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, 2022
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.001-35569

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.)
3661 Horseblock Rd, Medford NY	11763
(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 check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

Large accelerated filer ☐
Non-accelerated filer ☒

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 checkmark whether the registrant has filed a report on and attestation to its 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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 second fiscal quarter, the aggregate market value of voting and non-voting common equity held by non-affiliates was $18,739,117.

As of March 24, 2023, the registrant had 36,725,858 shares of common stock outstanding.

Documents Incorporated By Reference

None.

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

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

FORWARD-LOOKING STATEMENTS AND STATISTICAL ESTIMATES

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

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

Forward-looking statements and statistical estimates inherently involve risks and uncertainties that could cause actual results to differ materially from those predicted or expressed in this report. These risks and uncertainties include those described in "Item 1A. Risk Factors" of Part I of this report. 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

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

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

- Enhanced sensitivity and specificity: This is achieved via the Company's proprietary approach to separating the sample path from the buffer path, together with patent and other proprietary strategies, which differ significantly from traditional lateral flow test.

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

- Objective results: For some diagnostic applications, the Company's easy-to-use, highly portable, battery-operated DPP Micro Reader optical analyzers can report accurate results in approximately 15 seconds, making it well-suited for decentralized testing where real-time results enable patients to be clinically assessed while they are still on site. Objective results produced by the DPP Micro Reader can reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many rapid tests.

The Company targets the market for rapid diagnostic test solutions for infectious diseases, which is driven by the high prevalence of infectious diseases globally, an increase in the geriatric population, growing demand for rapid test results, and advancements in multiplexing. The Company has a broad portfolio of infectious disease products, which prior to 2020 were focused principally on sexually transmitted disease and fever and tropical disease. In February 2020 the Company began the process to leverage the DPP technology platform to address the acute and escalating need for diagnostic testing. The Company is continuing to pursue or has pursued:

- a 510(k) clearance from the U.S. Food and Drug Administration, (the "FDA") for the DPP SARS-CoV-2 Antigen test system;
- an Emergency Use Authorization ("EUA") from the FDA for the DPP Respiratory Antigen Panel; and
- a Clinical Laboratory Improvement Amendment ("CLIA"), waiver from the FDA for the DPP HIV-Syphilis test system, which was received in February 2023.

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

Pending Merger with Biosynex SA

The Company entered into an Agreement and Plan of Merger (the "Merger Agreement"), dated as of January 31, 2023, with Biosynex SA, a French société anonyme ("Biosynex"), and Project Merci Merger Sub, Inc., a Nevada corporation and wholly-owned indirect subsidiary of Biosynex (the "Purchaser"). Pursuant to the Merger Agreement, on February 14, 2023, the Purchaser commenced a tender offer (the "Offer") to purchase all of the issued and outstanding shares of the Company's common stock, par value $0.01 per share (the "Shares"), for a purchase price of $0.45 per share, net to the seller in cash, without interest and subject to any required tax withholding. On March 15, 2023, Biosynex announced an extension of the Offer until 6:00 p.m., New York City time, on March 28, 2023. Subsequently, on March 29, 2023, Biosynex announced an extension of the Offer until 6:00 p.m., New York City time, on April 12, 2023.

If the conditions to the Offer are satisfied and the Offer closes, Purchaser would acquire all remaining Chembio shares by a merger of Purchaser with and into Chembio (the "Merger"), with Chembio surviving the Merger as a wholly-owned indirect subsidiary of Biosynex. At the effective time of the Merger (the "Effective Time"), each Share issued and outstanding immediately prior to the Effective Time (including shares paid to holders of vested Chembio restricted stock units) will be converted into the right to receive $0.45 per share. Stock options that are outstanding immediately prior to the Effective Time will automatically terminate for no consideration.

The Merger Agreement and the transactions contemplated thereby, including the Merger, were unanimously approved by the Company's Board of Directors. Completion of the Merger is subject to certain customary conditions as set forth in the Merger Agreement and the successful completion of the Offer. There can be no assurance that the Merger will be consummated on the terms described above or at all.

The foregoing description of the Merger Agreement and the transactions contemplated thereby, including the Offer, does not purport to be complete and is subject to, and qualified in its entirety by reference to, the full text of the Merger Agreement, which has been filed as Exhibit 2.1 to our Current Report on Form 8-K filed with the SEC on January 31, 2023.

Likely Default Under Credit Agreement

On September 3, 2019, we and certain of our subsidiaries, as guarantors, entered into the Credit Agreement and Guaranty (the "Credit Agreement") with Perceptive Credit Holdings II, LP (the "Lender"), under which we received a $20.0 million senior secured term loan that was drawn in full on September 4, 2019. The Credit Agreement is secured by a first priority lien on substantially all of our property and assets. The Credit Agreement contains financial covenants requiring that we (a) maintain aggregate unrestricted cash of not less than $3.0 million at all times, and (b) achieve specified minimum total revenue requirements for the twelve months preceding each quarter end.

The Credit Agreement has a September 3, 2023 maturity date, and we do not currently believe that replacement debt or equity financing arrangements are or will be available to us or, if available to us, will be on acceptable terms. We do not believe that we will be in compliance with the minimum revenue covenant in the Credit Agreement for the four fiscal quarters ended March 31, 2023. Our Lender has previously informed us that it will not agree to any restructuring of the Credit Agreement, and as a result we may be forced to pursue a bankruptcy or restructuring proceeding when the debt matures (or earlier if the lender accelerates following a breach of the minimum total revenue covenant) or pursue a transaction or financing arrangement that could be dilutive to stockholders.

Operating Results and Working Capital

Total revenues were $49.5 million, an increase of 3.6% from 2021, and net product sales were $47.1 million, an increase of 35.6% from 2021. Our loss from operations was $23.6 million in 2022 compared to $31.1 million in 2021. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Consolidated Results of Operations."

In 2022 we continued to invest in automating our test manufacturing processes, most of which are now based in the United States. Among other actions, we expanded our manufacturing capabilities by validating and implementing automated lines. Our transition from manual to automated assembly is intended to add capacity, reduce variable costs and improve product margins. In order to address challenging economic conditions and implement our business strategy, we continued to execute a program to reduce operating expenses and better align our costs with revenues by eliminating positions that were no longer aligned with our strategy. Our cash and cash equivalents totaled $18.2 million at December 31, 2022, compared to $28.8 million at December 31, 2021.

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

Going Concern Considerations

The Company continued to experience market, clinical trial and regulatory complications in seeking to develop and commercialize a portfolio of COVID-19 test systems during the continuing, but evolving, uncertainty resulting from COVID-19. For the year ended December 31, 2022, the Company also continued to incur significant operating losses and significant expenses in connection with pending legal matters (see Note 12 – Commitments, Contingencies, and Concentrations: Litigation).

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

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

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

The Company's execution of its plans continue to depend, however, on factors and uncertainties that are beyond the Company's control, or that may not be addressable on terms acceptable to the Company or at all. The Company considered in particular how:

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

The Company further considered how these factors and uncertainties could impact its ability over the next year to meet the obligations specified in the Credit Agreement with the Lender. Those obligations include covenants requiring: i) minimum cash balance of $3.0 million and ii) minimum total revenue amounts for the twelve months preceding each quarter end. The minimum total revenue requirements are $48.8 million for the twelve months ending March 31, 2023 and $50.1 million for the twelve months ending June 30, 2023. We do not believe that we will comply with the minimum total revenue covenant for the twelve months ended March 31, 2023. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. Furthermore, all remaining principal and interest is due on or before September 3, 2023. There can be no assurance that the Company would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, the Company would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. The Company's inability to raise additional capital on acceptable terms in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for its operations, could have a material adverse effect on its business, prospects, results of operations, liquidity and financial condition and would likely result in the Company being forced to seek protection under a bankruptcy proceeding.

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

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

Industry

The DPP technology platform targets diagnostic disease states; (1) where rapid diagnosis impacts patient treatment and outcomes; (2) that are underserved by current diagnostic products due to performance or availability; (3) that present opportunities regionally, demographically or clinically. The Company is focused on test solutions associated with infectious diseases: respiratory viruses, sexually transmitted diseases, 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 achieved meaningful market share globally and include, SureCheck, Stat Pak and DPP. The Company will focus on internally developed products and pursue external opportunities to license novel technologies and products with the intent of leveraging Chembio's growing commercial infrastructure.

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

Products

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

COVID-19 Antibody Test System

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

COVID-19 Antigen Test System

In mid-2020 we began to focus on the development of a COVID-19 antigen test system based on DPP technology. In January 2021 we announced the CE mark for the DPP SARS-CoV-2 Antigen test system, providing regulatory approval to register and market the test systems in the European Union and other geographies that accept the CE mark.

In December 2020 we received a $12.7 million grant from the Biomedical Advanced Research and Development Authority, part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, ("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.

During the year ended December 31, 2021 we performed the clinical trials and on December 2, 2021 we submitted the DPP SARS-CoV-2 Antigen test system to the FDA, as a de Novo submission. We are in interactive review process with the FDA.

COVID-19 and Influenza Respiratory Antigen Panel Test System

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

During 2021, we developed and conducted clinical trials of the DPP Respiratory Antigen Panel, a test system being designed to provide simultaneous, discrete and differential detection of Influenza A, Influenza B and SARS-CoV-2 antigens from a single patient respiratory specimen, such as a nasal swab. As of December 31, 2021, we have submitted a request for the EUA approval by the FDA which in 2022, we were notified by the FDA that our request for EUA was no longer under review. In addition, in 2021 we submitted a request for approval to ANVISA in Brazil and CE in Europe, which was approved in 2022.

As a result, we earned $12.5 million of the $12.7 million available under the BARDA Agreement, dated December 2, 2020, with the remaining $0.2 million having not been earned because it was contingent on our receiving an emergency use authorization for the DPP SARS-CoV-2 Antigen by December 2, 2021.

HIV-Syphilis Diagnostic Test Systems

On February 23, 2023 we received notice from the FDA that we were granted Clinical Laboratory Improvement Amendment, or "CLIA", waiver for the DPP HIV-Syphilis test system.

Core Products

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

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

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

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

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

- HIV has claimed more than 40 million lives, including 650,000 in 2021. Approximately 38.4 million people were living with HIV at the end of 2021, and 1.5 million were newly infected during 2021.

We are seeking to address the global concerns related to HIV and syphilis co-infection through the development of a novel, multiplex test for both HIV and syphilis. We have developed a DPP HIV-Syphilis multiplex test and received regulatory approvals in the United States and a number of international markets, including Brazil, Europe, Africa, Malaysia and Mexico. Approval of a CLIA waiver for the DPP HIV-Syphilis test in the United States was received in February 2023.

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

We have received 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"), 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	✓	✓	✓	✓	CLIA Waived
DPP Dengue IgM/IgG System	Self-funded	✓	✓	✓	✓	CE and ANVISA
DPP Dengue NS1 Antigen System	Self-funded	✓	✓	✓	✓	CE and ANVISA pending
DPP Chikungunya IgM/IgG System	Self-funded	✓	✓	✓	✓	CE and ANVISA
DPP Zika Chikungunya Dengue IgM/IgG System	Self-funded	✓	✓	✓	✓	CE and ANVISA
DPP Ebola Antigen System	CDC	✓	✓	✓	✓	FDA-EUA
DPP Fever Assay Asia	FIND	✓	✓	✓	✓	
DPP Fever Assay Africa	Paul Allen Foundation	✓	✓	✓		
DPP Fever Assay Malaysia	Self-funded	✓	✓	✓	✓	
DPP SARS CoV-2 Antigen	BARDA	✓	✓	✓	✓	CE and ANVISA
DPP Respiratory Antigen Panel	BARDA	✓	✓	✓	✓	CE and ANVISA
DPP COVID-19 IgM/IgG System	Self-funded	✓	✓	✓	✓	CE and ANVISA
DPP SARS CoV-2 IgM/IgG System	Self-funded	✓	✓	✓	✓	CE

Sales Channels

Our products are sold globally, both directly and through distributors, to hospitals and clinics, physician offices, clinical laboratories, public health organizations, government agencies and consumers. Historically we marketed and sold our products only into a handful of countries and regions. During 2022, we expanded our U.S.-based sales, customer service, and marketing team to focus on the COVID-19, HIV-Syphilis, and future DPP platform product opportunities. With sales growth as an underlying objective, we are focused on increasing sales in geographies that support higher average selling prices. From lead generation through technical inquiries, Chembio has the internal resources to support customers through the commercial process including marketing, sales, sales support, order entry and product support.

Automation of U.S. Manufacturing

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

DPP Technology & Development

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

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

Competition

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

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

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

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

Human Capital

As of December 31, 2022, we had 188 full-time equivalent employees, of whom 20 were in administration, 127 were in manufacturing, 23 were in research and development, and 18 were in sales and marketing and customer service. Of these employees, approximately 151 were located in the United States, 17 were located in Germany and 20 were located in Brazil. We have never had a work stoppage, and none of our employees are represented by a labor organization or subject to any collective bargaining arrangements. We consider our employee relations to be good.

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

Health, Wellness and Safety

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

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

Workforce Stability

Retaining and developing our employees is an important factor in our continued success and growth. We regularly evaluate our employee retention and turnover rates.

Compensation and Benefits

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

Governmental Regulation

Certain of our activities are subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug, and Cosmetic Act and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing, and export of diagnostic products. Our clinical laboratory customers are subject to oversight by Centers for Medicare and Medicaid Services, or CMS, pursuant to CLIA, as well as agencies in various states. Failure to comply with applicable requirements can lead to sanctions, including withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, civil money penalties, injunctions, and criminal prosecution.

FDA Approval/Clearance Requirements

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

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

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

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

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

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

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

Premarket Approval Pathway

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

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

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

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

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

510(k) Clearance Pathway

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

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

Clinical Laboratory Improvement Amendments of 1988

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

The CLIA program is designed to establish quality laboratory testing by ensuring the accuracy, reliability and timeliness of patient test results. Under CLIA, a laboratory is a facility that does laboratory testing on specimens derived from humans and used to provide information for the diagnosis, prevention or treatment of disease, or impairment of, or assessment of health. Under the CLIA program, unless waived, laboratories must be certified by the government, satisfy governmental quality and personnel standards, undergo proficiency testing, be subject to inspections and pay fees. We have received a CLIA waiver for all of our lateral flow rapid HIV tests that we market in the United States. Specifically, the CLIA waiver was granted by the FDA for HIV 1/2 STAT-PAK in November 2006, for SURE CHECK HIV 1/2 in October 2007, DPP HIV 1/2 in October 2014 and DPP HIV-Syphilis in February 2023.

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, 3) Risk –Benefit Analysis, 4) No Alternatives. A sponsor seeking an EUA can submit its formal request in the form of an EUA submission, which includes data for clinical studies, non-clinical laboratory studies to assess the safety and effectiveness of the product as well as the discussion of Risks and Benefits of the product.

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

Pervasive and Continuing FDA Regulation

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

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

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

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

Government Regulation of Medical Devices for Animal Subjects

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

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

Climate Change and Environmental Laws

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

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

Intellectual Property

Intellectual Property Strategy

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

DPP Intellectual Property

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

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

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

Trademarks

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

Trade Secrets and Know-How

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

Rapid Diagnostic Technology and Reagent Licenses

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

Available Information

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

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

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

Corporate Information

Our principal executive offices are located at 3661 Horseblock Rd, Medford, New York 11763. 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 the Pending Merger with Biosynex SA and Project Merci Merger Sub, Inc.

- our ability to complete the pending Merger within the time frame we anticipate or at all;
- our ability to complete the Merger is subject to certain closing conditions;
- the pendency of the Merger could adversely affect our business, financial results and operations;
- stockholder litigation could prevent or delay the consummation of the Offer and the Merger;
- our stockholders will not be able to participate in any financial upside to our business after the Merger;
- costs we have incurred, and will continue to incur as a result of the pending Merger;
- restrictions on our business activities as a result of the Merger Agreement; and
- limitations our ability to pursue alternative transactions.

Risks Related to Our Business and Our Industry

- our dependence on the success of our DPP platform for our near term success;
- our ability to implement the transitions contemplated by our Strategic Planning Process;
- uncertainty and competition in the diagnostic testing market, particularly with respect to COVID-19;
- our ability to initiate and complete clinical trials necessary to support EUA, 510(k), PMA or de novo submissions;
- the effects of existing or future stockholder litigation;
- our allocation of a substantial portion of our resources to the development and production of our DPP SARS-CoV-2 Antigen system;
- impacts on our suppliers and employees due to the COVID-19 pandemic;
- the ability of our products to compete with the new or existing products of our competitors;
- the acceptance of our DPP platform in the market;
- 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;
- our ability to collect our outstanding accounts receivable;
- the continued funding of, and ability to participate in, large testing program in the United States;
- developments in diagnostic testing guidelines or recommendations;
- the effect of an increase in demand for our products on our available resources or customer relationships if we are unable to meet such demand;
- our ability to obtain government grant awards; and
- the vulnerability of our business to cyber-attacks.

Risks Related to Our Products

- the COVID-19 Diagnostic Test Systems not gaining wide industry acceptance;
- the impact of COVID-19 mutations on the detection ability of our COVID-19 Diagnostic Test Systems;
- our ability to successfully introduce and market our products;
- timely receipt and implementation of additional customized manufacturing automation equipment;
- variability and unpredictability due to lengthy sales cycles for our products;
- our customers not adopting rapid point-of-care diagnostic testing;
- the concentration of our customers;
- our ability to successfully defend ourselves against product liability claims; and
- our products not performing properly.

Financial, Economic and Financing Risks

- our liquidity limitations, including that we have concluded there is a substantial doubt about our ability to continue as a going concern;
- failure to meet the minimum bid price for continued listing on The Nasdaq Capital Market and the effect on our ability to sell equity securities and the liquidity of our common stock;
- failure to maintain effective internal controls and our ability to accurately report our financial results or prevent fraud;

- future dilution as a result of future equity offerings, exercises of outstanding options and vesting of options and restricted and performance stock units;
- our incurrence of losses in recent years and uncertainty about our future profitability;
- the fluctuation of our financial results;
- our compliance with the terms of the Credit Agreement;
- our ability to generate sufficient cash to service our debt;
- our ability to utilize our net operating loss carryforwards and certain other tax attributes;
- increased interest expenses due to changes in LIBOR;
- the negative impact of changes in foreign currency exchange rates on our operating results; and
- basing our estimates or judgments related to critical accounting policies on assumptions that can change or prove to be incorrect.

Risks Related to Intellectual Property

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

Risks Related to Our Reliance on Third Parties

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

Risks Related to Regulations

- the impact of changes in CLIA, FDA, ANVISA, and other regulators, on our products;
- our ability to receive and maintain necessary regulatory approvals for our products;
- the impact of governmental export controls on our ability to compete in international markets;
- our ability to comply with FDA and other regulatory requirements;
- our ability to respond to changes in regulatory requirements;
- the effect of FDA regulation of laboratory-developed tests and genetic testing on demand for our products;
- disruptions at the FDA and other government agencies 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 and 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 dilution of our current stockholders due to future equity offerings;
- management’s broad discretion as to the use of proceeds of the offering; and
- the depression of the market price of our common stock due to sale by existing stockholders, executive officers or directors.

General Risk Factors

- our ability to successfully generate the expected benefits of strategic transactions, if any;
- costs associated with compliance with public company regulations; and
- terrorist attacks or natural disasters.

Risks Related to the Pending Merger with Biosynex SA and Project Merci Merger Sub, Inc.

We may not complete the pending Merger with Biosynex SA and Project Merci Merger Sub, Inc. within the time frame we anticipate or at all, which could have an adverse effect on our business, financial results and operations.

On January 31, 2023, we entered into a Merger Agreement with Biosynex and the Purchaser. The Merger Agreement provides for, among other things and on the terms and subject to the conditions set forth therein, a two-step transaction in which the first step is an Offer by the Purchaser to purchase all of the Company's issued and outstanding Shares for a purchase price $0.45 per share, net to the seller in cash, without interest and subject to any required tax withholding. The Merger Agreement provides that, among other things, as soon as practicable after the consummation of the Offer, and subject to the satisfaction or waiver of the conditions in the Merger Agreement, the Purchaser will be merged with and into the Company with the Company continuing as the surviving corporation and a wholly owned subsidiary of Biosynex.

If the Merger is not completed within the expected time frame or at all, we may be subject to a number of material risks in addition to the risks of continuing to operate our business. The price of our common stock may decline to the extent that current market prices of our common stock reflect a market assumption that the Merger will be completed on a timely basis. We could be required to pay Biosynex a termination fee of $850,000 if the Merger Agreement is terminated under specific circumstances as described in the Merger Agreement. The failure to complete the transaction also may result in negative publicity and negatively affect our relationship with our stockholders, employees, strategic partners, suppliers and lender. We may also be required to devote significant time and resources to litigation related to any failure to complete the Merger or related to any enforcement proceeding commenced against us to perform our obligations under the Merger Agreement.

