanding under the SIP14 remain subject to and be paid under the SIP14, and any shares subject to outstanding awards under the SIP14 that expire, terminate, or are surrendered or forfeited for any reason without issuance of shares automatically become available for issuance under the 2019 Plan.

Effective June 18, 2019, the Company's stockholders voted to approve the 2019 Omnibus Incentive Plan ("2019 Plan"), with 2,400,000 shares of common stock available to be issued. In addition, shares of Common Stock underlying any outstanding award granted under the 2019 Plan that, following the effective date of the 2019 Plan, expires, or is 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, or other stock-based award's under the 2019 Plan (collectively, "2019 Equity Units"). The awards become vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through December 31, 2020, 489,294 2019 Equity Units have been exercised or forfeited. At December 31, 2020, 1,024,563 2019 Equity Units were outstanding, and 1,506,226 2019 Equity Units were available to be awarded under the 2019 Plan.

The Company's results for the years ended December 31, 2020 and 2019 include stock-based compensation expense totaling $1,098,698 and $1,655,900, respectively. Such amounts have been included in the Consolidated Statements of Operations within cost of product sales ($6,300 and $10,806, respectively), research and development ($386,016 and $228,597, respectively) and selling, general and administrative expenses ($706,382 and $1,416,497, respectively).

Stock option compensation expense in the years ended December 31, 2020 and 2019 represents the estimated fair value of options outstanding, which is being amortized on a straight-line basis over the requisite vesting period of the entire award. The stock compensation expense were $480,779 and $351,556 in December 31, 2020 and 2019, respectively.

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. Stock-based compensation expense for stock options is calculated using the Black-Scholes valuation model. Stock based compensation is reduced for actual forfeitures in the period in which the forfeiture occurs and generally recognized on a straight-line basis over the service period of the grant. During the year ended December 31, 2020 and 2019, 486,488 and 0 shares of restricted stock were forfeited, respectively. During the year ended December 31, 2020 and 2019, 123,127 and 0 options were forfeited, respectively.

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

	2020	2019
Expected term (in years)	6.29	n/a
Expected volatility	46.21%	n/a
Expected dividend yield	0	n/a
Risk-free interest rate	1.30%	n/a

The following table provides stock option activity for the years ended December 31, 2020 and 2019:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2019	642,625	$ 5.79	2.57 years	$ 285,925
Granted	726,280	$ 2.59		-
Exercised	36,000	$ 6.30		95,976
Forfeited/expired/cancelled	358,127	$ 2.44		-
Outstanding at December 31, 2020	**974,778**	**$ 4.12**	**5.19 years**	**$ 1,520,910**
Exercisable at December 31, 2020	**257,211**	**$ 7.42**	**2.87 years**	**$ -**

The following table summarizes information about stock options outstanding at December 31, 2020:

	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	636,364	6.21	$ 2.36	$ 1,520,910	-	$ -	$ -
2.8 to 4.59999	-	-	-	-	-	-	-
4.6 to 6.39999	83,664	4.25	5.53	-	39,961	5.53	-
6.4 to 8.19999	207,875	3.05	7.31	-	189,125	7.22	-
8.2 to 12	46,875	2.60	11.45	-	28,125	11.45	-
Total	974,778	5.19	$ 4.12	$ 1,520,910	257,211	$ 7.42	$ -

As of December 31, 2020, there was $736,339 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 2.11 years. The total fair value of shares vested during the year ended December 31, 2020, was $326,630.

The following table summarizes information about restricted stock and restricted stock units outstanding as of December 31, 2020:

	Number of Shares & Units	Weighted Average Grant Date Fair Value
Unvested at December 31, 2019	545,986	$ 7.47
Granted	656,759	2.75
Vested	112,726	5.63
Forfeited/expired/cancelled	486,488	6.43
Unvested at December 31, 2020	603,531	3.08

As of December 31, 2020, there was $1,215,441 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 1.8 years. Stock based compensation cost related to restricted stock and restricted stock units recognized during the years ended December 31, 2020 and 2019 was $617,919 and $1,394,814, respectively.