Our ability to complete the Merger is subject to certain closing conditions that could adversely affect us or cause the Merger to be abandoned.

The Purchaser's obligation to accept the Shares tendered in the Offer is subject to certain closing conditions, including: (a) that the number of Shares validly tendered and not validly withdrawn equals a majority of the outstanding Shares; (b) the absence of any injunction or legal restraint that has the effect of prohibiting the consummation of the Offer or the Merger or making the Offer or the Merger illegal or prohibiting or making illegal the acquisition of or payment for Shares pursuant to the Offer or the consummation of the Merger; (c) that, since the date of the Merger Agreement, there shall not have occurred any event that would be reasonably likely to have a Company material adverse effect; (d) compliance by the Company with its obligations, covenants and agreements under the Merger Agreement; (e) the accuracy of representations and warranties made by us in the Merger Agreement; (f) the absence of any pending legal proceeding in which a governmental body is a party challenging the Offer or the Merger; and (g) other customary conditions. We cannot provide any assurance that the conditions to the consummation of the Merger will be satisfied or waived, or will not result in the abandonment or delay of the Merger.

The pendency of the Merger with Biosynex and the Purchaser could adversely affect our business, financial results and operations.

Our efforts to complete the transaction with Biosynex and the Purchaser could cause substantial disruptions in, and create uncertainty surrounding, our business, which may materially adversely affect our results of operation and our business. Uncertainty as to whether the Merger will be completed may affect our ability to retain and motivate employees. Employee retention may be particularly challenging while the Merger is pending because employees may experience uncertainty about their roles following consummation of the Merger. A substantial amount of our management's and employees' attention is being directed toward the completion of the Merger and thus is being diverted from our day-to-day operations. Uncertainty as to our future could adversely affect our business and our relationship with strategic partners, suppliers and our lender. Changes to or termination of existing business relationships could adversely affect our results of business, financial results and operations, as well as the market price of our common stock. The adverse effects of the pendency of the Merger could be exacerbated by any delays in completion of the Merger or termination of the Merger Agreement.

Stockholder litigation could prevent or delay the consummation of the Offer and the Merger or otherwise negatively impact our business, financial results and operations.

We may incur costs in connection with the defense or settlement of existing and future stockholder litigation and demands in connection with the Offer and the Merger. In connection with the Offer and Merger, as of March 24, 2023, two complaints had been filed by certain purported stockholders alleging that the Schedule 14D-9, which we filed with the SEC on February 14, 2023 in connection with the Offer (as amended and supplemented, the "Schedule 14D-9"), contains omissions and misrepresentations that render it materially deficient and misleading. Additionally, as of March 24, 2023, we had received thirteen stockholder demand letters, which similarly allege that the Schedule 14D-9 contains omissions and misrepresentations that render it materially deficient and misleading. Such litigation could adversely effect our ability to complete the Offer and the Merger and result in the Merger being delayed or enjoined by a court of competent jurisdiction, which could prevent the consummation of the Merger. We could also incur significant costs in connection with any such litigation and demands, including costs associated with the indemnification of our directors and officers and settlement payments.

If the Merger occurs, our stockholders will not be able to participate in any financial upside to our business after the Merger.

The nature of the Merger means that the stockholders will not participate in future earnings or growth of the Company upon completion of the Merger and will not benefit from any appreciation in value of the surviving corporation.

We have incurred, and will continue to incur, direct and indirect costs as a result of the pending Merger.

We have incurred, and will continue to incur, significant costs and expenses, including fees for professional services and other transaction costs, in connection with the pending Merger. We must pay substantially all of these costs and expenses whether or not the Merger is completed. There are a number of factors beyond our control that could affect the total amount or the timing of these costs and expenses.

While the Merger Agreement is in effect, we are subject to restrictions on our business activities.

The Merger Agreement includes restrictions on the conduct of our business prior to the completion of the Merger, generally requiring us to conduct our business and operations in the ordinary course and in accordance, in all material respects, with past practice and all applicable legal requirements, and otherwise in accordance with the Merger Agreement. Without limiting the generality of the foregoing, we are subject to a variety of specified restrictions. Unless we obtain Biosynex's prior written consent and except (i) as expressly permitted by the Merger Agreement, (ii) as required by applicable law, or (iii) as set forth in the disclosure schedule delivered by us to Biosynex, we may not, among other things and subject to certain exceptions, (a) pay dividends, (b) complete any stock splits or combinations, (c) issue additional shares of our common stock, except pursuant to the terms of our outstanding equity awards, (d) hire or terminate any employees, (e) amend our certificate of incorporation or bylaws, (f) form any subsidiaries, (g) enter into certain material contracts or amend or modify our current material contracts, (h) acquire or dispose of any rights or assets other than in the ordinary course of business or that are immaterial to our business, (i) make any pledge or mortgage of any material assets, (j) settle or release certain legal actions or proceedings, or (k) make or authorize any capital expenditure, except for such expenditures that fall under certain dollar thresholds. We may find that these and other contractual restrictions in the Merger Agreement delay or prevent us from responding, or limit our ability to respond, effectively to competitive pressures, industry developments and future business opportunities that may arise during such period, even if our management believes they may be advisable. If any of these effects were to occur, it could materially and adversely impact our operating results, financial position, cash flows and/or the price of our common stock.

The Merger Agreement limits our ability to pursue alternative transactions, which could deter a third party from proposing an alternative transaction.

The Merger Agreement contains provisions that, subject to certain exceptions, preclude us from soliciting alternative acquisition proposals. It is possible that these or other provisions in the Merger Agreement might discourage a potential competing acquirer that might have an interest in acquiring all or a significant part of the outstanding shares of our common stock from considering or proposing an acquisition or might result in a potential competing acquirer proposing to pay a lower per share price to acquire our common stock than it might otherwise have proposed to pay.

Risks Related to Our Business and Our Industry

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

We do not currently have an EUA from the FDA for any of the COVID-19 Diagnostic Test Systems or for our DPP Respiratory Panel. Market and regulatory requirements continue to change at a rapid pace. There can be no assurance that, if we make a submission of any future EUA, 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 the DPP SARS-CoV-2 Antigen test system or DPP Respiratory Panel in the United States.

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

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

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

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

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

The transitions contemplated by our Strategic Planning Process may not be successful.

Our going forward business strategy is based on our Strategic Planning Process and the transitions contemplated thereby (including our Global Competitiveness Program). The transitions may be disruptive to, or cause uncertainty in, our business and strategic direction. If we are unable to achieve the milestones set forth in the strategy, or the strategies implemented by our management team are not successful, our business could be materially harmed.

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

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

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

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

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

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

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

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

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

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

We have been allocating a substantial portion of our resources to the development and commercialization of DPP SARS-CoV-2 Antigen test system, and our long term business success could be negatively impacted by our diversion of resources from our legacy business of diagnostic testing for other infectious diseases.

In the first quarter of 2020 we began committing substantially all of our financial and personnel resources to the development, manufacturing and commercialization of the DPP SARS-CoV-2 Antigen test system. Because we do not currently have an EUA from the FDA for the DPP SARS-CoV-2 Antigen test system, starting in the first quarter of 2021 we began allocating an increased portion of our resources to our legacy products. Our earlier and continuing resource allocation to the DPP SARS-CoV-2 Antigen test system may have negatively impacted, and may continue to negatively impact, our legacy product portfolio, as we have spent limited funds and time on updating pre-existing products and regulatory approvals and on completing products that were in development prior to our strategic decision to focus on the DPP SARS-CoV-2 Antigen test system. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could dissipate; there is no guarantee that current or anticipated demand will continue, or if demand does continue, that we will be able to produce in quantities to meet the demand. We intend to continue to reestablish our legacy business, but there can be no assurance that we will be able to successfully recommence the development and commercialization of our legacy products and products under development.

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

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

- patent protection;
- scientific expertise;
- ability to develop and market products and processes;
- ability to obtain required regulatory approvals;
- access to adequate capital; and
- ability to attract and retain qualified personnel.

Numerous companies in the United States and internationally have introduced or announced their intention to introduce new products, services and technologies that could be used in substitution for the DPP SARS-CoV-2 Antigen test system. Many of those competitors are significantly larger, and have substantially greater financial, engineering and other resources, than we do. In addition, our competitors may have or may develop products or technologies that currently or in the future will enable them to produce competitive products with greater capabilities or at lower costs than ours. If we are unable to compete effectively, we may fail to meet our strategic objectives, and our business, financial condition and operating results could be harmed. In addition, the production of an efficacious vaccine or other treatment for a disease underlying one of our products may reduce the demand for relevant diagnostic products. The success or failure, or perceived success or failure, of other companies may adversely impact our ability to obtain any future funding, or to ultimately commercialize the DPP SARS-CoV-2 Antigen test system.

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

We may incur costs in connection with the defense or settlement of existing and any future stockholder litigation, including the securities class-action and stockholder derivative lawsuits that have been brought against us. See "Part I, Item 3. Legal Proceedings" above and the information set forth under "Note 12 – Commitments, Contingencies And Concentrations – Litigation" to the consolidated financial statements included in this Annual Report on Form 10-K for additional information regarding certain existing lawsuits. These lawsuits or other future litigation may adversely affect the ability of our technical and management personnel, and our directors, to perform their normal responsibilities. We could incur significant costs in connection with any such litigation, including costs associated with the indemnification of obligations to our directors, officers and other employees, as well as to third parties.

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

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

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

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

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

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

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

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

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

Although we own DPP patents, lateral flow technology is still a competitive platform to DPP, and lateral flow technology has a lower cost of manufacture than DPP products. Although the DPP platform has shown improved sensitivity as compared with conventional lateral flow platforms in a number of studies, several factors go into the development and performance attributes of products. Therefore the ability of our products to successfully compete will depend on several other factors, including our having a patented rapid test platform technology that differentiates DPP from lateral flow as well as from other diagnostic platform technologies. There can be no assurance that our DPP patents or our products incorporating those patents will not be challenged at some time in the future.

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

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

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

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

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

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

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

As new products incorporating new technologies enter the market, our products may become obsolete or a competitor's products may be more effective or more effectively marketed and sold. If our competitors' products take market share from our products through more effective marketing or competitive pricing, our revenues, margins and operating results could be adversely affected. In addition, our revenues and operating results could be negatively impacted if some of our customers internally develop or acquire their own sample collection devices and use those devices in place of our products in order to reduce costs.

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

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

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

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

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

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

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 United States and worldwide, the funding of which may be reduced or discontinued or otherwise be unavailable to us.

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

Developing testing guidelines could negatively affect sales of our products.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Products

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

Customers or the industry as a whole could adopt alternative technologies for testing, including molecular point of care testing, which could result in lower demand for our antigen test. Various advances in the treatment and monitoring of patients could cause lower demand for the COVID-19 Diagnostic Test Systems, including our revised DPP SARS-CoV-2 Antigen System or for antigen testing for COVID-19 as a whole.

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

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

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

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

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

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

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

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

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

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

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

Customer concentration creates risks for our business.

A significant portion of our revenues each year comes from a few large customers. Bio-Manguinhos constituted 38% of our total revenues in 2022 and 51% of our total revenues in 2021. We had another customer that accounted for 16% of our total revenues in 2022, and a third customer that accounted for 10% of our total revenue in 2021. To the extent that Bio-Manguinhos or any other large customer fails to meet its purchase commitments, changes its ordering patterns or business strategy, or otherwise reduces its purchases or stops purchasing our products, or if we experience difficulty in meeting the demand by these customers for our products, our revenues and results of operations could be adversely affected.

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

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

We may face product liability claims for injuries.

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

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

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

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

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

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

Financial, Economic and Financing Risks

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

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

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

As of December 31, 2022, we had a loan balance, net of unamortized discounts and debt issuance costs, of $18.6 million under the Credit Agreement. We may face further liquidity challenges if we are unable to meet our obligations set forth in the Credit Agreement, including a financial covenant requiring that we achieve specified minimum total revenue amounts measured as of the end of each quarter. A breach of the minimum total revenue covenant or any other covenant in the Credit Agreement would result in a default under the Credit Agreement, which could enable the Lender to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. We do not believe that we will comply with the minimum total revenue covenant for the twelve months ended March 31, 2023. We cannot assure you that, in such an event, we would have sufficient assets to pay amounts due under the Credit Agreement. If we are unable to pay any such amounts due under the Credit Agreement, we would likely be forced to pursue a reorganization proceeding under Chapter 11 of the U.S. Bankruptcy Code.

As a result, we will need to raise capital in one or more debt or equity offerings to fund our operations and obligations. There can be no assurance, however, that we will be successful in raising the necessary capital or that any such offering will be available to us on terms acceptable to us, or at all. If we are unable to raise additional capital that may be needed on terms in sufficient amounts or on terms acceptable to us, it could have a material adverse effect on our company. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to delay the implementation of our new strategic plan and otherwise significantly delay, scale back or discontinue our deliveries under our outstanding customer purchase orders or the development or commercialization of one or more of our products or one or more of our other research and development initiatives. The effects of COVID-19 have significantly disrupted world financial markets and negatively impacted U.S. market conditions, and they may reduce opportunities for us to seek out additional funding. A decline in the market price of our common stock, whether or not coupled with the suspension of trading of our common stock on The Nasdaq Capital Market, could make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate, or at all. Moreover, on April 5, 2022, we received notification from the Listing Qualifications Department of Nasdaq stating that the Company did not comply with the Bid Price Requirement. In accordance with Nasdaq listing rules, the Company was afforded 180 calendar days (until October 3, 2022) to regain compliance with the Bid Price Requirement. On October 4, 2022, the Company received written notice from Nasdaq stating that, although the Company had not regained compliance with the Bid Price Requirement by October 3, 2022, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company is eligible for an additional 180 calendar day period, or until April 3, 2023, to regain compliance with the Bid Price Requirement. To regain compliance, the closing bid price of the Company's common stock must meet or exceed $1.00 per share for a minimum of ten consecutive business days during this additional 180-day period, all as described in more detail in the Current Reports on Form 8-K we filed with the SEC on April 7, 2022 and October 4, 2022. We do not believe that we will regain compliance with the Bid Price Requirement by the April 3, 2023 deadline, and there can be no assurance that we will ever be able to do so. Given the current trading price of our common stock, it is likely that we will receive a delisting notification from Nasdaq. Our inability to regain compliance with the Bid Price Requirement would, and the existence of the pending deficiency letter could, materially impair our ability to raise capital.

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

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

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

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

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

On April 5, 2022, we received notification from the Listing Qualifications Department of The Nasdaq Stock Market, or Nasdaq, stating that the Company did not comply with the minimum $1.00 bid price requirement for continued listing set forth in Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement"). In accordance with Nasdaq listing rules, the Company was afforded 180 calendar days (until October 3, 2022) to regain compliance with the Bid Price Requirement. On October 4, 2022, the Company received written notice from Nasdaq stating that, although the Company had not regained compliance with the Bid Price Requirement by October 3, 2022, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company is eligible for an additional 180 calendar day period, or until April 3, 2023, to regain compliance with the Bid Price Requirement. To regain compliance, the closing bid price of the Company's common stock must meet or exceed $1.00 per share for a minimum of ten consecutive business days during this additional 180-day period, all as described in more detail in the Current Reports on Form 8-K filed with the SEC on April 7, 2022 and October 4, 2022. The closing price of our common stock was $0.39 on March 24, 2023. We do not believe that we will regain compliance with the Bid Price Requirement by the April 3, 2023 deadline, and there can be no assurance that we will ever be able to do so. Given the current trading price of our common stock, it is likely that we will receive a delisting notification from Nasdaq. Our inability to regain compliance with the Bid Price Requirement would, and the existence of the pending deficiency letter could, materially impair our ability to raise capital. Moreover, if we were unable to regain compliance with the Bid Price Requirement, our common stock would likely then trade only in the over-the-counter market and the market liquidity of our common stock could be adversely affected and its market price could decrease. If our common stock were to trade on the over-the-counter market, selling our common stock could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and we could face significant material adverse consequences, including: a limited availability of market quotations for our securities; reduced liquidity with respect to our securities; a determination that our shares are a "penny stock," which will require brokers trading in our securities to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our securities; a reduced amount of news and analyst coverage; and a decreased ability to issue additional securities or obtain additional financing in the future. These factors could result in lower prices and larger spreads in the bid and ask prices for our common stock and would substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

Failure to maintain effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls are not effective, we may not be able to accurately report our financial results or prevent fraud.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. In connection with the audit of our financial statements for the year ended December 31, 2022, our independent registered public accounting firm identified a material weakness. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal controls over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness that has been identified by our independent registered public accounting firm relates to the inventory costing process. While we intend to take steps to remediate the material weakness in our internal control over financial reporting by formalizing certain accounting policies and internal control documentation, we may not be successful in remediating such weaknesses in a timely manner, if at all, which may undermine our ability to provide accurate, timely and reliable reports on our financial and operating results. Furthermore, if we remediate our current material weakness but identify new material weaknesses in our internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may be negatively affected. As a result of such failures, we could also become subject to investigations by Nasdaq, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation, financial condition or divert financial and management resources from our business.

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

On July 19, 2021, we entered into the ATM Agreement, pursuant to which we may sell from time to time, at our option, up to an aggregate of $60,000,000 of shares of common stock through Craig-Hallum, as sales agent. As of the filing date of this report, we have issued and sold pursuant to the ATM Agreement a total of 16,175,519 shares of common stock at a volume-weighted average price of $2.81 per share for gross proceeds of $45.4 million and net proceeds, after giving effect to placement fees and other transaction costs, of $43.1 million. For additional information about the at-the-market offerings pursuant to the ATM Agreement, see "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations".

In order to raise additional capital, we may seek to offer pursuant to the ATM Agreement additional shares of common stock for up to $14.6 million in gross proceeds and we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock. There can be no assurance that we will be able to sell additional shares in at-the-market offerings made pursuant to the ATM Agreement, or in any other offering, at a price per share that is equal to or greater than the price per share paid by existing stockholders. Investors purchasing securities in other offerings in the future could have rights superior to existing stockholders.

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

As of the close of business on December 31, 2022, our market capitalization was approximately $1.15 million. Existing stockholders may experience significant dilution in connection with our issuance and sale of up to $14.6 million of additional shares of common stock pursuant to the ATM Agreement. In addition, as of December 31, 2022, 226,702 shares of common stock were reserved for future issuance under our 2019 Omnibus Incentive Plan, 3,657,163 shares were subject to outstanding options, and 1,588,387 shares were subject to outstanding restricted and performance stock units. Stockholders will incur dilution upon vesting of restricted and performance stock units, and they may incur dilution upon exercises of stock options.

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

We incurred an operating loss every year from 2014 through 2022. Under our operating plans, we have made, and plan to continue to make, significant investments in our production capacity, including in expanding facilities and automating manufacturing, and in our sales and marketing, regulatory approval, and research and development activities. Our ability to achieve profitability and generate cash flow in the future will depend on our ability to increase sales of our existing products and to successfully introduce new and enhanced products into the marketplace, all while controlling and managing our expenses consistent with our operating plan.

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

- We could reduce the level, or otherwise delay the timing, of the anticipated investments in our production capacity and other activities, which would likely curtail or delay the growth in our business contemplated by our operating plan and could impair or defer our ability to achieve profitability and generate cash flow. Moreover, if we were to further reduce the number of our personnel, there can be no assurance that we would be able, when desirable, to successfully rehire or rebuild our workforce.

- We could raise additional funds through public or private financings, strategic relationships, or other arrangements, to the extent funding would be available to us on acceptable terms or at all. If we succeed in raising additional funds through the issuance of equity or convertible securities, then the issuance could result in substantial dilution to existing stockholders. Furthermore, the holders of these new securities or debt may have rights, preferences and privileges senior to those of the holders of our common stock.

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

Our financial results may fluctuate.

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

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

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

On September 3, 2019, we and certain of our subsidiaries, as guarantors, entered into the Credit Agreement, under which we received a $20.0 million senior secured term loan credit facility that was drawn in full on September 4, 2019 and matures on September 3, 2023. The Credit Agreement is secured by a first priority, perfected lien on substantially all of our property and assets. See "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Likely Default Under Credit Agreement" and "—Liquidity and Capital Resources—Sources of Funds—Credit Agreement" below.

The Credit Agreement also contains financial covenants requiring that we (a) maintain aggregate unrestricted cash of not less than $3.0 million at all times, and (b) achieve specified minimum total revenue requirements for the twelve months preceding each quarter end. These minimum revenue requirements were developed for purposes of the Credit Agreement and do not reflect the internal estimates and plans used by our management and board of directors to establish operational goals for managing our business. Similarly, the minimum revenue requirements do not reflect our new strategic plan, and as we execute our new strategic plan it will likely be more difficult for us to comply with such minimum revenue requirements.