NOTE 11 — GEOGRAPHIC INFORMATION AND ECONOMIC DEPENDENCY:

The Company produces only one group of similar products known collectively as “rapid medical tests,” and it operates in a single operating segment. Product revenue by geographic area are as follows:

	Year Ending December 31,	
	2020	2019
Africa	**$ 4,890,370**	$ 7,564,360
Asia	**824,488**	888,800
Europe & Middle East	**5,274,927**	3,781,761
Latin America	**9,841,772**	11,808,767
United States	**3,935,592**	4,801,309
	$ 24,767,149	$ 28,844,997

Long-lived assets by geographic area are as follows:

	2020	2019
Asia	**$ 326,267**	$ 393,299
Europe & Middle East	**147,692**	165,029
Latin America	**14,719**	60,527
United States	**8,199,725**	5,314,715
	$ 8,688,403	$ 5,933,569

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 $843,292 per year, and they expire in December 2021 and December 2022. The following table is a schedule of future minimum salary commitments:

2021	$843,292
2022	460,000
2023	-

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 $87,377 and $93,892 for the years ended December 31, 2020 and 2019, 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, 2020	Year Ended December 31, 2019
Operating lease expense	**$ 1,669,105**	$ 1,655,573
Finance lease cost		
Amortization of right-of-use assets	**$ 58,414**	$ 23,372
Interest on lease liabilities	**19,986**	7,892
Total finance lease expense	**$ 78,400**	$ 31,264

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

	Year Ended December 31, 2020	Year Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	**$ 1,139,944**	$ 632,952
Operating cash flows for finance leases	**19,987**	7,892
Financing cash flows for finance leases	**51,166**	19,875
Right-of-use assets obtained in exchange for lease obligations:		7,892
Operating leases	**$ -**	$ 7,030,744
Finance leases	**69,528**	210,350

Supplemental balance sheet information related to leases was as follows:

	December 31, 2020	December 31, 2019
Finance Leases		
Finance lease right of use asset	**$ 315,154**	$ 233,722
Accumulated depreciation	**(82,020)**	(23,372)
Finance lease right of use asset, net	**$ 233,134**	$ 210,350
Current portion of finance lease liability	**58,877**	41,894
Finance lease liability	**185,239**	171,953
Total finance lease liabilities	**$ 244,116**	$ 213,847
Weighted Average Remaining Lease Term		
Operating leases	**9.0** years	9.3 years
Finance leases	**3.7** years	4.8 years
Weighted Average Discount Rate		
Operating leases	8.58%	8.67%
Finance leases	8.18%	7.00%

During 2019, the Company executed an operating sublease related to its former Holbrook, New York facility. The sublease ran conterminously with the base lease in Holbrook, for which the Company was primarily responsible until the end of the lease term in April 2020.

Maturities of lease liabilities as of December 31, were as follows.

	December 31, 2020		December 31, 2019	
	Operating Leases	Finance Leases	Operating Leases	Finance Leases
2021	**$ 1,209,787**	**$ 76,904**	$ 1,205,161	$ 55,536
2022	**1,057,757**	**76,904**	1,209,787	55,536
2023	**1,026,272**	**76,904**	1,057,757	55,536
2024	**1,018,875**	**49,136**	1,026,272	55,536
2025	**1,049,442**	**5,755**	1,018,875	27,767
Thereafter	**4,724,445**	-	5,773,887	-
Total lease payments	**$ 10,086,578**	**$ 285,603**	$ 11,291,739	$ 249,911
Less: imputed interest	**(3,116,975)**	**(41,487)**	(3,753,842)	(36,064)
Total	**$ 6,969,603**	**$ 244,116**	$ 7,537,897	$ 213,847

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, 2020		December 31, 2019		December 31, 2020	December 31, 2019
	Net Sales	% of Net Sales	Net Sales	% of Net Sales		
Customer 1	$ 6,224,737	25.1%	$ 11,263,573	39%	$ 522,218	$ 941,962
Customer 2	2,955,312	11.9%	5,782,543	20%	1,987	16,033
Customer 3	2,956,945	11.9%	*	*	*	*

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, 2020		December 31, 2019		December 31, 2020	December 31, 2019
	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	$ 2,222,182	13.0%	*	*	$ 222,588	*

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:*

Employee Litigation

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

Stockholder Litigation

Putative Stockholder Securities Class Action Litigation

As we reported previously, four purported securities class action lawsuits were filed by alleged stockholders of our Company in the United States District Court for the Eastern District of New York:

- Sergey Chernysh v. Chembio Diagnostics, Inc., Richard L. Eberly, and Gail S. Page, filed on June 18, 2020, which we refer to as the Chernysh case;
- James Gowen v. Chembio Diagnostics, Inc., Richard L. Eberly, and Gail S. Page, filed on June 22, 2020, which we refer to as the Gowen case;
- Anthony Bailey v. Chembio Diagnostics, Inc. Richard J. Eberly, Gail S. Page, and Neil A. Goldman, filed on July 3, 2020, which we refer to as the Bailey case; 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, which we refer to as the Special Situations Funds case.