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

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

A breach of the minimum total revenue covenant or any other covenant in the Credit Agreement would result in a default under the Credit Agreement. The minimum total revenue requirements are $48.8 million for the twelve months ending March 31, 2023 and $50.1 million for the twelve months ending June 30, 2023. We do not believe that we will comply with the minimum total revenue covenant for the twelve months ended March 31, 2023. Upon not meeting the minimum total revenue requirement for the four quarters ending March 31, 2023, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. In such an event or upon all amounts owing under the Credit Agreement otherwise maturing on September 3, 2023, there can be no assurance that we would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, we would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. Our inability to raise additional capital on acceptable terms in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for our operations, could have a material adverse effect on our business, prospects, results of operations, liquidity and financial condition. If we are unable to repay amounts owed under the Credit Agreement or to raise such additional capital, we would likely be forced to pursue a reorganization proceeding under Chapter 11 of the U.S. Bankruptcy Code.

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

Our ability to make payments on and to refinance our debt, to fund planned capital expenditures, and to maintain sufficient working capital depends on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control. We cannot assure you that our business will generate sufficient cash flow from operations or from other sources in an amount sufficient to enable us to service our debt or to fund our other liquidity needs. Our operations used $12.7 million in cash in 2022. If our cash flow and capital resources are insufficient to allow us to make scheduled payments on our debt, we may need to seek additional capital or restructure or refinance all or a portion of our debt on or before the maturity thereof, any of which could have a material adverse effect on our business, financial condition or results of operations. We cannot assure you that, if needed, we would be able to refinance any of our debt on commercially reasonable terms or at all, or that the terms of that debt will allow any of the above alternative measures or that these measures would satisfy our scheduled debt service obligations. If we are unable to generate sufficient cash flow to repay or refinance our debt on favorable terms, it could significantly adversely affect our financial condition. Our ability to restructure or refinance our debt will depend on the condition of the capital markets and our financial condition. Any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. There can be no assurance that we will be able to obtain any financing when needed, and if we are unable to do so, we would likely be forced to pursue a reorganization proceeding under Chapter 11 of the U.S. Bankruptcy Code.

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

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

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

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

Loans under the Credit Agreement bear interest at a rate per annum equal to the sum of (a) the greater of the one-month London Interbank Offered Rate ("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 ("IBA"), the administrator of LIBOR, with the support of the United States Federal Reserve and the United Kingdom's Financial Conduct Authority, announced plans to consult on ceasing publication of USD LIBOR on December 31, 2021 for only the one week and two month USD LIBOR tenors, and on June 30, 2023 for all other USD LIBOR tenors. While this announcement extended the transition period to June 2023, the United States Federal Reserve concurrently issued a statement advising banks to stop new USD LIBOR issuances by the end of 2021. In light of these recent announcements, the future of LIBOR at this time is uncertain and any changes in the methods by which LIBOR is determined or regulatory activity related to LIBOR's phaseout could cause LIBOR to perform differently than in the past or cease to exist.

In response to concerns regarding the future of LIBOR, the Board of Governors of the Federal Reserve System and the Federal Reserve Bank of New York convened the Alternative Reference Rates Committee ("ARRC"), to identify alternatives to LIBOR. The ARRC has recommended benchmark replacement procedures to assist issuers in continued capital market entry while safeguarding against LIBOR's discontinuation. The initial steps in the ARRC's recommended provision reference variations of the Secured Overnight Financing Rate ("SOFR"). It is not possible to predict the effect of these changes, other reforms or the establishment of alternative reference rates in the United States or elsewhere.

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

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

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

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

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

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

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

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

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

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States and our discussion and analysis of financial condition and results of operations is based on such statements. The preparation of financial statements requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We continuously evaluate significant estimates used in preparing our financial statements, including those related: to (1) revenue recognition, including uncertainties related to variable consideration, milestones and bill and hold arrangements; (2) stock based compensation; (3) allowance for uncollectible accounts receivable; (4) inventory reserves and obsolescence; (5) customer sales returns and allowances; (6) contingencies; (7) income taxes; (8) goodwill and intangibles; (9) business acquisition; (10) research and development costs; (11) insurance receivable; and (12) litigation reserve.

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.

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Reliance on Third Parties

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

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

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

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

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

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

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

Relying on distributors or third parties to market and sell our products could negatively impact our business for various reasons, including: (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 increase our risk and liability.

We are currently receiving funding from the U.S. government related to the DPP SARS-CoV-2 Antigen System, the DPP Respiratory Antigen Panel and DPP Zika, and our growth strategy may target sales to U.S. government entities. As a result of our U.S. government funding and potential product sales to the U.S. government, we must comply with laws and regulations relating to the award, administration and performance of U.S. government contracts. U.S. government contracts typically contain a number of extraordinary provisions that would not typically be found in commercial contracts and which may create a disadvantage and additional risks to us as compared to competitors that do not rely on government contracts. As a U.S. government contractor, we are subject to increased risks of investigation, criminal prosecution and other legal actions and liabilities to which purely private sector companies are not. The results of any such actions could adversely impact our business and have an adverse effect on our consolidated financial performance.

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

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

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

Risks Related to Regulations

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

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

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

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

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

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

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

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

Changes or developments in government regulations, policies or interpretations could increase our costs and could require us to undergo additional trials or procedures, or could make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all. For example, on June 16, 2020, the FDA revoked the EUA it had granted for the DPP COVID-19 IgM/IgG System based in part on performance criteria identified after the EUA was granted on April 14, 2020. We do not currently have an EUA from the FDA for any of the COVID-19 Diagnostic Test Systems. Moreover, FDA regulations, policies and procedures with respect to COVID-19 tests may be significantly impacted by the availability of vaccines for COVID-19 and changes in the FDA's prioritization guidance. Similarly, the regulatory pathway to 510(k) clearance by the FDA for COVID-19 tests is unclear in light of limited FDA feedback resulting in part from the FDA's constrained resources.

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

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

Regulations of the FDA and other federal, state and foreign regulatory agencies have significant effects on many aspects of our operations and the operations of our suppliers and distributors, including packaging, labeling, manufacturing, adverse event reporting, recalls, distribution, storage, advertising, promotion and record keeping. We are subject to routine inspection by the FDA and other agencies to determine compliance with FDA regulatory requirements, including Quality System Regulations ("QSRs"), in the United States and other applicable regulations worldwide, including International Organization for Standardization ("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 initially received a "not approvable" letter from the FDA with respect to our premarket approval submission on our DPP HIV Syphilis multiplex test for commercial use in the United States, in June 2020 we received notice from the FDA that the EUA for the DPP COVID-19 IgM/IgG System had been revoked, and in January 2021 we received notice from the FDA that it was declining to review the DPP SARS CoV 2 Antigen System based on its updated prioritization guidance, under which review of the system was not a priority. The ability of our suppliers to supply critical components or materials and of our distributors to sell our products could also be adversely affected if their operations are determined to be out of compliance. Such actions by the FDA and other regulatory bodies could adversely affect our revenues, costs and results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

There have been several proposed changes in the United States at the federal and state level for comprehensive reforms regarding the payment for, the availability of and reimbursement for healthcare services. These proposals have ranged from fundamentally changing federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under government-funded programs, to minor modifications to existing programs.

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 affect our financial condition and results of operations.

The E.U. In-Vitro Diagnostic Regulation entered into force, which repeals and replaces the Council Directive 98/79/EC, or E.U. In-Vitro Diagnostic Directive. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable (i.e., without the need for adoption of E.U. member state laws implementing them) in all E.U. member states and are intended to eliminate current differences in the regulation of medical devices among E.U. member states. Devices lawfully placed on the market pursuant to the E.U. In-Vitro Diagnostic Directive prior to May 26, 2022 may generally continue to be made available on the market or put into service until May 26, 2027, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the E.U. In-Vitro Diagnostic Regulation with regard to registration of economic operators and of devices, post-market surveillance, market surveillance and vigilance requirements.

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

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

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

We believe that we are not a covered entity nor a business associate of a covered entity and are not responsible for complying with the Health Insurance Portability and Accountability Act of 1996 ("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 E.U. and U.K. data protection requirements could increase our costs.

The E.U. adopted a comprehensive overhaul of its data protection regime from the prior national legislative approach to a single European Economic Area Privacy Regulation called the General Data Protection Regulation (the "GDPR"), which came into effect on May 25, 2018. The E.U. data protection regime extends the scope of the E.U. data protection law to all foreign companies processing data of E.U. residents. It imposes a strict data protection compliance regime with severe penalties of up to the greater of 4% of worldwide turnover and €20 million and includes new rights such as the "portability" of personal data. Although the GDPR applies across the E.U. without a need for local implementing legislation, as had been the case under the prior data protection regime, local data protection authorities have the ability to interpret the GDPR, which has the potential to create inconsistencies on a country-by-country basis. We have evaluated these new requirements and have implemented a plan to ensure compliance. Complying with the enhanced obligations imposed by the GDPR may result in significant costs to our business and require us to amend certain of our business practices. Further, we have no assurances that violations will not occur, particularly given the complexity of the GDPR, as well as the uncertainties that accompany new, comprehensive legislation. Further, from January 1, 2021, we have to comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the E.U. in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which may expose us to further compliance risk. The European Commission has adopted an adequacy decision in favor of the U.K., enabling data transfers from E.U. member states to the U.K. without additional safeguards. However, the U.K. adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/extends that decision.

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

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

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

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

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

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

There are several of factors that could adversely affect the performance of our business and/or cause us to incur substantially increased costs because of our international presence and sales, including: (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 may have limited liquidity, and investors may not be able to sell as much common stock as they want at prevailing market prices or at all.

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

Decreased trading volume in our stock would make it more difficult for investors to sell their shares in the public market at any given time at prevailing prices. Although there is no affiliation between our management and our larger stockholders, they could exercise significant control over our company if they voted their shares in a similar manner.

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

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

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

We have sold 16,175,519 shares of common stock, for gross proceeds of $45.4 million and net proceeds, after giving effect to commissions and other transaction costs, of $43.1 million under the At the Market Offering Agreement, entered into July 19, 2021, pursuant to which we may sell from time to time, at our option, up to an aggregate of $60.0 million of shares of common stock through Craig-Hallum Capital Group LLC, as sales agent (the "ATM Agreement"). These sales include sales of common stock for gross proceeds of $4.6 million and net proceeds of $4.3 million since December 31, 2022. We are currently subject to General Instruction I.B.6 to Form S-3 (the "baby shelf rule") and are generally limited to sales pursuant to our existing shelf registration statement during any twelve-month period of an amount equal to one-third of the aggregate market value of our common equity held by non-affiliates. For additional information about the at-the-market offerings pursuant to the ATM Agreement, see "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations."

In order to raise additional capital and subject to having available shares of common stock under our articles of incorporation, we may in the future seek to offer pursuant to the ATM Agreement additional shares of common stock for up to $14.6 million in gross proceeds and we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock. There can be no assurance that we will be able to sell additional shares in at-the-market offerings made pursuant to the ATM Agreement, or in any other offering, at a price per share that is equal to or greater than the price per share paid by existing stockholders. Investors purchasing securities in other offerings in the future could have rights superior to existing stockholders.

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

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

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.

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. The payment of dividends is restricted by the Credit Agreement and will depend on our earnings, capital requirements, financial condition, prospects and other factors our board of directors may deem relevant. We are also limited under the terms of the Merger Agreement from paying cash dividends without the consent of Biosynex, Therefore, the success of an investment in our common stock will depend entirely upon any future increase in value of our common stock. There is no guarantee that our common stock will gain value or even maintain the price at which investors purchased their shares.

General Risk Factors

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

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

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

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

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

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, 2023, with an option to renew each year.

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

On January 25, 2023, the lease in Hauppauge, New York was terminated and a new lease was entered into for a 50,000 square foot space in Bayshore, New York. The lease has an initial term of seven years and one month. Rent under the lease, which is payable in monthly installments, has a minimum annual rent of approximately $996,240.

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

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

N/A

PART II

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

Listing Information

Our stock is currently listed on the Nasdaq Capital Market of the Nasdaq Stock Market LLC under the symbol "CEMI."

Holders

As of March 24, 2023, there were 114 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, 2022, we have issued, in the aggregate, 48,117 shares of common stock to Marco Collovati pursuant to a consulting agreement between us, our subsidiary Chembio Diagnostics Brazil LLC, and Mr. Collovati, upon the achievement of certain regulatory milestones in Brazil. The Company issued the foregoing securities in transactions not involving an underwriter and not requiring registration under Section 5 of the Securities Act in reliance on the exemption afforded by Section 4(a)(2) thereof.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the year ended December 31, 2022.

Dividend Policy

We have never paid dividends and do not anticipate paying dividends in the foreseeable future. The payment of dividends is restricted by the Credit Agreement and will depend on our earnings, capital requirements, financial condition, prospects and other factors our board of directors may deem relevant. We are also limited under the terms of the Merger Agreement from paying cash dividends without the consent of Biosynex. We intend to retain any future earnings for reinvestment in our business.

ITEM 6. [RESERVED]

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

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

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

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

- an emergency use authorization, or EUA, from the U.S. Food and Drug Administration, or FDA, as well as 510(k) clearance from the FDA, for the DPP SARS-CoV-2 Antigen test system;
- an EUA from the FDA for the DPP Respiratory Panel; and
- a Clinical Laboratory Improvement Amendment ("CLIA"), waiver from the FDA for the DPP HIV-Syphilis test system, which was received in February 2023.

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

Pending Merger with Biosynex SA

The Company has entered into a Merger Agreement with Biosynex and Purchaser. Pursuant to the Merger Agreement, on February 14, 2023, the Purchaser commenced the Offer to purchase all of the issued and outstanding Shares for a purchase price of $0.45 per share, net to the seller in cash, without interest and subject to any required tax withholding. On March 15, 2023, Biosynex announced an extension of the Offer until 6:00 p.m., New York City time, on March 28, 2023. Subsequently, on March 29, 2023, Biosynex announced an extension of the Offer until 6:00 p.m., New York City time, on April 12, 2023.

If the conditions to the Offer are satisfied and the Offer closes, Purchaser would acquire all remaining Chembio shares by a merger of Purchaser with and into Chembio, with Chembio surviving the Merger as a wholly-owned indirect subsidiary of Biosynex. At the Effective Time, each Share issued and outstanding immediately prior to the Effective Time (including shares paid to holders of vested Chembio restricted stock units) will be converted into the right to receive $0.45 per share. Stock options that are outstanding immediately prior to the Effective Time will automatically terminate for no consideration.

The Merger Agreement and the transactions contemplated thereby, including the Merger, were unanimously approved by the Company's Board of Directors. Completion of the Merger is subject to certain customary conditions as set forth in the Merger Agreement and the successful completion of the Offer. There can be no assurance that the Merger will be consummated on the terms described above or at all.

The foregoing description of the Merger Agreement and the transactions contemplated thereby, including the Offer, does not purport to be complete and is subject to, and qualified in its entirety by reference to, the full text of the Merger Agreement, which has been filed as Exhibit 2.1 to our Current Report on Form 8-K filed with the SEC on January 31, 2023.

Likely Default Under Credit Agreement

On September 3, 2019, we and certain of our subsidiaries, as guarantors, entered into the Credit Agreement and Guaranty (the "Credit Agreement") with Perceptive Credit Holdings II, LP (the "Lender"), under which we received a $20.0 million senior secured term loan that was drawn in full on September 4, 2019. The Credit Agreement is secured by a first priority lien on substantially all of our property and assets. The Credit Agreement contains financial covenants requiring that we (a) maintain aggregate unrestricted cash of not less than $3.0 million at all times, and (b) achieve specified minimum total revenue requirements for the twelve months preceding each quarter end.

The Credit Agreement has a September 3, 2023 maturity date, and we do not currently believe that replacement debt or equity financing arrangements are or will be available to us or, if available to us, will be on acceptable terms. We do not believe that we will be in compliance with the minimum revenue covenant in the Credit Agreement for the four fiscal quarters ended March 31, 2023. Our Lender has previously informed us that it will not agree to any restructuring of the Credit Agreement, and as a result we may be forced to pursue a bankruptcy or restructuring proceeding when the debt matures (or earlier if the lender accelerates following a breach of the minimum total revenue covenant) or pursue a transaction or financing arrangement that could be dilutive to stockholders.

Going Concern Considerations

The Company continued to experience market, clinical trial and regulatory complications in seeking to develop and commercialize a portfolio of COVID-19 test systems during the continuing, but evolving, uncertainty resulting from COVID-19. For the year ended December 31, 2022, the Company also continued to incur significant operating losses and significant expenses in connection with pending legal matters (see Note 12 – Commitments, Contingencies, and Concentrations: Litigation).

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

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

- Focus on higher margin business in growth markets
- Lower manufacturing costs
- Reduce infrastructure costs

- Strategic review of non-core businesses and assets

The Company's execution of its plans continue to depend, however, on factors and uncertainties that are beyond the Company's control, or that may not be addressable on terms acceptable to the Company or at all. The Company considered in particular how:

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

The Company further considered how these factors and uncertainties could impact its ability over the next year to meet the obligations specified in the Credit Agreement with the Lender. Those obligations include covenants requiring: i) minimum cash balance of $3.0 million and ii) minimum total revenue amounts for the twelve months preceding each quarter end. The minimum total revenue requirements are $48.8 million for the twelve months ending March 31, 2023 and $50.1 million for the twelve months ending June 30, 2023. We do not believe that we will comply with the minimum total revenue covenant for the twelve months ended March 31, 2023. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. Furthermore, all remaining principal and interest is due on or before September 3, 2023. There can be no assurance that the Company would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, the Company would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. The Company's inability to raise additional capital on acceptable terms in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for its operations, could have a material adverse effect on its business, prospects, results of operations, liquidity and financial condition and would likely result in the Company being forced to seek protection under a bankruptcy proceeding.

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

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

Consolidated Results of Operations

The results of operations for the years ended December 31, 2022 and 2021 were as follows:

	Year Ended December 31, (in thousands)			
	2022		2021	
TOTAL REVENUES	$ 49,522	100%	$ 47,818	100%
COSTS AND EXPENSES:				
Cost of product sales	38,578	78%	34,496	72%
Research and development expenses	7,068	14%	12,487	26%
Selling, general and administrative expenses	24,278	49%	24,841	52%
Impairment, restructuring, severance and related costs	3,236	7%	7,048	15%
TOTAL OPERATING COST AND EXPENSES	73,160		78,872	
LOSS FROM OPERATIONS	(23,638)		(31,054)	
INTEREST (EXPENSE) / INCOME AND OTHER INCOME	382		(2,912)	
LOSS BEFORE INCOME TAXES	(23,256)		(33,966)	
Income tax (expense) / benefit	(34)		62	
NET LOSS	$ (23,290)	(47%)	$ (33,904)	(71%)

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during 2022 were $49.5 million, an increase of $1.7 million, or 3.6%, compared to 2021. The increase in total revenues reflected a $12.4 million, or 36%, increase in net product sales, which was principally comprised of higher sales in the United States and Africa, offset by a decrease in government grant revenue of $9.7 million related to the completion of the BARDA $12.7 million agreement in 2021.

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 increased by $8.3 million, or 3,433% compared to 2021. The following schedule calculates gross product margin:

	For the years ended December 31 (in thousands)		Favorable/ (unfavorable)	% Change
	2022	2021		
Net product sales	$ 47,092	$ 34,737	$ 12,355	36%
Less: Cost of product sales	(38,578)	(34,496)	(4,082)	12%
Gross product margin	$ 8,514	$ 241	$ 8,273	3,433%
Gross product margin %	18%	1%		

In 2022, we continued to invest in automation in order to reduce our reliance on manual labor and improve our product margins. The $8.3 million increase in gross product margin resulted from favorable product margins related to the impact of geographic mix on average selling price.

Research and Development

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

	For the years ended December 31		Favorable/	
	2022	2021	(unfavorable)	% Change
	(in thousands)			
Clinical and regulatory affairs	$ 1,637	$ 5,109	$ 3,472	68%
Other research and development	5,431	7,378	1,947	26%
Total research and development	$ 7,068	$ 12,487	$ 5,419	43%

The overall decrease in total research and development costs for 2022 as compared to 2021 was primarily associated to decreased clinical trial costs and other R&D costs related to the BARDA $12.7 million agreement which was completed on December 2, 2021. Total research and development costs incurred for the year ended 2022 were primarily related to ongoing projects in our new product pipeline.

Selling, General and Administrative Expense

Selling, general and administrative expenses include administrative expenses, sales and marketing costs (including commissions), and other corporate items. The $0.6 million, or 2%, decrease in selling, general and administrative expenses for 2022 as compared to 2021 primarily reflected decrease in professional fees, commissions and recruiting fees.

Impairment, Restructuring, Severance and Related Costs

Impairment, restructuring, severance and related costs include an impairment loss of $3.0 million during the first quarter of 2022 as a result of an impairment of goodwill due to the substantial decrease in our share price at March 31, 2022. The low price per share value at March 31, 2022 caused our book value to exceed our fair value. During the year ended 2022, $0.2 million of severance cost was recorded.