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

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

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

The CAC purports to assert five counts under the Securities Act and the Exchange Act of 1934. Counts I through III are brought under the Securities Act, allegedly on behalf of a purported class consisting of all persons who purchased Chembio common stock directly in or traceable to the Company's May 2020 offering pursuant to the Company's Form S-3 Registration Statement and its Prospectus and Prospectus Supplement dated May 7, 2020 (the "Securities Act Class"). Count I purports to allege a claim for violation of Section 11 of the Securities Act against all defendants other than Messrs. Eberly and Esfandiari. Count II purports to allege a claim for violation of Section 12 of the Securities Act against all defendants other than Messrs. Eberly and Esfandiari. Count III purports to allege a claim under Section 15 of the Securities Act against Ms. Davis, Dr. Polan, Dr. Potthoff, Ms. Page, and Mr. Goldman.

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

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

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

On March 5, 2021, the Court entered an Order in which the Court advised the parties that it had determined that a pre-motion conference was not necessary and established a briefing schedule on the defendants' anticipated motions to dismiss. Pursuant to that schedule, defendants' motions and supporting papers are due to be filed no later than March 19, 2021, the Lead Plaintiffs' opposition papers are due to be filed no later than April 2, 2021, and the defendants' reply papers are due to be filed no later than April 9, 2021. We have agreed with Plaintiffs' counsel to a modification of the schedule such that defendants' motions and supporting papers would be due to be filed no later than March 26, 2021, the Lead Plaintiffs' opposition papers would be due to be filed no later than April 16, 2021, and the defendants' reply papers would be due to be filed no later than April 30, 2021. This schedule modification is subject to the Court's approval.

Putative Stockholder Derivative Litigation

On September 11, 2020, a putative stockholder derivative action was filed purportedly on our Company's behalf in the United States District Court for the Eastern District of New York captioned Karen Wong, derivatively on behalf of Chembio Diagnostics, Inc., Plaintiff v. Richard L. Eberly, Gail S. Page, Neil A. Goldman, Javan Esfandiari, Katherine L. Davis, Mary Lake Polan, and John G. Potthoff, Defendants, and Chembio Diagnostics, Inc., Nominal Defendant, which we refer to as the Wong complaint. The Wong complaint purports to assert a claim for violation of Section 14(a) of the Exchange Act and Rule 14a-9 thereunder based on ostensibly false and misleading statements and omissions concerning our rapid COVID-19 antibody test in the proxy statement disseminated in advance of our Annual Meeting of Stockholders held on July 28, 2020. The Wong complaint also asserts claims against the individual defendants for purported breaches of fiduciary duties owed to our Company, 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 our Company, an award of damages to our Company, 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 our Company's corporate governance and internal procedures regarding compliance with laws. Pursuant to a stipulation by which the individual defendants in the Wong action 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 Wong action pending final disposition of motions to dismiss the pending putative class action litigation, subject to certain conditions. The Court entered an order granting the requested stay on November 3, 2020.

Commercial Litigation

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

f) *Governmental Regulation:*

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

NOTE 13 — LONG-TERM DEBT:

In September 2017, the Company entered into an agreement with an equipment vendor to purchase automated assembly equipment for approximately $660,000. The terms call for payments of 30% down, 60% at time of factory acceptance testing and 10% after delivery. The vendor agreed to lend the Company 15%, 40%, and 10%, of each originally scheduled payment, respectively. The Company paid interest at an annual rate of 12% until delivery. Beginning in September 2018, the Company began making monthly payments of principal and interest of approximately $20,150, at an annual rate of 12% over a twenty-four month period. The remaining balance was entirely short-term as of December 31, 2019. This balance was fully paid during 2020.

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, 2020 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, 2020, the loan balance, net of unamortized discounts and debt issuance costs, was $18.2 million, and Chembio was in compliance with its loan covenants.

NOTE 14 — WARRANTS:

In connection with entering into the Credit Agreement, on September 3, 2019, the Company issued to the Lender a seven-year warrant (the "Warrant") to purchase up to 550,000 shares of the Company's common stock at a per-share exercise price of $5.22. The Warrant was exercisable for cash or on a net, or "cashless," basis, and the exercise price of the Warrant was subject to price-based, weighted-average antidilution adjustments for one year after issuance.