During 2021, $7.0 million of impairment, restructuring, severance and related costs was incurred, of which $5.9 million was related to the write-off of intangible assets, net leasehold improvements, and net right-of-use assets for leases associated with our Malaysian operations, and a write down of finite-lived intangible assets and goodwill, $1.1 million was related to restructuring matters and $0.1 million was related to severance charges.

Interest (Expense) / Income and Other Income

Interest (expense) / income and other income was principally comprised of interest expense (net of interest income) offset by $3.2 million cash receipt for the Employee Retention Credit (ERC) that we qualified for in the second and third quarter of 2021. Interest expense decreased by $0.1 million for 2022 as compared to 2021, due to the interest paid on the term loan debt we incurred in September 2019 as a result of repayment of principal starting in September 2022.

Income Tax Benefit

For 2022 we recognized a tax expense of $0.04 million primarily attributable to state taxes, compared to a tax benefit of $.01 million recorded in 2021. As of December 31, 2022 and 2021, the Company recorded a full valuation allowance against its net deferred tax assets.

Liquidity and Capital Resources

Our cash and cash equivalents totaled $18.2 million at December 31, 2022, a decrease of $10.6 million from $28.8 million at December 31, 2021. We are obligated to maintain aggregate unrestricted cash of not less than $3,000,000 at all times under a covenant in the Credit Agreement.

During the year ended December 31, 2022, we funded our business operations, including capital expenditures and working capital requirements, principally from cash and cash equivalents, using $14 million of cash. We also issued and sold 6,466,191 shares of common stock for net proceeds of $4.3 million pursuant to the ATM agreement.

Additionally, the Merger Agreement with Biosynex contains certain termination rights for Biosynex and us. Upon termination of the Merger Agreement under specified circumstances, we may be required to pay Biosynex a termination fee of $850,000.

Factors and considerations with respect to our liquidity raised substantial doubt as to our ability to continue as a going concern through one year after the filing date of this report, when the accompanying financial statements are being issued. See "Likely Default Under Credit Agreement" and "Going Concern Considerations" above.

We have considered how the uncertainties around the delivery of the full number of tests covered by customer orders may be affected by limitations of our staffing, supply chain and liquidity and other matters outside our control. We further considered how those uncertainties could impact our ability to meet the obligations specified in the Credit Agreement over the next twelve months, which include (a) a covenant requiring minimum total revenues for the twelve months preceding each quarter end and (b) an obligation requiring the payment of principal installments, commencing with the payment of $300,000 on September 30, 2022. The minimum total revenue requirements are $48.8 million for the twelve months ending March 31, 2023 and $50.1 million for the twelve months ending June 30, 2023. We do not believe that we will comply with the minimum total revenue covenant for the twelve months ended March 31, 2023. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. Furthermore, all remaining principal and interest is due on or before September 3, 2023. There can be no assurance that we would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, we would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. Our inability to raise additional capital on acceptable terms or to otherwise generate cash in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for our operations, could have a material adverse effect on our business, prospects, results of operations, liquidity and financial condition and would likely result in the Company being forced to seek protection under a bankruptcy proceeding.

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

Please see Note 2 to the accompanying financial statements for additional information regarding our going concern assessment in connection with the accompanying financial statements. You are urged to read carefully the information provided in "Because of our liquidity limitations, we have concluded there is a substantial doubt about our ability to continue as a going concern and we may require additional capital to fund our operations, which capital may not be available to us on acceptable terms or at all." "The failure to comply with the terms of the Credit Agreement could result in a default under its terms and, if uncured, could result in action against our pledged assets and dilution of our stockholders" under Part I, Item 1A, "Risk Factors" of this report.

On April 5, 2022, we received notification from the Listing Qualifications Department of The Nasdaq Stock Market, or Nasdaq, stating that the Company did not comply with the minimum $1.00 bid price requirement for continued listing set forth in Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement"). In accordance with Nasdaq listing rules, the Company was afforded 180 calendar days (until October 3, 2022) to regain compliance with the Bid Price Requirement. On October 4, 2022, the Company received written notice from Nasdaq stating that, although the Company had not regained compliance with the Bid Price Requirement by October 3, 2022, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company is eligible for an additional 180 calendar day period, or until April 3, 2023, to regain compliance with the Bid Price Requirement. To regain compliance, the closing bid price of the Company's common stock must meet or exceed $1.00 per share for a minimum of ten consecutive business days during this additional 180-day period, all as described in more detail in the Current Reports on Form 8-K filed with the SEC on April 7, 2022 and October 4, 2022. The closing price of our common stock was $0.39 on March 24, 2023. We do not believe that we will regain compliance with the Bid Price Requirement by the April 3, 2023 deadline, and there can be no assurance that we will ever be able to do so. Given the current trading price of our common stock, it is likely that we will receive a delisting notification from Nasdaq. The existence of the pending deficiency letter could, materially impair our ability to raise capital. Moreover, if we were unable to regain compliance with the Bid Price Requirement, our common stock would likely then trade only in the over-the-counter market and the market liquidity of our common stock could be adversely affected and its market price could decrease. If our common stock were to trade on the over-the-counter market, selling our common stock could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and we could face significant material adverse consequences, including: a limited availability of market quotations for our securities; reduced liquidity with respect to our securities; a determination that our shares are a "penny stock," which will require brokers trading in our securities to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our securities; a reduced amount of news and analyst coverage; and a decreased ability to issue additional securities or obtain additional financing in the future. These factors could result in lower prices and larger spreads in the bid and ask prices for our common stock and would substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends. We have not entered into, and do not expect to enter into, investments for trading or speculative purposes. Our accounts receivable, accounts payable and inventory balances fluctuate from period to period, which affects our cash flow from operating activities. The amounts of these fluctuations vary depending on cash collections, client mix, raw material lead times, the mix of vendor terms, the timing of shipment of our products and the invoicing of our research and development activities. As of December 31, 2022, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K under the Securities Exchange Act of 1934.

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

Sources of Funds

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

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

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

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

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

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

As of the filing date of this report, we have issued and sold pursuant to the ATM Agreement a total of 16,175,5195 shares of common stock at a volume-weighted average price of $2.81 per share for gross proceeds of $45.4 million and net proceeds, after giving effect to placement fees and other transaction costs, of $43.1 million. Additional shares of common stock may be issued and sold pursuant to the ATM Agreement, but we cannot provide any assurance that will be able to issue any additional shares under the ATM Agreement at an acceptable price or at all. Furthermore, any such sales shall be subject to the Baby Shelf Rule.

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

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

- Interest Rate. Principal outstanding under the Credit Agreement bears interest at a rate per annum equal to the sum of (a) the greater of the one-month London Interbank Offered Rate and 2.5% plus (b) 8.75%. At any time at which an event of default (as described under "—Default Provisions" below) has occurred and is continuing, the interest rate will increase by 4.0%. Accrued interest is payable on a monthly basis. On December 31, 2022, the interest rate was 12.88%.

- Scheduled Repayment. No principal repayments were due prior to September 30, 2022. The Company did not elect to prepay principal as described under "—Optional Prepayment" below and an event of default as described under "—Default Provisions" below did not occur. Principal installments in the amount of $300,000 are payable on the last day of each of the eleven months from September 2022 through July 2023, and all remaining principal is payable at maturity on September 3, 2023. We also have certain obligations under the Credit Agreement which include covenants requiring: i) the minimum cash balance of $3.0 million and ii) minimum total revenue amounts for the twelve months preceding each quarter end. The minimum total revenue requirements are $48,8 million for the twelve months ending March 31, 2023 and $50.1 million for the twelve months ending June 30, 2023. We do not believe that we will comply with the minimum total revenue covenant for the twelve months ended March 31, 2023. A breach of the minimum total revenue covenant or any other covenant in the Credit Agreement would result in a default under the Credit Agreement and the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable.

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

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

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

- Representations and Warranties; Financial and Other Covenants. In the Credit Agreement we made customary representations and warranties as well as customary affirmative and negative covenants, including covenants limiting additional indebtedness, liens, guarantees, mergers and acquisitions, substantial asset sales, investments and loans, sale and leasebacks, transactions with affiliates, and fundamental changes. The Credit Agreement also contains financial covenants requiring that (i) we maintain aggregate unrestricted cash of not less than $3,000,000 at all times and (ii) we achieve specified minimum rolling four-quarter (“last twelve month”) total revenue amounts as of September 30, 2019 and the last day of each calendar quarter thereafter. The minimum total revenue requirements are $48.8 million for the twelve months ending March 31, 2023, and $50.1 million for the twelve months ending June 30, 2023. We do not believe that we will comply with the minimum total revenue covenant for the twelve months ended March 31, 2023. The minimum total revenue amounts were developed for purposes of the Credit Agreement and do not reflect the internal estimates and plans used by our management and board of directors to understand and evaluate our operating performance, to establish budgets, and to establish operational goals for managing our business. We therefore do not believe that the covenant requirements provide useful information to investors or others in enhancing an understanding of our future prospects.

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

Research and Development Awards. Under a contract we entered into with the CDC, effective September 1, 2022, a total of up to $3.2 million of awards are available to assist us in developing a rapid POC Syphilis Diagnostic Test using the Company's DPP Technology. Of the total awards available under this contract, we recognized government grant income totaling $0.6 million during the year ended December 31, 2022.

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

	December 31, 2022
Cash and cash equivalents	18,179
Accounts receivable, net	6,536
Inventories, net	7,715
Insurance receivable	12,186
Prepaid expenses and other current assets	3,835
Total current assets	48,451
Less: Total current liabilities	(39,300)
Working capital	9,151

Our cash and cash equivalents at December 31, 2022, were held for working capital purposes. We currently intend to retain all available funds in excess of required minimum cash balance related to the Credit Agreement 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 $12.7 million of cash during the year ended December 31, 2022, primarily due to the net loss adjusted for non-cash items of $14.7 million. Those uses of cash were the result of $4.8 million decrease in accounts receivable, a $4.6 million decrease in inventory, and $14.0 million increase in Prepaid and other current assets, offset in part by a $6.6 million increase in accounts payable and other accrued liabilities.

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

Capital Expenditures. Our capital expenditures totaled $1.5 million in the year ended December 31, 2022, all of which related to investments in automated manufacturing equipment, facilities, and other fixed assets. As of December 31, 2022, we had capital purchase obligations of $0.01 million related to additional automated manufacturing equipment, with payments expected to come due during 2023 based on vendor performance milestones.

Significant Accounting Policies and Critical Accounting Estimates

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

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

Revenue Recognition

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

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

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

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

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

Goodwill

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

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

The company operates as a single operating segment and has one reporting unit. During the year ended December 31, 2022, the Company performed a quantitative analysis and determined that the carrying value exceeded its fair value and recorded a goodwill impairment charge of $3.0 million.

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, 2022 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 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined by Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of December 31, 2022. 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 not effective as of December 31, 2022 due to a material weakness in internal control over financial reporting described below.

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, 2022. 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 not effective as of December 31, 2022.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the assessment of our internal control over financial reporting described above, management identified the following deficiencies that constituted individually, or in the aggregate, material weakness in our internal control over financial reporting as of December 31, 2022:

- *Inventory Costing Process* – We did not appropriately include all direct labor in the products unit cost, freight in charges and adjustments for products not shipped when establishing the inventory balance as of December 31, 2022. These adjustments indicate ineffective or insufficient review of the inventory accounts.

The errors arising from the underlying deficiencies are not material to the financial statements reported in any interim or prior annual period and therefore did not result in a restatement to previously filed financial statements. These control deficiencies, however, could result in misstatements of the aforementioned accounts and disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected in a timely manner. Accordingly, we have determined that these control deficiencies constitute a material weakness.

Remediation of the Material Weaknesses in Internal Control Over Financial Reporting

Management is committed to the planning and implementation of remediation efforts to address the material weakness. These remediation efforts, which have been implemented or are in process of implementation, are intended to both address the identified material weakness and to enhance our overall financial control environment. These efforts include revisiting the review controls and control owners involved in the inventory costing process. We identified and implemented additional internal controls to strengthen account analyses related to inventory costing and have personnel with additional cost accounting experience. In addition, we began the process to review all internal controls related to cost accounting and established procedures for cost data validation and reporting. As we continue to solidify our internal controls over the financial closing and reporting processes, we expect to fully remediate this material weakness.

Previously Identified Material Weaknesses in Internal Control Over Financial Reporting

None.

Changes in Internal Control over Financial Reporting

Other than the ongoing remediation efforts described above, 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 three months ended December 31, 2022 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Internal Control

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

ITEM 9B. Other Information

None.

ITEM 9C. Disclosure Regarding Foreign Jurisdiction that Prevent Inspections

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Identification of Directors

Name	Age	Position with the Company	Director Since
David W.K. Acheson, M.D.	67	Director	2020
David W. Bespalko	67	Director	2021
Katherine L. Davis	66	Chair of the Board, Director	2007
Richard L. Eberly	62	Director, Chief Executive Officer and President	2020
John G. Potthoff	55	Director	2018
Leslie Teso-Lichtman	64	Director	2022

Dr. David W.K. Acheson, M.D.

Professional Experience
- Director since December 2020
- President and Chief Executive Officer of The Acheson Group, a global food safety consulting group, since 2013
- Partner and Managing Director of Leavitt Partners, a health care consulting firm, where he founded and managed the firm's food safety services business, from 2009 to 2013
- From 2002 to 2009, served at the U.S. Food and Drug Administration in various positions, progressing from Chief Medical Officer of the Center for Food Safety and Applied Nutrition to Associate Commissioner for Foods, where he held an agency-wide leadership role for food issues
- Prior to joining the U.S. Food and Drug Administration, he practiced in the areas of internal medicine and infectious diseases in the United Kingdom from 1980 to 1987
- After his internal medicine practice, he served as an Associate Professor at Tufts University studying the molecular pathogenesis of foodborne pathogens
- Fellow of the Royal College of Physicians (London) and the Infectious Disease Society of America

Education
- Doctor in Medicine degree, Bachelor of Science degree, Bachelor of Medicine degree, and Bachelor of Surgery degree from the University of London

Relevant Skills
- Leadership
- Policy/Government
- Industry

David W. Bespalko

Professional Experience
- Director since March 2021
- Founder and Chief Executive Officer of BMC Consulting, a management consulting firm for in vitro diagnostics companies, since September 2019
- From 2017 to April 2019, Group Vice President, Global Commercial Operations Specialty Diagnostics Group of Thermo Fisher Scientific Inc., or Thermo Fisher, a provider of scientific instrumentation, reagents and consumables, and software and services to healthcare and other laboratories from December 2017 to April 2019
- President of Anatomical Pathology and Healthcare Market Divisions of Thermo Fisher from 2015 to December 2017
- President of Fisher Healthcare at Thermo Fisher from 2011 to 2015

- Prior to his appointment as President of Fisher Healthcare, he served as Corporate Vice President, North America Commercial Operations at Beckman Coulter, Inc.
- Before joining Beckman Coulter, Inc., he served in commercial and general management roles at Baxter Healthcare Corporation and Dade Behring, Inc.

Education
- Bachelor of Science degree from the University of Alberta

Relevant Skills
- Leadership
- Governance
- Industry

Katherine L. Davis

Professional Experience
- Director since 2007 and served as Chair of the Board from March 2014 to April 2020 and since July 2020
- Owner of Davis Design Group LLC, a provider of analytical and visual tools for public policy design, since 2007
- Chief Executive Officer of Global Access Point, a start-up company with products for data transport, data processing, and data storage network and hub facilities, from 2005 to 2006
- Lieutenant Governor of the State of Indiana from 2003 to 2005
- Controller of the City of Indianapolis from 2000 to 2003
- Financial Advisor to the Mayor of Indianapolis since 2016

Education
- Master of Business Administration degree from Harvard Business School
- Bachelor of Science degree in mechanical engineering from the Massachusetts Institute of Technology

Relevant Skills
- Leadership
- Governance
- Policy / Government

Richard L. Eberly

Professional Experience
- Chief Executive Office and President since March 2020 and a director since May 2020
- Managing Director at Solid Rock Principled Capital of Solid Rock Principled Capital LLC, a private equity firm focused on biomedical companies, from March 2018 to March 2020
- Executive Vice President and President, Chief Commercial Officer at Meridian Bioscience, Inc. from 2016 to February 2018
- President of Meridian Life Science from 2012 to 2016
- Chief Commercial Officer of Meridian Life Science from 2011 to February 2018
- Executive Vice President from 2005 to 2011, Executive Vice President, General Manager from 2003 to 2005, Executive Vice President from 2000 to 2003 and Vice President of Sales and Marketing from 1997 to 2000, all at Meridian Life Science
- Prior to his appointment to Vice President of Sales and Marketing, he served as Director of Sales for Meridian
- Before joining Meridian, Mr. Eberly held sales and marketing positions at Abbott Diagnostics, Division of Abbott Laboratories

Education
- Master of Business Administration degree from Xavier University
- Bachelor of Science degree in Biochemistry from Juniata College

Relevant Skills
- Industry
- Leadership
- Innovation

Dr. John G. Potthoff, Ph.D.

Professional Experience
- Director since May 2018
- Chief Executive Officer, co-founder and director of Elligo Health Research, a clinical research company, since 2016
- President and Chief Executive Officer of Theorem Clinical Research Inc., a global contract research organization providing comprehensive clinical services, from 2011 until its acquisition by Chiltern International in 2015
- Chief Operating Officer of INC Research Holdings, Inc. from its acquisition of Tanistry, Inc. in 2001 until its acquisition by private equity investors in 2010
- Chief Executive Officer and founder of Tanistry, Inc., a contract research organization focused on the central nervous system, from 2000 to 2001

Education
- Doctor of Philosophy degree in Psychology from the University of Texas-Austin
- Master of Arts degree in Psychology from the University of Texas-Austin
- Bachelor of Arts degree in Psychology from the University of Texas-Austin

Relevant Skills
- Finance
- Industry
- Leadership

Ms. Leslie Teso-Lichtman

Professional Experience
- Director since May 2022
- Senior Vice President and Chief Financial Officer of CereVasc, Inc., a medical device company developing treatments for neurological diseases, since 2014
- Senior Vice President Finance and Treasurer of Roche Diagnostics Hematology, Inc. (formerly Constitution Medical Investors, Inc.), a developer of hematology testing systems, from 2011 to 2014
- Vice President and Controller of Hologic, Inc. (formerly Cytyc Corporation), a manufacturer of diagnostic and surgical products for cancer and women’s health, from 1998 to 2006

Education
- Master of Business Administration from Southern New Hampshire University (formerly New Hampshire College)
- Bachelor of Science degree in Business Management from Daniel Webster College
- Associate of Science degree in Accounting from Daniel Webster College

Relevant Skills
- Leadership
- Finance
- Industry

Identification of Executive Officers

Name	Age	Position with the Company	Date First Appointed
Paul Angelico	66	Executive Vice President and Chief Operations Officer	January 2022
Charles Caso	61	Senior Vice President, Global Commercial Operations	January 2022
Richard L. Eberly	62	Director, Chief Executive Officer and President	March 2020
Javan Esfandiari	56	Executive Vice President and Chief Scientific and Technology Officer	2004
Lawrence J. Steenvoorden	53	Executive Vice President and Chief Financial Officer	January 2022

Paul J. Angelico

Professional Experience

- Executive Vice President and Chief Operations Officer since January 2022, Vice President of Global Operations from April 2020 to January 2022 and Vice President of Manufacturing Operations from October 2019 to April 2020
- Executive Vice President of Global Operations of US Nonwovens LLC, a private label manufacturer of personal, fabric and home-care products for consumer products retailers, from December 2017 to October 2019
- Principal and Owner of The Dover Group, a management consultancy servicing multiple industry sectors, from 2009 to December 2017
- President, Chief Executive Officer and Director of Cyclica Inc., a life sciences technology provider of proprietary software solutions to drug discovery and development companies, from 2015 to 2016

Education

- Bachelor of Science degree in Mechanical Engineering from Worcester Polytechnic Institute

Charles Caso

Professional Experience

- Senior Vice President, Global Commercial Operations since January 2022, Vice President, North American Sales & Global Marketing from May 2020 to January 2022
- Vice President, Global Sales and Customer Success of ArcherDX, Inc., (now Invitae Corporation) a life sciences tool company, from July 2019 to April 2020
- Senior Vice President, Commercial Operations – Global Diagnostics from March 2018 to April 2019 and Vice President, Sales & Marketing – Global Diagnostics from August 2016 to March 2018 at Meridian Bioscience, a global provider of molecular and immunological reagents and life science raw materials for diagnostic applications
- Served in a series of positions at Beckman Coulter Genomics (operating company of Danaher Inc.) from 2011 to 2016, including as Director of Worldwide Commercial Operations from 2015-2016

Education

- Bachelor of Science degree in Marketing from Indiana University of Pennsylvania
- Master of Business Administration degree from University of Pittsburgh Katz Graduate School of Business

Richard L. Eberly is discussed above under “Identification of Directors.”

Javan Esfandiari

Professional Experience
- Executive Vice President and Chief Scientific and Technology Officer since 2004 and Director of Research and Development, from 2000 to 2004
- Co-founder and Director of Research and Development of Sinovus Biotech AB, a developer of lateral flow technology, from 1997 to 2000
- Director of Research and Development with On-Site Biotech/National Veterinary Institute, a government agency for veterinary medicine, from 1993 to 1997

Education
- Master of Science degree in Molecular Biology from Lund University, Sweden
- Bachelor of Science degree in Clinical Chemistry from Lund University, Sweden

Lawrence J. Steenvoorden

Professional Experience
- Senior Director at Accordion Partners, a private equity-focused financial consulting and technology firm, from December 2018 to December 2021, Director from December 2017 to December 2018
- Chief Accounting & Financial Officer of Onyx Renewable Partners, LP, a renewable energy development company managed by Blackstone Energy Partners, from March 2016 to November 2017
- Various accounting roles of increasing responsibility at Siemens Healthcare Diagnostics Inc., Siemens Corporation and Siemens AG, including most recently Global Controller, Business Planning & Controlling of Siemens Healthcare Diagnostics Inc, from 2001 to February 2016.
- Certified Public Accountant

Education
- Bachelor of Science degree in Accounting from the University of Delaware
- Master of Business Administration degree from Rider University

Family Relationships

There are no family relationships between our Directors or executive officers.

Delinquent Section 16(a) Reports

Section 16(a) of the Securities Exchange Act requires the Company's directors and certain of its executive officers and persons who beneficially own more than 10% of the Company's common shares to file reports of and changes in ownership with the SEC. Based solely on the Company's review of copies of SEC filings it has received or filed, the Company believes that each of its directors, executive officers, and beneficial owners of more than 10% of the shares satisfied the Section 16(a) filing requirements during the fiscal year-ended December 31, 2022, except that a Form 3 for each of Paul Angelico and Charles Caso were filed on April 27, 2022 after each became subject to reporting his beneficial ownership of our common stock on April 11, 2022.

Code of Business Conduct and Ethics

Our board of directors has adopted a Code of Business Conduct and Ethics applicable to all of our directors, officers and employees. We have posted the Code of Business Conduct and Ethics on our website at *https://chembiodiagnosticsinc.gcs-web.com/static-files/bca4f259-b35e-4280-a17f-2509fb6ff007*. We will post any amendments to the Code of Business Conduct and Ethics on our website. In accordance with the requirements of the SEC and Nasdaq, we will also post waivers applicable to any of our officers or directors from provisions of the Code of Business Conduct and Ethics on our website. We have not granted any such waivers to date.

We have implemented whistleblower procedures, which establish format protocols for receiving and handling complaints from employees. We have posted copies of our whistleblower procedures on our website at *https://chembio.com/investors/corporate-governance/*. Any concerns regarding accounting or auditing matters reported under these procedures are to be communicated to the audit committee or our President and Chief Executive Officer.

Audit Committee

The principal responsibilities of the audit committee are:

- appointing, approving the compensation of, and assessing the independence of our independent auditor;
- approving all audit and non-audit services of the independent auditor;
- evaluating our independent auditor's qualifications, performance and independence;
- reviewing our financial statements and financial disclosure;
- conducting periodic assessments of our accounting practices and policies;
- furnishing the audit committee report required by SEC rules;
- reviewing and approving of all related-party transactions;
- setting hiring policies for the hiring of employees and former employees or our independent auditor and ensuring that those policies comply with all applicable regulations;
- developing and monitoring compliance with a code of ethics for senior financial officers and a code of conduct for our employees, officers and directors;
- establishing procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls or auditing matters;
- establishing procedures for the confidential, anonymous submission by employees of concerns regarding questionable accounting or auditing matters;
- overseeing the work of our independent auditor, including resolution of disagreements between management and our independent auditor; and
- reviewing and discussing our annual and quarterly financial statements and related disclosures with management and our independent auditor.

Our independent auditor is ultimately accountable to the audit committee. The audit committee has the ultimate authority and responsibility to select, evaluate, approve terms of retention and compensation of, and, where appropriate, replace the independent auditor.

The current members of the audit committee are John Potthoff, who serves as chair, David Acheson, David Bespalko, and Leslie Teso-Lichtman. The board determined that each of the current audit committee members is (a) independent, as defined in the listing standards of Nasdaq, (b) a "non-employee director," as defined in Rule 16b-3 under the Securities Exchange Act, (c) an "outside director," as defined in Section 162(m) of the Internal Revenue Code of 1986, or the Code, and (d) financially literate. The board also determined that Dr. Potthoff is an audit committee financial expert in accordance with the standards of the SEC.

ITEM 11. EXECUTIVE COMPENSATION

Director Compensation

Our director compensation program is intended to enhance our ability to attract, retain and motivate non-employee directors of exceptional ability and to promote the common interest of directors and stockholders in enhancing the value of the common stock. The board of directors reviews director compensation annually based on recommendations by the nominating and corporate governance committee. The nominating and corporate governance committee has the sole authority to engage a consulting firm to evaluate director compensation.

Under our non-employee director compensation program, each non-employee director is eligible to receive compensation for board and committee service consisting of annual cash retainers and equity awards. Directors also may be paid for serving on ad hoc committees of the board. Richard Eberly, our President and Chief Executive Officer, does not receive any additional compensation for his service as a director.

Under our non-employee director compensation program, in 2022 our non-employee directors were eligible to receive the following annual cash compensation for their service on the board and the board's standing committees:

NON-EMPLOYEE DIRECTOR ANNUAL RETAINERS

Position	Annual Cash Retainer
Chair of the Board	$ 70,000
All Other Independent Directors	35,000
Audit Committee Chair	15,000
Other Audit Committee Members	7,500
Compensation Committee Chair	10,000
Other Compensation Committee Members	5,000
Nominating and Governance Committee Chair	7,500
Other Nominating and Governance Committee Members	3,750

The following table shows the total compensation for non-employee directors during 2022.

2022 NON-EMPLOYEE DIRECTOR COMPENSATION TABLE

Non Employee Director	Fees Earned or Paid in Cash ($)(1)	Option Awards($)(2)(3)(5)	Stock Awards($)(2)(4)	Total($)
David W.K. Acheson	$ 50,000	$ 19,196	$ 22,365	$ 91,561
David W. Bespalko	52,500	19,196	22,365	94,061
Katherine L. Davis	82,325	19,196	22,365	123,886
John G. Potthoff	58,750	19,196	22,365	100,311
Leslie Teso-Lichtman	27,829	52,987	62,611	143,427

(1) Consist of annual retainer fees, as described in the preceding table.

(2) Reflects the aggregate grant date fair value of any restricted stock units and stock options granted determined in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, Compensation—Stock Compensation. Assumptions used in the calculation of this amount are included in Note 10. Equity Incentive Plans to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022. This amount does not reflect the actual economic value that will ultimately be realized by each director.

(3) Upon appointment to the board, Ms. Teso-Lichtman was awarded nonqualified stock options to acquire 41,143 shares of common stock, each with an exercise price of $1.25 per share. The nonqualified stock options will vest in full immediately prior to the earlier of (i) the 2023 annual meeting of stockholders and (ii) a Change in Control (as defined in the 2019 Omnibus Incentive Plan).

(4) Upon appointment to the board, Ms. Teso-Lichtman was awarded 32,000 restricted stock units, each to acquire one share of common stock. The restricted stock units vest in full immediately prior to the earlier of (i) the 2023 annual meeting of stockholders and (ii) a Change in Control (as defined in the 2019 Omnibus Incentive Plan).

(5) As of December 31, 2022, there were 462,9007 shares of unexercised options of which, 288,001 were not yet vested.

As discussed under "Executive Compensation—Summary Compensation Table—Narrative Explanation of Summary Compensation Table," on February 20, 2020, the board adopted the Grant Guidelines in the form recommended by the compensation committee. The Grant Guidelines provide for the grant of equity awards to non-employee directors once annually, on the date of our annual meeting of stockholders at which the non-employee directors are elected (or re-elected) to the board unless such annual stockholder meeting occurs either (a) earlier than the third trading day following the date on which we file our Quarterly Report on Form 10-Q for the quarter ended March 31 of such year, in which case the grant date generally shall be the first Monday that follows the date of such filing, or (b) on or after June 1 of such year, in which case the grant date generally shall be the first Monday that follows the date on which we next file an Annual Report on Form 10-K or Quarterly Report on Form 10-Q.

Outside Director Compensation Policy: In January 2022, the Compensation Committee approved the adoption of the Outside Director Compensation Policy, effective immediately. The purpose of the Outside Director Compensation Policy is to provide a total compensation package that enables us to attract and retain, on a long-term basis, high-caliber directors. The Outside Director Compensation Policy applies to each non-employee who serves on the board. The Compensation Committee approved the Outside Director Compensation Policy in after considering recommendations made by our compensation consultant based in part upon assessments of our director compensation relative to that of a peer group of comparable companies.

The Outside Director Compensation Policy sets forth (a) cash and equity compensation for directors serving during calendar year 2022 and (b) one-time equity compensation for new directors joining the board on or after January 1, 2022. The board reviews and approves director compensation annually and will amend or restate the Outside Director Compensation Policy accordingly.

Compensation for 2022 Services. Under the Outside Director Compensation Policy, the following terms applied during calendar year 2022:

- Cash Compensation. Each non-employee director was entitled to a cash retainer of $35,000 for service on the board of directors for 2022, except that the Chair of the Board would receive a cash retainer of $70,000. In addition, a non-employee director serving on the board's audit committee, compensation committee, or nominating and corporate governance committee in a non-Chair capacity was entitled to a cash retainer of $7,500, $5,000 or $3,750, respectively, for services on those committees for the year. The Chair of one of those committees was entitled to a cash retainer twice the amount payable to other members of that committee. Directors were not entitled to receive attendance fees for any meetings of the board or its committees.

- Equity Awards. Under the Outside Director Compensation Policy, each of the non-employee directors elected (or re-elected) to the board at the 2022 annual meeting of stockholders would have received annual equity-based awards under our 2019 Omnibus Incentive Plan having an aggregate value of $80,000, based upon the fair market value of common stock on the grant date and consisting of $40,000 in value of restricted stock units and $40,000 in value of nonqualified stock options. These awards would have been granted as of the date of the 2022 annual meeting and would have vested immediately prior to the Annual Meeting.

One-time Equity Award for New Directors. Each non-employee director who is initially elected to the board after January 1, 2022 will receive equity awards with an aggregate value of $160,000, which will consist of $80,000 in value of restricted stock units and $80,000 in value of nonqualified stock options unless otherwise determined by the compensation committee. These awards are to be granted upon commencement of board service. The restricted stock units will vest on the first, second and third anniversaries of the grant date, and the nonqualified stock options will vest in full immediately prior to second annual meeting of stockholders following the grant (unless the director is first elected at an annual meeting, in which case the nonqualified stock option will vest in full immediately prior to the next annual meeting). All of the restricted stock units and nonqualified stock options will be subject to accelerated vesting upon a defined change in control.

Executive Compensation

Summary Compensation Table

We are eligible, and have chosen, to comply with the scaled executive and director compensation disclosure rules applicable to a "smaller reporting company," as defined in applicable SEC rules.

The following table provides information concerning the compensation paid for 2022 and 2021 to our "named executive officers" as of December 31, 2022, who consisted of our President and Chief Executive Officer and our next two most highly compensated executive officers during 2022.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)(2)(5)	Option Awards ($)(1)(3)(6)	All Other Compensation ($)(4)(7)	Total ($)
Richard L. Eberly	2022	$ 459,887	$ 453,100	$ 301,925	$ 393,371	$ 2,123	$ 1,610,406
President and Chief Executive Officer	2021	476,764	186,300	540,000	938,774	1,062	2,142,900
Lawrence J. Steenvoorden	2022	334,966	269,920	180,000	244,626	14,999	1,044,510
Executive Vice President and Chief Financial Officer	2021	-	-	-	-	-	-
Javan Esfandiari	2022	383,000	143,625	100,642	131,123	7,574	765,964
Executive Vice President and Chief Science and Technology Officer	2021	397,453	108,389	180,002	312,993	2,380	1,001,217

(1) Reflects the aggregate grant date fair value of any restricted stock units and stock options granted determined in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, Compensation—Stock Compensation. Assumptions used in the calculation of this amount are included in Note 10. Equity Incentive Plans to the Consolidated Financial Statements. This amount does not reflect the actual economic value that will ultimately be realized by each NEO.

(2) Consist of restricted stock units that vest over three years, one-third of which vested on March 11, 2023, and with one-third vesting on each of March 11, 2024 and 2025, subject to continued service through each vesting date.

(3) Consist of option awards exercisable for common stock. The option awards are scheduled to vest and become exercisable over four years, one-fourth of each vested on March 11, 2022 and March 11, 2023, and with one-fourth vesting on each of March 11, 2024 and 2025, subject to continued service through each vesting date.

(4) Consists of matching contributions to 401(k) plan, car allowance, and relocation.

(5) Consist of restricted stock units that vest over three years, one-third of which vested on January 05, 2023, and with one-third vesting on each of January 05, 2024 and 2025, subject to continued service through each vesting date.

(6) Consist of option awards exercisable for common stock. The option awards are scheduled to vest and become exercisable over four years, one-fourth of which vested on January 05, 2023, and with one-fourth vesting on each of January 05, 2024, 2025, and 2026 subject to continued service through each vesting date.

(7) Mr. Steenvoorden received $12,000 for relocation expenses and $2,999 for 401(k) match.

Narrative Explanation of the Summary Compensation Table

The compensation paid to executives for 2022 consisted of the following components:

- base salary;
- cash bonuses, consisting of annual performance-based bonuses and one-time incentive bonuses;
- long-term incentive compensation in the form of stock options and restricted stock units, or RSUs; and
- benefits consisting principally of health and welfare plan contributions.

Following a review of market benchmarks in December 2022, it was determined that 2022 total compensation, and in particular target cash compensation (base salary and target annual cash bonuses), for our executives approached the market medians, but continued to be below that of similarly sized companies. We continue to believe that a performance-based compensation program calibrated to market median balances stockholder interests with our ability to attract and engage our executives.

2022 Cash Bonuses

Annual Performance-Based Bonuses. At meetings held in March 2022, the compensation committee, with the assistance of our independent compensation consultant Pearl Meyer, approved a formulaic structure for bonus determinations for executives with respect to 2022. In accordance with this structure:

- Annual cash bonus payments for executives for 2022 were determined based on achievement of weighted metrics with respect to three corporate goals: revenue, 55%; adjusted EBITDA, 15%; and specified organizational goals aligned with our strategic plan (including regulatory, product development, manufacturing automation, employee retention and inventory-related milestones), 30%. In the first quarter of 2023, the compensation committee confirmed that NEOs had achieved, on a weighted basis, 68% of the target bonus amounts, as the result of substantial achievement of the targeted revenue metric and overachievement of the pre-determined organizational goals but no achievement of the targeted adjusted EBITDA metric.

As the result of the above computations, 2022 annual cash bonus payments were made to Richard Eberly in the amount of $386,400, Javan Esfandiari in the amount of $88,090, and Lawrence J. Steenvoorden in the amount of $184,920.

One-Time Incentive Bonuses.

In August 2021 the board of directors, upon the recommendation of the compensation committee, approved the adoption of a One-Time Incentive Plan, or the OTIP, under which up to $1.5 million, or the OTIP Pool, was made available for cash awards to a number of employees, including executives. The board intended that the OTIP would help us: retain the employment of employees in the light of our liquidity challenges and a highly competitive employment market stemming, in part, from the ongoing COVID-19 pandemic; optimize our potential to deliver tests in accordance with the two significant customer purchase orders received in July 2021; and position our company on a solid path for the future. The company made OTIP payments of $163K and $637K for year ending 2021 and 2022, respectively.

- Sixty percent, or up to $900,000, of the OTIP Pool was made available upon compliance with three performance milestones based on our receipt of payment for tests delivered under the two significant customer purchase orders, as follows: 20%, or up to $180,000, would be payable to OTIP participants following our receipt of payment for the initial delivery of tests under either order; 30%, or up to $270,000, would be payable to OTIP participants following our receipt of payments under the orders totaling approximately $16.2 million (one-half of the aggregate purchase prices of the two orders); and 50%, or up to $450,000, would be payable to OTIP participants upon our receipt of payment for the total purchase prices of the two orders. Compliance with the performance milestones was completed by March 31, 2022.

- The remaining forty percent, or $600,000, of the OTIP Pool is designed for employee retention, and will be available to OTIP participants who were employees in good standing as of August 31, 2022. Approximately $1.3 million of the cash awards under the OTIP was available for awards to 37 identified “critical employees,” who included each of the NEOs. Eligible employees were assigned to two tiers, with the 19 members of Tier I having potential awards of up to 25% of their annual base salaries and the 18 members of Tier II having potential awards of up to 15% of their annual base salaries. Each of our NEOs was a member of Tier 1, and their maximum award amounts, payable during 2022, were: Richard Eberly, $66,700; Javan Esfandiari, $55,535.

2022 Equity Awards

Prior to 2020, we did not typically grant equity awards to executives on an annual basis. From time to time, however, we did grant stock options, when appropriate, as a long-term incentive component of our compensation program. With respect to our long-term incentive program for 2022, the compensation committee adopted Pearl Meyer’s recommendation to grant to executives equity awards approaching the market median at similarly sized companies in our sector and we delivered equity grants in March 2022 in a combination of stock options (60% of value) and time-vesting RSUs (40% of value). The compensation committee determined, based on information compiled by Pearl Meyer, this structure is consistent with that of comparable companies. The compensation committee further determined that use of 2022 grant values approaching the market median appropriately balanced a recognition of our performance in 2021 and a desire to align the compensation of the executive team with future value creation.

Our stock options allow our executives to purchase covered shares at a price equal to the fair market value on the date of grant. In some cases, we attach performance criteria to the vesting of the stock options.

See also “—Outstanding Equity Awards at December 31, 2022” below.

On February 20, 2020, the board of directors adopted Equity Award Grant Guidelines, or the Grant Guidelines, in the form recommended by the compensation committee. The Grant Guidelines are intended to establish procedures for granting of equity-based awards that minimize the opportunity – or the perception of an opportunity – for us to time an equity award grant in a manner that could take advantage of any material nonpublic information or could result in an assertion that the equity award has been are priced at a value less than the fair market value of common stock on the grant date. Under the Grant Guidelines, the compensation committee generally is to consider and, if approved, grant equity awards to our employees once annually during the first quarter of the fiscal year, on the first Monday that follows the date on which we file our Annual Report on Form 10-K. The Grant Guidelines contemplate that the compensation committee may, from time to time, determine that it is in our best interests to deviate from the foregoing terms with respect to the grant of an equity award, in which case such Equity Award must be reviewed and approved by the board.

Outstanding Equity Awards at December 31, 2022

The following table sets forth information regarding each unexercised option or unvested RSU held by each of our named executive officers as of December 31, 2022:

		Option Awards				Stock Awards	
Name		Number of Securities Underlying Unexercised Options (#)Exercisable	Number of Securities Underlying Unexercised Options (#)Unexercisable	Option Exercise Price($)	Option Expiration Date	Number of Shares or Units of Stock that have not Vested(#)	Market Value of Shares or Units of Stock that have not Vested
Richard L. Eberly	(1)(4)	-	-	-	-	288,000	-
	(2)(4)	208,285	624,858	1.25	3/10/2032	-	-
	(1)(6)	-	-	-	-	38,710	-
	(2)(7)	160,714	160,715	4.65	3/14/2028	-	-
Lawrence J. Steenvoorden	(1)(9)	-	-	-	-	107,143	-
	(2)(10)	75,000	225,000	1.12	1/5/2029	-	-
Javan Esfandiari	(1)(4)	-	-	-	-	96,000	-
	(2)(5)	69,428	208,286	1.25	3/10/2032	-	-
	(1)(6)	-	-	-	-	12,904	-
	(2)(7)	53,571	53,572	4.65	3/14/2028	-	-
	(3)(8)	-	188,064	2.36	3/15/2027	-	-

(1) RSUs subject to vesting, to acquire common stock.
(2) Options exercisable, subject to vesting, to acquire common stock.
(3) Restricted stock award, or RSA.
(4) RSU was granted on March 11, 2022. RSU vests over three years, with one-third vesting on each of the first, second and third anniversary of the grant date, subject to continued service through each vesting date.
(5) Option was granted on March 11, 2022. Option vests and becomes exercisable over four years, with one-fourth vesting on each of the first, second, third and fourth anniversary of the grant date, subject to continued service through each vesting date.
(6) RSU was granted on March 15, 2021. RSU vests over three years, with one-third vesting on each of the first, second and third anniversary of the grant date, subject to continued service through each vesting date.
(7) Option was granted on March 15, 2021. Option vests and becomes exercisable over four years, with one-fourth vesting on each of the first, second, third and fourth anniversary of the grant date, subject to continued service through each vesting date.
(8) Option was granted on March 16, 2020. Option vests and becomes exercisable over three years, with one-third vesting on each of the first, second and third anniversary of the grant date, subject to continued service through each vesting date.
(9) RSU was granted on January 05, 2022. RSU vests over three years, with one-third vesting on each of the first, second and third anniversary of the grant date, subject to continued service through each vesting date.
(10) Option was granted on January 05, 2022. Option vests and becomes exercisable over four years, with one-fourth vesting on each of the first, second, third and fourth anniversary of the grant date, subject to continued service through each vesting date.