The Warrant was evaluated by the Company and classified within stockholder's equity. Its fair value was estimated using a Black-Scholes option-pricing model using the assumptions below.

Stock price on issuance date	$	5.40
Strike Price	$	5.22
Risk-free interest rate		1.45%
Volatility		43.65%
Expected life		7 years

The fair value of the Warrant was determined to be approximately $1.4 million at $2.49 per share.

As of December 31, 2020, the Warrant was fully exercised.

NOTE 15 - GOODWILL AND INTANGIBLE ASSETS:

For the years ended December 31, 2020 and 2019, there was no impairment of goodwill and other intangible assets.

Following is a table that reflects changes in Goodwill:

Beginning balance January 1, 2020	$5,872,690
Changes in foreign currency exchange rate	91,054
Balance at December 31, 2020	$5,963,744

Intangible assets consist of the following at:

		December 31, 2020			December 31, 2019		
	Weighted Average Remaining Life	**Cost**	**Accumulated Amortization**	**Net Book Value**	Cost	Accumulated Amortization	Net Book Value
Intellectual property	5	$1,638,699	$472,190	$1,166,509	$1,418,681	$299,232	$1,119,449
Developed technology	5	2,102,526	594,186	1,508,340	1,922,682	266,550	1,656,132
Customer contracts/relationships	6	1,323,424	423,093	900,331	1,325,521	270,902	1,054,619
Trade names	7	115,318	44,512	70,806	114,946	30,794	84,152
		$5,179,967	$1,533,981	$3,645,986	$4,781,830	$867,478	$3,914,352

Amortization expense for the year ended December 31, 2020 and 2019 was $588,962 and $515,263, respectively, and is recorded within COGS, R&D and Selling, General and Administrative expenses. Amortization expense, subject to changes in currency exchange rates, is expected to be approximately $617,000 per year from 2021 through 2025, and total $561,000 million for all of the years thereafter.

NOTE 16 — SUBSEQUENT EVENTS:

Restructuring

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

Costs associated with the 2021 Plan are primarily related to Severance and Legal costs. Severance payouts are expected to be substantially completed by the end of the six months ending June 30, 2021. Under the 2021 Plan, the Company expects to incur pre-tax charges between approximately $0.1 million and $0.2 million.

Exhibit 4.2

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

We have one class of securities registered under Section 12 of the Securities Exchange Act of 1934 (the "*Exchange Act*"): common stock, $0.01 par value per share ("*Common Stock*").

Description of Common Stock

The following is a description of the material terms and provisions relating to Common Stock. Because it is a summary, the following description is not complete and is subject to and qualified in its entirety by reference to our Articles of Incorporation, as amended, our Amended and Restated Bylaws, and provisions of Nevada law which define the rights of our stockholders.

Holders of common stock are entitled to one vote for each share held by them of record on our books in all matters to be voted on by the stockholders.

Holders of common stock are entitled to receive dividends as may be legally declared from time to time by the board of directors, and, in the event of our liquidation, dissolution or winding up, to share ratably in all assets remaining after payment of liabilities and amounts owed with respect to any preferred stock or other senior securities. Declaration of dividends on common stock is subject to the discretion of the board of directors and will depend upon a number of factors, including our future earnings, capital requirements, financial condition, and/or restrictions, if any, imposed by debt instruments or senior securities. We have not declared dividends on common stock in the past and we currently anticipate that retained earnings, if any, in the future will be applied to our expansion and development rather than the payment of dividends.

Holders of common stock have no preemptive or subscription rights and are not subject to further calls or assessments. There are no redemption or sinking fund provisions applicable to common stock.

Under our corporate documents and Nevada law, the election of directors requires a plurality of the votes cast by holders of our outstanding common stock at the annual meeting while other fundamental corporate actions, such as mergers and other business combinations, or amendments of our Articles of Incorporation, require the approval of the holders of a majority of our outstanding common stock.

The number of shares of our authorized common stock may be increased and altered from time to time through an amendment to our Articles of Incorporation in the manner prescribed by Nevada law upon the approval of the holders of a majority of our outstanding common stock.

Nasdaq Capital Market

Our Common Stock is traded on The Nasdaq Capital Market under the symbol "CEMI."

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is Action Stock Transfer Corp.