For information regarding the vesting acceleration provisions applicable to the options held by our named executive officers, please see "—Employment Agreements" below.

Employment Agreements

Richard L. Eberly
Effective as of March 16, 2020 and as amended on February 9, 2022, we entered into an employment agreement with Richard Eberly to serve as our President and Chief Executive Officer. The employment agreement, as amended, provides for our at-will employment of Mr. Eberly as our President and Chief Executive Officer through December 31 of each calendar year, which term will extend automatically for additional calendar years as of each January 1 unless either party delivers, by no later than the immediately preceding October 1, a written notice to the other party that the term will not be extended. Under the terms of the employment agreement, we will pay Mr. Eberly an annual base salary of $400,000, which amount is subject to annual review by the compensation committee and may be increased, but not decreased. In accordance with the terms of the employment agreement, we granted to Mr. Eberly on March 16, 2020 an RSU, award covering 233,589 shares of common stock. Subject to Mr. Eberly's continued service with us, the RSU award vests in three equal instalments, two of which vested as of March 16 of each of 2021, 2022 and with the final instalment vesting on March 16, 2023, except that vesting with respect to each outstanding equity award agreement executed by us and Mr. Eberly will accelerate if Mr. Eberly's employment is terminated or not renewed by us without Cause or by Mr. Eberly for Good Reason within 12 months following a Change in Control (each such capitalized term as defined in the employment agreement), to the extent such vesting is based solely on Mr. Eberly's continued service over a period of time (rather than any performance-related metric). If Mr. Eberly's employment is terminated or not renewed by us without Cause or by Mr. Eberly for Good Reason within 12 months of a Change in Control, we will be required to pay Mr. Eberly an amount equal to twice his base salary with respect to the year in which the termination occurs, in addition to the pro rata bonus amount.

Javan Esfandiari
Effective as of March 5, 2016 and as amended on March 20, 2019 and November 30, 2021, we entered into an employment agreement with Javan Esfandiari to continue as our Executive Vice President and Chief Scientific and Technology Officer for an additional term through December 31, 2024. The term will extend automatically for additional calendar years as of each January 1 (commencing January 1, 2025), unless either party delivers, by no later than three months prior to the scheduled expiration (initially September 31, 2024), a written notice to the other party that the term will not be extended. In the event Mr. Esfandiari's employment is terminated by reason of Disability or for Cause, (as defined in the employment agreement), or due to Mr. Esfandiari's resignation or voluntary termination, all compensation, including his base salary, his right to receive a performance bonus, and benefits, and the vesting of any unvested equity awards, will cease as of his termination date, and Mr. Esfandiari will receive no severance benefits. If Mr. Esfandiari's employment agreement is terminated by us without Cause, or if Mr. Esfandiari terminates his employment agreement for a Reasonable Basis(as defined in the employment agreement), including within 12 months of a Change in Control (as defined in the employment agreement), we will be required to pay his base salary. Mr. Esfandiari's employment agreement also contains provisions prohibiting Mr. Esfandiari from (a) soliciting our employees for a period of 24 months following his termination, (b) soliciting our customers, agents, or other sources of distribution of our business for a period of twelve months following his termination, and (c) except where termination is involuntary upon a "Change in Control," for a period of twelve months following his termination, competing with us.

Lawrence J. Steenvoorden
Effective January 5, 2022, we entered into an employment agreement with Lawrence J. Steenvoorden to serve as our Executive Vice President and Chief Financial Officer. The employment agreement provides for Mr. Steenvoorden's at-will employment as our Executive Vice President and Chief Financial Officer for an initial term commencing January 5, 2022 and expiring December 31, 2022. The term will extend automatically for an additional calendar year as of each January 1 (commencing January 1, 2023), unless either party delivers, by no later than the immediately preceding October 1 (initially October 1, 2022), a written notice to the other party that the term will not be extended. Under the terms of the employment agreement, we will pay Mr. Steenvoorden an annual base salary of $335,000, which amount is subject to annual review by the compensation committee and may be increased, but not decreased. In addition, we agreed to pay Mr. Steenvoorden (a) a cash signing bonus totaling $85,000, of which $40,000 was paid in January 2022 and $45,000 is payable in July 2022, and (b) a non-accountable allowance totaling $12,000 for living expenses associated with his relocation to a new principal place of employment with us, paid in equal monthly installments in January, February and March 2022. In accordance with the terms of the employment agreement, we granted to Mr. Steenvoorden on January 5, 2022 (a) a nonqualified stock option to acquire 300,000 shares of common stock at a price of $1.12 per share, expiring on January 5, 2029, and (b) a restricted stock unit award to acquire, without payment of any purchase price, up to 160,714 shares of common stock. Subject to Mr. Steenvoorden's continued service with us, the shares subject to the nonqualified stock option will vest in four equal annual installments and the shares subject to the restricted stock unit award will vest in three equal annual installments, except that, in each case, vesting will accelerate in full upon (a) our termination of Mr. Steenvoorden's employment without Cause, Mr. Steenvoorden's termination of his employment for Good Reason or the expiration of the Term upon notice of nonrenewal delivered by Chembio, in each case within 12 months following a Change in Control, or (b) Mr. Steenvoorden's death or Permanent Disability (each such capitalized term as defined in the employment agreement). Pursuant to the employment agreement, if Mr. Steenvoorden's employment is terminated or not renewed by us without Cause or by Mr. Steenvoorden for Good Reason, we will be required to pay to Mr. Steenvoorden (a) a lump sum amount equal to his annual base salary and a pro rata bonus amount, each with respect to the year in which the termination occurs, and (b) on a monthly basis, for a period of up to one year, an amount equal to the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) premium for the highest level of coverage available under our group health plans, but reduced by the monthly amount that Mr. Steenvoorden would pay for such coverage if he were an active employee.

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

Beneficial Ownership of Common Stock

The following table sets forth the number of outstanding shares of common stock beneficially owned, and the percentage of the class beneficially owned, as of March 28, 2023, by:

- each named executive officer included in "Executive Compensation—Summary Compensation Table";
- each current director and the additional nominee for election as a director; and
- all of our current executive officers and directors and the additional nominee for election as a director, as a group

The number of shares of common stock beneficially owned by each person is determined under the rules of the SEC. Under these rules, beneficial ownership includes any shares as to which the individual has sole or shared voting power or investment power and also any shares that the individual has the right to acquire by May 27, 2023 (60 days after March 28, 2023) through the exercise or conversion of a security or other right. Unless otherwise indicated, each person has sole investment and voting power, or shares such power with a family member, with respect to the shares set forth in the following table. The inclusion in this table of any shares deemed beneficially owned does not constitute an admission of beneficial ownership of those shares for any other purpose. As of March 28, 2023, there were 36,725,858 shares of common stock outstanding. Shares not outstanding, but deemed beneficially owned by virtue of the right of a person to acquire those shares, are treated as outstanding only for purposes of determining the number and percent of shares of common stock owned by such person or group. There are no persons known to us to be the beneficial owners of more than five percent of the shares of common stock outstanding as of March 28, 2023. Unless otherwise noted below, the address of each person listed in the table is in care of Chembio Diagnostics, Inc., 3661 Horseblock Rd., Medford, New York 11763.

	Common Stock	
Named Executive Officers and Directors	**Shares**	**%**
Richard L. Eberly(1)	797,557	2.2%
Javan Esfandiari(2)	522,957	1.4
Lawrence J. Steenvoorden(3)	128,571	*
Katherine L. Davis(4)	150,481	*
John G. Potthoff(5)	137,213	*
David W.K. Acheson(6)	38,459	*
David W. Bespalko(7)	43,215	*
Leslie Teso-Lichtman	—	*
All current executive officers and directors as a group (10 persons)(8)	2,128,856	5.8

* Less than 1%.

(1) Includes (a) 368,999 shares issuable under options exercisable by May 27, 2023 and (b) 51,413 shares held by Mr. Eberly's spouse.

(2) Includes 337,849 shares issuable under options exercisable by May 27, 2023.
(3) Includes 75,000 shares issuable under options exercisable by May 27, 2023.
(4) Includes 36,252 shares issuable under options exercisable by May 27, 2023.
(5) Includes 83,127 shares issuable under options exercisable by May 27, 2023.
(6) Includes 23,781 shares issuable under options exercisable by May 27, 2023.
(7) Includes 31,746 shares issuable under options exercisable, by May 27, 2023.
(8) Includes, in addition to the foregoing, 180,215 shares issuable under options exercisable, by May 27, 2023.

Equity Compensation Plan Information

The following table provides information as of December 31, 2022 with respect to shares of common stock that may be issued under equity plans and standalone option grants:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity compensation plans approved by stockholders	4,706,973(1)	$ 2.01	226,702(2)
Equity compensation plans not approved by stockholders	538,577(3)	$ 1.30	--
Totals	5,245,550	$ 1.94	226,702

(1) Consists of 21,061 shares to be issued under the 2014 Stock Incentive Plan and 205,641 shares to be issued under the 2019 Omnibus Incentive Plan.
(2) Consists of shares available under the 2019 Omnibus Incentive Plan.
(3) Consists of (i) 77,863 shares issued as an inducement grant under our employment agreement with Richard L. Eberly and (ii) 460,714 shares issued as an inducement grant under our employment agreement with Lawrence J. Steenvoorden.

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

Procedures for Approval of Related Person Transactions

The board of directors reviews all transactions involving us in which any of our directors, significant stockholders and executive officers and their immediate family members are participants, in order to determine whether any such party has a direct or indirect material interest in the transaction. All directors and executive officers must notify us of any proposed transaction involving us in which such person has a direct or indirect material interest. The proposed transaction is then reviewed by either the board of directors as a whole or the audit committee, which determines whether to approve the transaction. After such review, the reviewing body approves the transaction only if it determines that the transaction is in, or not inconsistent with, the best interests of our company and stockholders.

Conflict of Interest Policy

The board of directors has adopted a Conflict of Interest Policy applicable to all directors, officers, and employees of our company and our subsidiaries.

The Conflict of Interest Policy requires each director and executive officer, including their immediate family members, to provide written notice of any potential related-party transaction, defined by the policy to mirror the definition of Item 404 of Regulation S-K of the SEC (with the exception that the policy includes a monetary threshold of $100,000) to the Chair of the Board of Directors (or to the Chief Executive Officer if such transaction involves the Chair of the Board of Directors, or to the Chief Financial Officer if such transaction involves the Chief Executive Officer), including all information that the Chair of the Board of Directors, the Chief Executive Officer or the Chief Financial Officer may request. Upon receiving all relevant information, the board of directors may approve the transaction if it determines that the transaction is in the Company's best interests and fair to us, may require modifications to the transaction to make it acceptable for approval, or may reject it. The board of directors may also establish guidelines for ongoing management of a specific related-party transaction. The policy requires that continuing related-party transactions are reviewed on at least an annual basis. Additionally, the policy requires that all directors and executive officers complete a director and officer questionnaire in connection with each of our annual proxy statements, in which they are asked to disclose family relationships and other related-party transactions.

2022 Related Person Transactions

Since January 1, 2022, we have not engaged in any related-party transactions in which the amount involved exceeded $100,000 and in which any of our directors or executive officers or any holder of more than 5% of our common stock, or any member of the immediate family of any of these persons or entities controlled by any of them, had or will have a direct or indirect material interest, other than the compensation arrangements described in "Director Compensation" and "Executive Compensation" of Item 11 above. It is our intention to ensure that any future transactions between us and our officers, directors and significant stockholders and their affiliates are approved by the audit committee and a majority of the members of the board of directors, including a majority of the independent and disinterested members of the board of directors, and are on terms no less favorable to us than those that we could obtain from unaffiliated third parties.

Independence of Directors

The board of directors must consist of a majority of independent directors under both the Corporate Governance Guidelines and the applicable requirements of the Nasdaq.

Under Nasdaq rules, independent directors must comprise a majority of a listed company's board of directors. In addition, Nasdaq rules require that, subject to specified exceptions, each member of a listed company's audit, compensation, and nominating and corporate governance committees be independent. Under Nasdaq rules, an individual will qualify as an "independent director" only if, in the opinion of the company's board of directors, he or she does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. The Corporate Governance Guidelines effectively mandate compliance with these Nasdaq requirements.

- Audit committee members must also satisfy additional independence criteria, including those set forth in Rule 10A-3 under the Securities Exchange Act of 1934 or the Securities Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries, other than compensation for board or committee service, and may not be an affiliated person of the listed company or any of its subsidiaries; and

- Compensation committee members must also satisfy additional independence criteria, including those set forth in Rule 10C-1 under the Securities Exchange Act. In determining independence requirements for members of compensation committees, Nasdaq and other national securities exchanges and national securities associations are to consider relevant factors that include (a) the source of compensation of a director, including any consulting, advisory or other compensatory fee paid by the listed company to the director, and (b) whether the director is affiliated with the listed company, a subsidiary of the listed company or an affiliate of a subsidiary of the listed company.

The board annually reviews the independence of all non-employee directors. The board has determined that each of David Acheson, David Bespalko, Katherine Davis, John Potthoff and Leslie Teso-Lichtman qualifies as an independent director in accordance with the rules of Nasdaq and Rules 10C-1 and 10A-3 under the Securities Exchange Act.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth the aggregate fees billed to us by E&Y, our current independent auditor, for professional services rendered for the fiscal year ended December 31, 2022 and 2021 and the aggregate fees billed to us by BDO USA, LLP, our former independent auditor, for professional services rendered for the fiscal year ended December 31, 2021.

	2022			2021		
	E&Y	BDO	Total	E&Y	BDO	Total
Audit Fees(1)	$ 526,000	$ -	$ 526,000	$ 615,000	$ -	$ 615,000
Audit-related Fees(2)	$ 0	$ 50,000	$ 50,000	$ 0	$ 50,000	$ 50,000
Tax Fees(3)	$ 40,945	$ -	$ 40,945	$ 25,750	$ -	$ 25,750
All Other Fees	$ -	$ -	$ -	$ -	$ -	$ -
Total Fees	$ 566,945	$ 50,000	$ 616,945	$ 640,750	$ 50,000	$ 690,750

(1) Includes services relating to the audit of annual consolidated financial statements, review of quarterly consolidated financial statements, statutory audits, comfort letters, and consents and review of documentation filed with SEC-registered and other securities offerings.
(2) Includes services related to assistance with general accounting matters, work performed on acquisitions and divestitures, employee benefit plan audits and assistance with statutory audit matters.
(3) Includes services for tax compliance, tax advice and tax planning.

Audit Committee Pre-Approval Policies and Procedures

The audit committee approves in advance all audit and non-audit services performed by the independent registered public accounting firm. There are no other specific policies or procedures relating to the pre-approval of services performed by the independent registered public accounting firm.

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) See “Item 8. Financial Statements and Supplementary Data – Index to Consolidated Financial Statements” above.
(b) Exhibits

Exhibit No.	Description
3.1	Articles of Incorporation, as amended, of Chembio Diagnostics, Inc. (incorporated herein by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q filed on July 29, 2010)
3.2	Amended and Restated Bylaws, of Chembio Diagnostics, Inc. (incorporated herein by reference to Exhibit 3.2 to the Current Report on Form 8-K filed on September 17, 2018)
3.3	Amendment No. 1 to Amended and Restated Bylaws of Chembio Diagnostics, Inc. (incorporated herein by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q filed on August 9, 2021)
4.1	Description of Securities (incorporated herein by reference to Exhibit 4.2 to the Annual Report on Form 10-K filed on March 11, 2021)
10.1(a)*	2008 Stock Incentive Plan, as amended (incorporated herein by reference to Attachment B to the Proxy Statement on Form DEF 14A filed on 2012)
10.1(b)*	Form of Option for 2008 Stock Incentive Plan (incorporated herein by reference to Exhibit 4.4 to the Quarterly Report on Form 10-Q filed on May 8, 2014)
10.2(a)*	2014 Stock Incentive Plan (incorporated herein by reference to Attachment A to the Proxy Statement on Form DEF 14A filed on April 29, 2014)
10.2(b)*	Form of Option for 2014 Stock Incentive Plan (incorporated herein by reference to Exhibit 4.7 to the Quarterly Report on Form 10-Q filed on August 7, 2014)
10.3*	2019 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Annual Report on Form 10-K filed on March 13, 2020)
10.4*	Restated Annual Incentive Bonus Plan of Chembio Diagnostics, Inc., adopted as of March 15, 2019 (incorporated herein by reference to Exhibit 10.3 to the Annual Report on Form 10-K filed on March 18, 2019)
10.5*	Outside Director Compensation Policy of Chembio Diagnostics, adopted as of December 15, 2020 (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on December 17, 2020)
10.6(a)*	Employment Agreement, dated as of March 4, 2020 and effective as of March 16, 2020 between Chembio Diagnostics, Inc. and Richard L. Eberly (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on March 20, 2020)
10.6(b)*	Amendment No. 1 dated February 9, 2022 between Chembio Diagnostics, Inc. and Richard L. Eberly, amending the Employment Agreement dated March 4, 2020 (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on February 14, 2022)
10.6(c)*	Non-Disclosure, Intellectual Property, Non-Competition and Non-Solicitation Agreement, dated as of March 16, 2020, between Chembio Diagnostics, Inc. and Richard L. Eberly (incorporated herein by reference to Exhibit (e)(9) to the Schedule 14D-9 filed on February 14, 2023)
10.7(a)*	Employment Agreement dated March 5, 2016 between Chembio Diagnostics, Inc. and Javan Esfandiari (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on March 14, 2016)
10.7(b)*	Amendment No. 1 dated March 20, 2019 between Chembio Diagnostics, Inc. and Javan Esfandiari, amending the Employment Agreement dated March 5, 2016 (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on March 25, 2019)
10.7(c)*	Amendment No. 2 dated November 30, 2021 between Chembio Diagnostics, Inc. and Javan Esfandiari, amending the Employment Agreement dated March 5, 2016 (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on December 6, 2021)
10.8(a)*	Employment Agreement, dated as of December 30, 2021 and effective as of January 5, 2022, between Chembio Diagnostics, Inc. and Lawrence J. Steenvoorden (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on January 6, 2022)
10.8(b)*	Non-Disclosure, Intellectual Property, Non-Competition and Non-Solicitation Agreement, dated as of January 5, 2022, between Chembio Diagnostics, Inc. and Lawrence J. Steenvoorden (incorporated herein by reference to Exhibit (e)(14) to the Schedule 14D-9 filed on February 14, 2023)
10.9(a)	Lease Agreement, dated February 15, 2017, between Horseblock Associates and Chembio Diagnostics, Inc. with respect to 3661 Horseblock Road, Medford, New York, as amended (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on October 22, 2018)
10.9(b)	Agreement of Sublease dated February 5, 2019 between Chembio Diagnostic Systems Inc., as sublessor, and Reliance Communications of New Jersey, LLC, as sublessee, with respect to 3661 Horseblock Road, Medford, New York, as amended (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on February 11, 2019)
10.10	Lease Agreement, dated February 4, 2013, between Sherwood Corporate Center LLC and Chembio Diagnostics, Inc. with respect to 91-1A Colin Drive, Holbrook, New York, as amended on September 19, 2017 (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on October 22, 2018)
10.11	Lease Agreement dated February 5, 2019 between Myra Properties, LLC, as lessor, and Chembio Diagnostic Systems Inc., as lessee, with respect to 555 Wireless Boulevard, Hauppauge, New York (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on February 11, 2019)

10.12†	Credit Agreement and Guaranty dated as of September 3, 2019, among Chembio Diagnostics, Inc., as the Borrower, the Guarantors from time to time party thereto, and Perceptive Credit Holdings II, LP and its successors and assigns party thereto, as Administrative Agent and as a Lender (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 5, 2019)
10.13	At the Market Offering Agreement, dated July 19, 2021, between Chembio Diagnostics, Inc. and Craig-Hallum Capital Group LLC (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on July 19, 2021)
10.14*	Retention Agreement with Paul Angelico, dated as of February 9, 2022 (incorporated herein by reference to Exhibit (e)(15) to the Schedule 14D-9 filed on February 14, 2023)
10.15(a)*	Retention Agreement with Charles Caso, dated as of February 9, 2022 (incorporated herein by reference to Exhibit (e)(16) to the Schedule 14D-9 filed on February 14, 2023)
10.15(b)*	Non-Disclosure, Intellectual Property, Non-Competition and Non-Solicitation Agreement, dated as of February 9, 2022, between Chembio Diagnostics, Inc. and Charles Caso (incorporated herein by reference to Exhibit (e)(17) to the Schedule 14D-9 filed on February 14, 2023)
14.1	Ethics Policy (incorporated herein by reference to Exhibit 14.1 to the Annual Report on Form 10-KSB filed on March 30, 2006)
21.1	List of Subsidiaries of Chembio Diagnostics, Inc. (incorporated herein by reference to Exhibit 21.1 to the Annual Report on Form 10-K filed on March 3, 2022)
23.1	Consent of EY, Independent Registered Public Accounting Firm
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Definition Linkbase Document
101.LAB	XBRL Taxonomy Label Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document
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.