Transactions with Interested Persons

Under Nevada law, a transaction with the Company (i) in which a Company director or officer has a direct or indirect interest, or (ii) involving another corporation, firm or association in which one or more of the Company's directors or officers are directors or officers of the corporation, firm or association or have a financial interest in the corporation firm or association, is not void or voidable solely because of the director's or officer's interest or common role in the transaction if any one of the following circumstances exists:

- the fact of the common directorship, office or financial interest is known to the board of directors or a committee of the board of directors and a majority of disinterested directors on the board of directors (or on the committee) authorized, approved or ratified the transaction;
- the fact of the common directorship, office or financial interest is known to the stockholders and disinterested stockholders holding a majority of the shares held by disinterested stockholders authorized, approved or ratified the transaction;
- the fact of the common directorship, office or financial interest is not known to the director or officer at the time the transaction is brought to the board of directors for action; or
- the transaction was fair to the Company at the time it is authorized or approved.

Control Share Acquisition Provisions

Nevada law precludes an acquirer of the shares of a Nevada corporation who crosses one of three ownership thresholds (20%, 33 1/3% or 50%) from obtaining voting rights with respect to those shares unless the disinterested holders of a majority of the shares of the Company held by disinterested stockholders vote to accord voting power to those shares. Nevada permits a corporation to opt out of the application of these control share acquisition provisions by so providing in the articles of incorporation or bylaws. The Company has opted out of the application of these control share acquisition provisions in our Amended and Restated Bylaws, as amended.

Combinations with Interested Stockholders

Under Nevada law, except under certain circumstances, a corporation is not permitted to engage in a business combination with any “interested stockholder” for a period of two years following the date such stockholder became an interested stockholder. An “interested stockholder” is a person or entity who owns 10% or more of the outstanding shares of voting stock. Nevada permits a corporation to opt out of the application of these business combination provisions by so providing in the articles of incorporation. Although we did not opt out of the application of these business combination provisions in it our Articles of Incorporation, as amended, the business combination provisions are not applicable to an interested stockholder if the transaction by which the person first became an interested stockholder is approved before the persons becomes an interest stockholder.

Exhibit 21.1

CHEMBIO DIAGNOSTICS, INC.
Subsidiaries of the Registrant

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

Exhibit 22.1

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. 333-227398) of Chembio Diagnostics, Inc.,

2. Registration Statement (Form S-3 No. 333- 215813) of Chembio Diagnostics, Inc.,

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

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

of our report dated March 11, 2021, 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, 2020.

/s/ Ernst & Young, LLP

Jericho, New York
March 11, 2021

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Chembio Diagnostics, Inc.
Hauppauge, New York

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-3 (No. 333-227398 and No. 333-215813) and Forms S-8 (No. 333-151785 and No. 333-203633) of Chembio Diagnostics, Inc. of our report dated March 13, 2020, relating to the consolidated financial statements of Chembio Diagnostics, Inc which appears in this Annual Report on Form 10-K.

/s/ BDO USA, LLP
Melville, NY
March 11, 2021

Exhibit 31.1

CERTIFICATION

I, Richard L. Eberly, certify that:

1. I have reviewed the Form 10-K of Chembio Diagnostics, Inc.;

2. Based on my knowledge, the 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 the report;

3. Based on my knowledge, the financial statements, and other financial information included in the 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 the 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 the 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 the report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by the report based on such evaluation; and

   (d) Disclosed in the 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 11, 2021

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

Exhibit 31.2

CERTIFICATION

I, Neil A. Goldman, certify that:

1. I have reviewed the Form 10-K of Chembio Diagnostics, Inc.;

2. Based on my knowledge, the 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 the report;

3. Based on my knowledge, the financial statements, and other financial information included in the 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 the 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 the 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 the report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by the report based on such evaluation; and

   (d) Disclosed in the 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 11, 2021

/s/ Neil A. Goldman
Neil A. Goldman
Executive Vice President and 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, 2020, each of the undersigned Richard L. Eberly, the Chief Executive Officer and President of the Company, and Neil A. Goldman, the Executive Vice President and 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) The Form 10-K for the year ended December 31, 2020 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-K for the year ended December 31, 2020 fairly presents, in all material respects, the financial condition and results of operations of Chembio Diagnostics, Inc. for the periods presented therein.

Dated: March 11, 2021 /s/ Richard L. Eberly
Richard L. Eberly
Chief Executive Officer and President

Dated: March 11, 2021 /s/ Neil A. Goldman
Neil A. Goldman
Executive Vice President and Chief Financial Officer