** 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.

ITEM 16. FORM 10-K SUMMARY

None.

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 29, 2023

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 29, 2023
/s/ Lawrence J. Steenvoorden Lawrence J. Steenvoorden	Chief Financial Officer (Principal Financial & Accounting Officer)	March 29, 2023
/s/ Katherine L. Davis Katherine L. Davis	Chair of the Board	March 29, 2023
/s/ David W. K. Acheson David W. K. Acheson	Director	March 29, 2023
/s/ David W. Bespalko David W. Bespalko	Director	March 29, 2023
/s/ John G. Potthoff John G. Potthoff	Director	March 29, 2023
/s/ Leslie Teso-Lichtman Leslie Teso-Lichtman	Director	March 29, 2023

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
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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, 2022 and 2021, the related consolidated statements of operations, comprehensive loss**,** stockholders' equity and cash flows for the years ended December 31, 2022 and 2021, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

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

Basis for Opinion

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

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

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

Critical Audit Matters

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

Insurance Receivable

Description of the Matter

As discussed in the consolidated financial statements, the Company recorded a receivable for expected recoveries from insurance carriers related to legal costs and settlements. As of December 31, 2022, the Company recorded an estimated insurance receivable of $12.2 million.

Auditing management's accounting for the insurance receivable was especially challenging due to the complexity of the underlying claims and determining the amount recoverable. Evaluating the likelihood and amount of recoveries from insurance carriers was highly subjective and required significant judgment. Specifically, there was significant judgment around management's estimation of how much of the legal costs incurred and settlements to date are expected to be recovered from the insurance carriers.

How We Addressed the Matter in Our Audit

To test the expected recoveries from insurance carriers, we performed audit procedures that included, among others, reading and understanding the Company's insurance policies, testing the legal costs and settlements submitted under the Company's insurance policies on a case-by-case basis, and, when applicable, vouching cash receipts from the insurance carriers for previously submitted claims.

Goodwill and Long-Lived Assets Impairment

Description of the Matter

As discussed in the consolidated financial statements, the Company identified indicators of impairment, which resulted in the Company assessing the value of goodwill and its long-lived asset group for recoverability. The Company's analysis resulted in goodwill impairment charges of $3.0 million. No impairment charges were recorded relating to the Company's long-lived assets.

Auditing the Company's assessment and measurement of impairment involved a high degree of subjectivity as estimates underlying the determination of fair values of the consolidated business and the Company's long-lived assets were based on assumptions about future economic conditions. Significant inputs used in the Company's fair value estimates included the market capitalization of the business as of its testing dates and the implied control premium.

How We Addressed the Matter in Our Audit

To test the future economic conditions, as part of our audit, we assessed the methodologies and significant inputs used in the impairment tests, among other procedures. We tested the significant inputs discussed above, as well as the completeness and accuracy of the underlying data used in the valuations. We tested the reconciliation of the fair value of the reporting unit developed by

management to the market capitalization of the Company as of the valuation dates and evaluated the implied control premium for reasonableness.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2020.
Jericho, New York
March 29, 2023

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

	December 31,	
	2022	2021
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 18,178,985**	$ 28,772,892
Accounts receivable, net of allowance for doubtful accounts of $346,896 and $243,042 at December 31, 2022 and 2021, respectively	**6,536,415**	11,441,107
Inventories, net	**7,715,413**	12,920,451
Prepaid expenses and other current assets	**3,834,560**	1,710,194
Insurance receivable, current	**12,186,322**	-
TOTAL CURRENT ASSETS	**48,451,695**	54,844,644
FIXED ASSETS:		
Property, plant and equipment, net	**8,154,651**	8,556,773
Finance lease right-of-use assets, net	**136,976**	191,870
OTHER ASSETS:		
Operating right-of-use assets, net	**5,433,211**	5,891,906
Goodwill	**-**	3,022,787
Deposits and other assets	**434,872**	358,010
Insurance receivable, long-term	**-**	386,205
TOTAL ASSETS	**$ 62,611,405**	$ 73,252,195
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 19,730,697**	$ 13,127,993
Current portion of long term debt	**18,577,693**	1,200,000
Operating lease liabilities	**914,857**	886,294
Finance lease liabilities	**76,869**	68,176
TOTAL CURRENT LIABILITIES	**39,300,116**	15,282,463
OTHER LIABILITIES:		
Long-term operating lease liabilities	**5,426,030**	5,976,151
Long-term finance lease liabilities	**76,705**	139,678
Long-term debt, less current portion, net	**10,197**	17,589,003
TOTAL LIABILITIES	**44,813,048**	38,987,295
COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding	**-**	-
Common stock – $0.01 par value; 100,000,000 shares authorized, 36,765,785 and 30,104,986 shares issued and outstanding at December 31, 2022 and 2021, respectively	**367,658**	301,050
Additional paid-in capital	**172,275,057**	165,772,636
Accumulated deficit	**(154,300,517)**	(131,009,860)
Treasury stock – 48,057 and 48,057 shares at cost, at December 31, 2022 and 2021, respectively	**(206,554)**	(206,554)
Accumulated other comprehensive loss	**(337,287)**	(592,372)
TOTAL STOCKHOLDERS' EQUITY	**17,798,357**	34,264,900
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 62,611,405**	$ 73,252,195

See accompanying notes to consolidated financial statements

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

	December 31,	
	2022	2021
REVENUES:		
Net product sales	**$ 47,091,673**	$ 34,737,444
R&D revenue	**112,986**	1,159,381
Government grant income	**1,182,023**	10,891,726
License and royalty revenue	**1,135,241**	1,029,901
TOTAL REVENUES	**49,521,923**	47,818,452
COSTS AND EXPENSES:		
Cost of product sales	**38,578,098**	34,495,802
Research and development expenses	**7,067,852**	12,487,424
Selling, general and administrative expenses	**24,277,834**	24,840,611
Impairment, restructuring, severance and related costs	**3,236,186**	7,047,779
TOTAL COSTS AND EXPENSES	**73,159,970**	78,871,616
LOSS FROM OPERATIONS	**(23,638,047)**	(31,053,164)
OTHER INCOME (EXPENSE):		
Interest (expense)/ income, net	**(2,812,772)**	(2,912,415)
Other income	**3,194,567**	-
LOSS BEFORE INCOME TAXES BENEFIT	**(23,256,252)**	(33,965,579)
Income tax (expense)/benefit	**(34,405)**	62,050
NET LOSS	**$ (23,290,657)**	$ (33,903,529)
Basic and diluted loss per share	**$ (0.72)**	$ (1.40)
Weighted average number of shares outstanding, basic and diluted	**32,269,147**	24,299,465

See accompanying notes to consolidated financial statements

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

	December 31,	
	2022	2021
Net loss	**$ (23,290,657)**	$ (33,903,529)
Other comprehensive loss:		
Foreign currency translation adjustments	**255,085**	(501,456)
COMPREHENSIVE LOSS	**$ (23,035,572)**	$ (34,404,985)

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, 2022, AND 2021

	Common Stock		Additional Paid-in-Capital	Treasury Stock		Accumulated Deficit	AOCL	Total
	Shares	Amount	Amount	Shares	Amount	Amount	Amount	Amount
Balance at December 31, 2020	20,223,498	$ 202,235	$ 124,961,514	(41,141)	$ (190,093)	$ (97,106,331)	$ (90,916)	$ 27,776,409
Common Stock:								
Issuance of stock, net	9,709,328	97,093	38,714,865	-	-	-	-	38,811,958
Restricted stock issued	135,908	1,359	105,582	-	-	-	-	106,941
Restricted stock compensation, net	-	-	1,160,953	-	-	-	-	1,160,953
Shares tendered for withholding taxes	-	-	(145,225)	-	-	-	-	(145,225)
Options:								
Exercised	36,252	363	85,192	-	-	-	-	85,555
Stock option compensation	-	-	873,294	-	-	-	-	873,294
Treasury Stock	-	-	16,461	(6,916)	(16,461)	-	-	-
Warrant exercised	-	-	-	-	-	-	-	-
Comprehensive loss	-	-	-	-	-	-	(501,456)	(501,456)
Net loss	-	-	-	-	-	(33,903,529)	-	(33,903,529)
Balance at December 31, 2021	**30,104,986**	**$ 301,050**	**$ 165,772,636**	**(48,057)**	**$ (206,554)**	**$ (131,009,860)**	**$ (592,372)**	**$ 34,264,900**
Common Stock:								
Issuance of stock, net	**6,466,191**	**64,662**	**4,246,824**	-	-	-	-	**4,311,486**
Restricted stock issued	**194,608**	**1,946**	**264,141**	-	-	-	-	**266,087**
Restricted stock compensation, net	-	-	**967,262**	-	-	-	-	**967,262**
Shares tendered for withholding taxes	-	-	**(41,537)**	-	-	-	-	**(41,537)**
Options:								
Exercised	-	-	-	-	-	-	-	-
Stock option compensation	-	-	**1,065,731**	-	-	-	-	**1,065,731**
Treasury stock	-	-	-	-	-	-	-	-
Comprehensive loss	-	-	-	-	-	-	**255,085**	**255,085**
Net loss	-	-	-	-	-	**(23,290,657)**	-	**(23,290,657)**
Balance at December 31, 2022	**36,765,785**	**$ 367,658**	**$ 172,275,057**	**(48,057)**	**$ (206,554)**	**$ (154,300,517)**	**$ (337,287)**	**$ 17,798,357**

See accompanying notes to consolidated financial statements

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

	December 31, 2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	**$ 53,886,080**	$ 37,232,082
Cash received from insurance receivable	**644,389**	861,902
Cash paid to suppliers and employees	**(63,624,525)**	(65,273,967)
Cash paid for operating leases	**(1,453,778)**	(1,404,532)
Cash paid for finance leases	**(17,015)**	(20,077)
Interest and taxes, net	**(2,129,104)**	(2,281,124)
Net cash used in operating activities	**(12,693,953)**	(30,885,716)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of and deposits on fixed assets	**(1,451,233)**	(1,824,285)
Patent application costs	**-**	(33,398)
Net cash used in investing activities	**(1,451,233)**	(1,857,683)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock, net	**4,311,486**	38,811,958
Proceeds from option exercises	**-**	85,555
Interest received on Employee Retention Credit	**67,818**	-
Principal payments for finance leases	**(70,514)**	(61,867)
Payments on note payable	**(900,000)**	-
Payments of tax withholdings on stock award	**(41,537)**	(145,225)
Net cash provided by financing activities	**3,367,253**	38,690,421
Effect of exchange rate changes on cash	**184,026**	(240,431)
INCREASE IN CASH AND CASH EQUIVALENTS	**(10,593,907)**	5,706,591
Cash and cash equivalents - beginning of the period	**28,772,892**	23,066,301
Cash and cash equivalents - end of the period	**$ 18,178,985**	$ 28,772,892
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net Loss	**$ (23,290,657)**	$ (33,903,529)
Adjustments:		
Depreciation and amortization	**2,552,969**	2,930,976
Share based compensation	**2,299,081**	2,431,982
Benefit from deferred tax liability	**—**	(69,941)
Provision for (recovery of) doubtful accounts	**103,854**	(53,751)
Non-cash inventory changes	**569,430**	4,054,701
Impairment charges	**3,033,565**	5,880,741
Changes in assets and liabilities:		
Accounts receivable	**4,800,838**	(8,009,969)
Inventories	**4,635,608**	(4,458,750)
Prepaid expenses and other current assets	**(2,124,366)**	(545,305)
Insurance receivable, current	**(12,186,322)**	—
Deposits and other assets	**(76,862)**	(234,874)
Insurance receivable, long-term	**386,205**	(386,205)
Accounts payable and accrued liabilities	**6,602,704**	3,085,205
Deferred revenue	**—**	(1,606,997)
Net cash used in operating activities	**$ (12,693,953)**	$ (30,885,716)

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 tests used to detect and diagnose infectious diseases, including sexually transmitted disease, insect vector and tropical disease, COVID-19 and other viral and bacterial infections, enabling expedited treatment.

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

- Enhanced sensitivity and specificity: This is achieved via the Company's proprietary approach to separating the sample path from the buffer path, together with patent and other proprietary strategies, which differ significantly from traditional lateral flow test.

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

- Objective results: For some diagnostic applications, the Company's easy-to-use, highly portable, battery-operated DPP Micro Reader optical analyzers can report accurate results in approximately 15 seconds, making it well-suited for decentralized testing where real-time results enable patients to be clinically assessed while they are still on site. Objective results produced by the DPP Micro Reader can reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many rapid tests.

The Company targets the market for rapid diagnostic test solutions for infectious diseases, which is driven by the high prevalence of infectious diseases globally, an increase in the geriatric population, growing demand for rapid test results, and advancements in multiplexing. The Company has a broad portfolio of infectious disease products, which prior to 2020 were focused principally on sexually transmitted disease and fever and tropical disease. In February 2020 the Company began the process to leverage the DPP technology platform to address the acute and escalating need for diagnostic testing. The Company is continuing to pursue or has pursued:

- a 510(k) clearance from the U. S. Food and Drug Administration (the "FDA") for the DPP SARS-CoV-2 Antigen test system;

- an Emergency Use Authorization from the FDA for the DPP Respiratory Antigen Panel; and

- a Clinical Laboratory Improvement Amendment ("CLIA"), waiver from the FDA for the DPP HIV-Syphilis test system, which was approved in February 2023.

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. Certain reclassifications have been made to the consolidated balance sheet of the prior year to conform to the current year presentation.

Going Concern Considerations

The Company continued to experience market, clinical trial and regulatory complications in seeking to develop and commercialize a portfolio of COVID-19 test systems during the continuing, but evolving, uncertainty resulting from COVID-19. For the year ended December 31, 2022, the Company also continued to incur significant operating losses and significant expenses in connection with pending legal matters (see Note 12 – Commitments, Contingencies, and Concentrations: Litigation).

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

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

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

The Company's execution of its plan continues to depend on factors and uncertainties that are beyond the Company's control, or that may not be addressable on terms acceptable to the Company or at all. The Company considered in particular how the ongoing healthcare and economic impacts of COVID-19 on the global customer base for the Company's non-COVID-19 products continue to negatively affect the timing and rate of recovery of the Company's revenues from those products.

The Company further considered how these factors and uncertainties could impact its ability over the next year to meet the obligations specified in the Credit Agreement with the Lender. Those obligations include covenants requiring: i) minimum cash balance of $3.0 million and ii) minimum total revenue amounts for the twelve months preceding each quarter end. The minimum total revenue requirements are $48.8 million for the twelve months ending March 31, 2023 and $50.1 million for the twelve months ending June 30, 2023. We do not believe that we will comply with the minimum total revenue covenant for the twelve months ended March 31, 2023. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. Furthermore, all remaining principal and interest is due on or before September 3, 2023. There can be no assurance that the Company would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, the Company would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. The Company's inability to raise additional capital on acceptable terms in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for its operations, could have a material adverse effect on its business, prospects, results of operations, liquidity and financial condition and would likely result in the Company being forced to seek protection under a bankruptcy proceeding.

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

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

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

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

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

The carrying value for cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate fair value due to the immediate or short-term maturity of these financial instruments. Included in cash and cash equivalents is $18.2 million and $28.8 million as of December 31, 2022 and 2021, respectively, of money market funds that are Level 1 fair value measurements under the hierarchy. The fair value of the Company's total debt of $19.1 million (carrying value of $18.6 million) and $20 million (carrying value of $18.8 million) as of December 31, 2022 and 2021, 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.

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

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

(f) ***Inventory:***

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

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

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

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

Long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the related carrying amounts may not be recoverable. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment. If there are indications of impairment, the Company uses future undiscounted cash flows of the related asset or asset grouping over the remaining life in measuring whether the assets are recoverable. In the event such cash flows are not expected to be sufficient to recover the recorded asset values, the assets are written down to their estimated fair value. A $0 and $3.3 million impairment of long-lived intangible assets was recorded for the years ended December 31, 2022 and 2021 (see Note 14 - Asset Impairment, Restructuring, Severance and related costs).

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

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

Product Revenue

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

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

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

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

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

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

Reserves for Discounts and Allowances

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

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

License and Royalty Revenues

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

R&D Revenue

All contracts with customers are evaluated under the five-step model described above. Such contracts are further described in Note 6 - Revenue. Grants are invoiced and revenue is recognized ratably as that is the depiction of the timing of the transfer of services. The R&D study, which encompasses various phases of product development processes: design feasibility & planning, product development and design optimization, design verification, design validation and process validation, and pivotal studies, is also recognized ratably.

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

Government Grant Income

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

In July 2020, the Company was awarded a grant of $0.6 million from BARDA to develop a SARS-CoV-2 Ag System. The Company earned $0 and $0.2 million for the years ended December 31, 2022 and 2021, respectively, and was recorded as government grant income.

In December 2020, the Company was awarded a grant of $12.7 million from BARDA to support the development and pursuit of FDA EUA for a rapid, multiplex DPP Respiratory Antigen Panel point-of-care test system. The Company earned $0 and $10.9 million for the years ended December 31, 2022 and 2021, respectively, and was recorded as government grant income. Cumulative through December 31, 2022, the Company recognized $12.5 million under this agreement, and the remainder $0.2 million is subject to obtaining the EUA for the DPP SARs-COV-2 Antigen test.

In September 2022, the Company was awarded a grant of $3.2 million from the Centers for Disease Control and Prevention (CDC) to develop a rapid POC Syphilis Diagnostic Test using Chembio DPP Technology. As of December 31, 2022, the company earned $0.6 million that was recorded as government grant income.

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, 2022 and 2021, the Company reported $0 in deferred revenue.

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

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

There were 1,588,387 and 705,325 restricted shares awards outstanding as of December 31, 2022 and 2021, respectively, that were not included in the calculation of diluted income per share for the year ended December 31, 2022 and 2021, because their effect would have been anti-dilutive. There were 3,657,163 and 1,600,372 options outstanding as of December 31, 2022 and 2021 respectively, that were not included in the calculation of diluted income per share for the twelve months ended December 31, 2022 and 2021, respectively, because their effect would have been anti-dilutive.

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

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

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

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

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

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

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

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

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

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

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

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

(n) ***Goodwill:***

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

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

The Company operates as a single operating segment and has one reporting unit. The Company recognized an impairment loss of its goodwill totaling $3.0 and $2.6 million for the year ended December 31, 2022 and 2021 respectively.

(*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) ***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 reported in other comprehensive income.

(q) ***Leases:***

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

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

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

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

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

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

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

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

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

Impairment charges for the Malaysian facility right-of-use asset recorded during the years ended December 31, 2022 and 2021 was $0 and $0.1 million, respectively (see Note 14 - Asset Impairment, Restructuring, Severance and related costs).

(r) ***Employee Retention Credit***

Accounting Standards Codification 105, "Generally Accepted Accounting Principles," describes the decision-making framework when no clear guidance exists in US GAAP for a particular transaction. Specifically, ASC 105-10-05-2 instructs companies to look for guidance for a similar transaction within US GAAP and apply that guidance by analogy. As such, forms of government assistance, such as the Employee Retention Credit, provided to business entities would not be within the scope of International Accounting Standards (IAS) 20 Accounting for Government Grants and Disclosure of Government Assistance, but it may be applied by analogy under ASC 105-10-05-2. We accounted for the Employee Retention Credit ("ERC") as a government grant in accordance with IAS 20 by analogy under ASC 105-10-05-2 and a current receivable and other income was recorded for the year ended December 31, 2022.

(s) ***Insurance Receivable***

Upon the recognition of a loss related to a pending, threatened or actual litigation for which the Company has insurance coverage, a related insurance receivable is recorded upon evaluation that an insurance contract is enforceable and the insurer has not disputed the claim. If the insurance is enforceable and not subject to dispute, the Company recognizes a receivable from the insurer when it is probable of recovery up to the loss recognized.

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

Recently Adopted

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

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

Not Yet Adopted

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

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

NOTE 3 — INVENTORIES:

Net inventories consist of the following at December 31:

	December 31	
	2022	2021
Raw Materials	**$ 4,539,346**	$ 7,306,095
Work in Process	**1,106,962**	3,556,878
Finished Goods	**2,069,105**	2,057,478
	$ 7,715,413	$ 12,920,451

During the year ended December 31, 2022 and 2021, the Company recognized inventory adjustments related to expired and obsolete items totaling $0.6 million and $4.1 million respectively.

NOTE 4 — FIXED ASSETS:

Fixed assets consist of the following at December 31:

	December 31	
	2022	2021
Machinery and Equipment	**$ 13,848,792**	$ 12,500,235
Furniture and Fixtures	**11,996**	6,631
Computer Equipment	**468,185**	465,576
Leasehold Improvements	**3,027,861**	2,933,159
Enterprise Business Systems	**2,953,221**	2,953,221
Subtotal:	**20,310,055**	18,858,822
Less: Accumulated Depreciation and Amortization	**(12,155,404)**	(10,302,049)
	$ 8,154,651	$ 8,556,773

Depreciation expense for the 2022 and 2021 years totaled $1.9 million and $1.8 million, respectively.

Effective May 2021, the Company discontinued its operations in Malaysia. Impairment charges recorded for the Malaysian fixed assets, net for the year ended December 31, 2022 and 2021 were $0 and $0.1 million, respectively.

As of December 31, 2022 and 2021, the Company has purchased manufacturing equipment that is not yet in use and therefore has not been depreciated, aggregating $3,192,824 and $1,970,652, respectively. These balances are reflected under the Machinery and Equipment line on the table above.

NOTE 5 — ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:

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

	December 31	
	2022	2021
Accounts Payable - suppliers	**$ 3,342,926**	$ 7,745,592
Accrued Commissions & Royalties	**2,425,302**	1,359,691
Accrued Payroll	**330,784**	494,258
Accrued Vacation	**400,409**	421,416
Accrued Bonuses	**1,467,756**	1,378,706
Accrued Professional Fees	**114,000**	122,935
Accrued Legal	**11,182,997**	400,000
Accrued Expenses - Other	**466,523**	1,205,395
	$ 19,730,697	$ 13,127,993

As of December 31, 2022, the amounts in other accrued expenses include expenses in connection with pending legal matters (see Note 12 – Commitments, Contingencies, and Concentrations: Litigation).

NOTE 6 — REVENUE:

Disaggregation of Revenue

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

The following tables disaggregates total revenues for the period ending December 31, 2022:

	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	$ 47,091,673	$ -	$ 47,091,673
R&D revenue	112,986	-	112,986
Government grant income	-	1,182,023	1,182,023
License and royalty revenue	1,135,241	-	1,135,241
	$ 48,339,900	$ 1,182,023	$ 49,521,923

The following tables disaggregates total revenues for the period ending December 31, 2022 by region:

	Total
Africa	$ 7,000,085
Asia	665,159
Europe & Middle East	4,518,475
Latin America	19,265,840
United States	18,072,364
	$ 49,521,923

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

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

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

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

NOTE 7 — INCOME TAXES:

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

	Year Ending December 31,	
	2022	2021
United States operations	**$ (18,425,426)**	$ (26,858,325)
International operations	**(4,830,826)**	(7,107,254)
Loss before taxes	**$ (23,256,252)**	$ (33,965,579)

The (benefit) provision for income taxes for the years ended December 31, 2022 and 2021 was comprised of the following:

	Year Ending December 31,	
	2022	2021
Current		
Federal	**$ -**	$ -
State	**33,948**	7,891
Foreign	**457**	-
Total current (benefit) provision	**34,405**	7,891
Deferred		
Federal	-	-
State	-	-
Foreign	-	(69,941)
Total deferred (benefit) provision	-	(69,941)
Total (benefit) provision	**$ 34,405**	$ (62,050)

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

	Year Ending December 31,	
	2022	2021
Federal income tax at statutory rates	**21.00%**	21.00%
State income taxes, net of federal benefit	**0.01%**	0.18%
Nondeductible expenses	**(3.69)%**	(2.04)%
Foreign rate differential	**0.40%**	0.32%
Change in valuation allowance	**(16.85)%**	(19.60)%
Other	**(1.02)%**	0.32%
Income tax (expense) benefit	**(0.15)%**	0.18%

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 2023 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 2023 through 2026.

After applying the above limitations, at December 31, 2022, the Company has post-change net operating loss carry-forwards of approximately $25,671,216 which expire between 2023 and 2037 and $66,924,161 which do not expire. In addition the Company has research and development tax credit carryforwards of approximately $1,632,846 for the year ended December 31, 2022, which expire between 2023 and 2036.

The Company has state net operating loss carryforwards of approximately $4,746,769 which generally expire between 2035 and 2042. The Company has foreign net operating loss carryforwards of approximately $3,207,825 which generally expire between 2025 and 2029 and foreign net operating loss carryforwards of $5,803,963 which do not expire.

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

	Year Ending December 31,	
	2022	2021
Inventory reserves	**$ 343,262**	$ 333,551
Accrued expenses	**822,145**	374,673
Net operating loss carry-forwards	**22,123,522**	20,401,828
Research and development credit	**1,632,846**	1,651,529
Research and development expenses	**628,711**	-
Stock-based compensation	**437,992**	259,106
Interest Expense	**1,825,347**	1,221,171
Lease obligations	**1,381,089**	1,504,433
Intangibles	**136,478**	137,142
Total deferred tax assets	**29,331,392**	25,883,433
Right-of-use assets	**(1,155,407)**	(1,294,519)
Depreciation	**(252,097)**	(560,754)
Total deferred tax liabilities	**(1,407,504)**	(1,855,273)
Net deferred tax assets before valuation allowance	**27,923,888**	24,028,160
Less valuation allowances	**(27,923,888)**	(24,028,160)
Net noncurrent deferred tax liabilities	**$ -**	$ -

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, 2022 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, 2022, the Company does not have any uncertain tax positions.

NOTE 8 — GOODWILL AND INTANGIBLE ASSETS:

Following is a table that reflects changes in Goodwill:

Beginning balance January 1, 2022	$ 3,022,787
Changes in foreign currency exchange rate	10,778
Impairment	(3,033,565)
Balance at December 31, 2022	$ —

During the Company's interim goodwill impairment testing conducted during the first quarter of 2022, it was concluded that goodwill was impaired and an impairment of $3.0 million was recognized during the period ended December 31, 2022. During the period ended December 31, 2021, $2.6 million was recognized as an impairment.

Intangible assets consist of the following at:

	Weighted Average Remaining Life	December 31, 2022 Cost	Accumulated Amortization	Impairment	Net Book Value	December 31, 2021 Cost	Accumulated Amortization	Impairment	Net Book Value
Intellectual property	-	$ -	$ -	$ -	$ -	$ 1,636,724	$ 546,252	1,090,472	$ -
Developed technology	-	-	-	-	-	1,944,500	828,681	1,115,819	-
Customer contracts/relationships	-	-	-	-	-	1,254,344	477,661	776,683	-
Trade names	-	-	-	-	-	110,853	43,696	67,157	-
		$ -	$ -	$ -	$ -	$ 4,946,421	$ 1,896,290	3,050,131	$ -

Intellectual property, developed technology, customer contracts/relationships and trade names were being amortized over 10, 7, 10 and 11 years, respectively. Amortization expense for the year ended December 31, 2022 and 2021 was $0 and $479,988, respectively.

As of December 31, 2021, the Company recognized an impairment loss of all its finite-lived intangible assets totaling $3.1 million. As of December 31, 2022, no additional finite-lived intangible assets remained.

NOTE 9 — STOCKHOLDERS' EQUITY:

(a) ***Common Stock***

On July 19, 2021, Chembio entered into an At the Market Offering Agreement (the "ATM Agreement") with Craig-Hallum Capital Group LLC ("Craig-Hallum"), pursuant to which Chembio may sell from time to time, at its option, up to an aggregate of $60,000,000 of shares of common stock through Craig-Hallum, as sales agent. During the year ended December 31, 2022, Chembio issued and sold pursuant to the ATM Agreement a total of 6,466,191 shares of common stock at a volume-weighted average price of $0.71 per share for gross proceeds of $4.6 million and net proceeds, after giving effect to placement fees and other transaction costs, of $4.3 million. Additional shares of common stock may be issued and sold pursuant to the ATM Agreement for gross proceeds of up to $6.3 million.

(b) ***Preferred Stock***

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

(c) ***Treasury Stock***

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

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

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

NOTE 10 — EQUITY INCENTIVE PLANS:

Effective June 19, 2014, Chembio's stockholders voted to approve the 2014 Stock Incentive Plan (the "2014 Plan"), with 800,000 shares of common stock available to be issued. Under the terms of the 2014 Plan, the Board or its Compensation Committee has the discretion to select the persons to whom awards are to be granted. Awards can be in the form of Equity Award Units. The awards vest at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through December 31, 2022, there were 732,064 Equity Award Units expired, forfeited or exercised. At December 31, 2022, 46,875 Equity Award Units were outstanding and 21,061 shares were not issued. All shares that expired, forfeited or were not issued rolled over into the 2019 Plan. No Equity Award Units remain available to be issued under the 2014 Plan.

Effective June 18, 2019, Chembio's stockholders voted to approve the 2019 Omnibus Incentive Plan (the "2019 Plan"), with 2,400,000 shares of common stock available to be issued. At the Annual Stockholder Meeting on June 25, 2021, Chembio's stockholders voted to approve an increase to the shares of common stock issuable under the SIP by 2,400,000 to 4,800,000. In addition, shares of common stock underlying any outstanding award granted under the 2019 Plan that, following the effective date of the 2019 Plan, expire, or are terminated, surrendered or forfeited for any reason without issuance of such shares, shall be available for the grant of new awards under the 2019 Plan. Under the terms of the 2019 Plan, the Board or its Compensation Committee has the discretion to select the persons to whom awards are to be granted. Awards can be in the form of options, stock appreciation rights, restricted stock, restricted stock units, performance stock units or other stock-based awards under the 2019 Plan (collectively, "2019 Equity Units"). The 2019 Equity Units become vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through December 31, 2022, 1,307,361 2019 Equity Units have been cancelled or forfeited. At December 31, 2022, 4,660,098 2019 Equity Units were outstanding, and 226,702 2019 Equity Units were available to be awarded.

The Company's results for the years ended December 31, 2022 and 2021 include stock-based compensation expense totaling $2,299,081 and $2,034,247, respectively. Such amounts have been included in the Consolidated Statements of Operations within cost of product sales ($209,792 and $174,537, respectively), research and development ($446,769 and $494,235, respectively) and selling, general and administrative expenses ($1,642,520 and $1,365,475, respectively).

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

	2022	2021
Expected term (in years)	**6.00**	5.10
Expected volatility	**91.62%**	78.95%
Expected dividend yield	**0**	0
Risk-free interest rate	**1.97%**	0.85%

The following table provides stock option activity for the years ended December 31, 2022:

	Number of Shares	**Weighted Average Exercise Price per Share**	**Weighted Average Remaining Contractual Term**	**Aggregate Intrinsic Value**
Outstanding at December 31, 2021	1,600,372	$ 4.18	6.59 years	$ -
Granted	2,481,968	$ 1.24		-
Exercised	—	$ —		-
Forfeited	154,076	$ 2.70		-
Expired/cancelled	271,101	5.01		
Outstanding at December 31, 2022	**3,657,163**	**$ 2.20**	**8.05 years**	**$ -**
Exercisable at December 31, 2022	**581,574**	**$ 3.98**	**5.42 years**	**$ -**

The following table summarizes information about stock options outstanding at December 31, 2022:

	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	2,824,519	8.26	$ 1.40	$ -	266,431	$ 2.36	$ -
2.8 to 4.59999	26,335	8.43	3.06	-	8,776	3.06	-
4.6 to 6.39999	759,434	7.69	4.80	-	259,492	4.93	-
6.4 to 8.19999	46,875	0.36	8.15	-	46,875	8.15	-
Total	3,657,163	8.04	$ 2.20	$ -	581,574	$ 3.98	$ -

As of December 31, 2022, there was $2,113,275 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 2.61 years. The total fair value of shares vested during the year ended December 31, 2022, was $962,801.

The following table summarizes information about restricted stock and restricted stock units outstanding as of December 31, 2022:

	Number of Shares & Units	Weighted Average Grant Date Fair Value
Unvested at December 31, 2021	705,325	$ 3.34
Granted	1,308,547	0.75
Vested	203,839	3.75
Forfeited/expired/cancelled	221,646	1.35
Unvested at December 31, 2022	**1,588,387**	**1.34**

As of December 31, 2022, there was $1,259,000 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 1.79 years. Stock based compensation cost related to restricted stock and restricted stock units recognized during the years ended December 31, 2022 and 2021 was $967,262 and $1,160,953, respectively.

One-Time Incentive Bonuses.

In August 2021 the board of directors approved the adoption of a One-Time Incentive Plan, or the OTIP, under which up to $1.5 million, was made available for cash awards to a number of employees, including executives.

The company made OTIP payments of $0.6 million and $0.1 million for years ending December 31, 2022 and 2021, respectively.

NOTE 11 — GEOGRAPHIC INFORMATION AND ECONOMIC DEPENDENCY:

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

	Year Ending December 31,	
	2022	2021
Africa	**$ 7,000,085**	$ 5,562,787
Asia	**626,210**	664,579
Europe & Middle East	**3,351,003**	4,067,682
Latin America	**19,253,504**	18,418,983
United States	**16,860,871**	6,023,413
	$ 47,091,673	$ 34,737,444

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

	2022	2021
Asia	**$ 81,536**	$ 86,041
Europe & Middle East	**74,815**	113,883
Latin America	**81,315**	36,224
United States	**7,916,985**	8,320,625
	$ 8,154,651	$ 8,556,773

NOTE 12 — COMMITMENTS, CONTINGENCIES AND CONCENTRATIONS:

a) Employment Contracts:

The Company has contracts with three key employees. The following table is a schedule of future minimum salary commitments:

2023	$ 1,178,000
2024	383,000

b) Benefit Plan:

The Company has a 401(k) plan established for its employees whereby it matches 40% of the first 5% (or 2% of salary) that an employee contributes to the plan. Matching contribution expenses totaled $191,113 and $138,513 for the years ended December 31, 2022 and 2021, 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, 2022	**Year Ended December 31, 2021**
Operating lease expense	**$ 1,630,609**	$ 1,625,280
Finance lease cost		
Amortization of right-of-use assets	**$ 71,129**	$ 66,872
Interest on lease liabilities	**17,015**	20,077
Total finance lease expense	**$ 88,144**	$ 86,949

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

	Year Ended December 31, 2022	Year Ended December 31, 2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	**$ 1,453,778**	$ 1,404,532
Operating cash flows for finance leases	**17,015**	20,077
Financing cash flows for finance leases	**70,514**	61,867
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	**$ 717,956**	$ -
Finance leases	**16,234**	25,609

Supplemental balance sheet information related to leases was as follows:

	December 31, 2022	December 31, 2021
Finance Leases		
Finance lease right of use asset	**$ 356,997**	$ 340,762
Accumulated depreciation	**(220,021)**	(148,892)
Finance lease right of use asset, net	**$ 136,976**	$ 191,870
Current portion of finance lease liability	**76,869**	68,176
Finance lease liability, net of current	**76,705**	139,678
Total finance lease liabilities	**$ 153,574**	$ 207,854
Weighted Average Remaining Lease Term		
Operating leases	**6.6 years**	7.5 years
Finance leases	**2.1 years**	2.9 years
Weighted Average Discount Rate		
Operating leases	**8.70%**	8.08%
Finance leases	**9.18%**	8.76%

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

	December 31, 2022		December 31, 2021	
	Operating Leases	Finance Leases	Operating Leases	Finance Leases
2023	**$ 1,428,821**	**$ 87,884**	$ 1,447,249	$ 83,624
2024	**1,220,150**	**60,116**	1,221,017	83,624
2025	**1,049,442**	**16,731**	1,018,875	55,856
2026	**1,080,925**	**5,940**	1,049,442	12,471
2027	**1,113,353**	**355**	1,080,925	1,680
Thereafter	**2,530,168**	-	3,643,520	-
Total lease payments	**$ 8,422,859**	**$ 171,026**	$ 9,461,028	$ 237,255
Less: imputed interest	**(2,081,972)**	**(17,452)**	(2,598,583)	(29,401)
Total	**$ 6,340,887**	**$ 153,574**	$ 6,862,445	$ 207,854

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, 2022		December 31, 2021		December 31, 2022	December 31, 2021
	Net Product Sales	% of Net Product Sales	Net Product Sales	% of Net Product Sales		
Customer 1	$ 18,050,287	38%	$ 17,576,641	51%	$ 1,630,007	$ 7,672,845
Customer 2	7,562,481	16%	*	*	2,062,431	*
Customer 3	*	*	3,606,552	10%	*	1,433,305.00

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 from vendors in excess of 10% of the Company's net purchases for the periods indicated:

	For The Years Ended				Accounts Payable	
	December 31, 2022		December 31, 2021		December 31, 2022	December 31, 2021
	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	$ 5,359,388	34%	$ *	*	$ 381,923	$ –
Vendor 2	$ *	*	$ 3,163,285	16%	$ *	$ 1,361,383
Vendor 3	$ 2,231,580	14%	$ 2,031,795	10%	$ 179,482	$ 353,097

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

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

e) Litigation:

SEC Investigation

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

On March 2, 2023, the Company and the SEC settled the SEC Investigation through an Administrative Order dated March 2, 2023, instituting cease-and-desist proceedings pursuant to Section 8A of the U.S. Securities Act of 1933, as amended. The Company agreed to cease and desist from committing or causing any violations or future violations of Sections 17(a)(2) and 17(a)(3) of the Securities Act and pay a one-time civil monetary penalty of $500,000. Under the terms of the settlement, the Company neither admitted nor denied the SEC's findings.

Legal Proceedings

Stockholder Litigation

Putative Stockholder Securities Class-Action Litigation

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

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

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

On December 29, 2020, the Court issued an Order consolidating the cases and appointing the Special Situations Funds and Municipal Employees' Retirement System of Michigan (together, the "Lead Plaintiffs"), as co-lead plaintiffs and their respective counsel as co-lead counsel. The consolidated cases are now pending under the caption "In re Chembio Diagnostics, Inc. Securities Litigation."

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

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

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

Defendants filed a motion to dismiss the CAC on March 26, 2021. The Court issued its Opinion and Order (the "February 23 Order") on the defendants' motions to dismiss on February 23, 2022. In its February 23 Order, the Court: (i) dismissed Counts I and II without prejudice as to all defendants named in those Counts except the Underwriter Defendants as to which Counts I and II were not dismissed; (ii) dismissed Count III without prejudice as to all defendants named in that Count; and (iii) dismissed Counts IV and V with prejudice as to all defendants named in those Counts.

On March 9, 2022, Lead Plaintiffs filed a motion for partial reconsideration of the Court's February 23 Order, which the Court denied on July 21, 2022.On July 14, 2022, all parties in the In re Chembio Diagnostics, Inc. Securities Litigation action participated in a mediation. The mediation was adjourned without an agreement to resolve the action, but the parties continued to discuss a potential negotiated resolution with the mediator's assistance.

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

On August 26, 2022, the Company and the other parties to the litigation reached an agreement in principle on the financial terms of a proposed settlement of all claims that were asserted, or could have been asserted, on an individual and class-wide basis against all defendants in the case, including under both the Securities Act and the Securities Exchange Act.

On December 28, 2022, plaintiffs filed a motion for preliminary approval of the class action settlement that included a stipulation of settlement. On February 3, 2023, the Court entered an opinion and order granting preliminary approval of the proposed settlement. The court set a hearing on June 5, 2023 to determine, inter alia, whether final approval should be given to the settlement. The principal terms of the settlement are:

- A cash payment to a settlement escrow account in the amount of $8,100,000 of which approximately $209,000 is payable by the Company and the remainder is payable by certain of the Company's insurers;

- The net proceeds of the settlement escrow, after deduction of Court-approved administrative costs and Court-approved attorneys' fees and costs, will be distributed to the class; and

- A release of claims (including unknown claims) and dismissal of the action with prejudice.

By entering into the settlement, the settling parties have resolved the class claims to their mutual satisfaction. However, the final determination is subject to approval by the Court.

Putative Stockholder Derivative Litigation

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

The Wong complaint requests a declaration that the individual defendants have breached or aided and abetted the breach of their fiduciary duties to Chembio, an award of damages to Chembio, restitution, and an award of the plaintiff's costs and disbursements in the action, including reasonable attorneys' and experts' fees, costs and expenses, and improvements to Chembio's corporate governance and internal procedures regarding compliance with laws.

On March 31, 2022, a second putative stockholder derivative action captioned Michelle Chen, derivatively on behalf of Chembio Diagnostics, Inc., Plaintiff v. Richard L. Eberly, Gail S. Page, Neil A. Goldman, Javan Esfandiari, Katherine L. Davis, Mary Lake Polan and John G. Potthoff, Defendants, and Chembio Diagnostics, Inc., Nominal Defendant (the "Chen complaint") was filed purportedly on behalf of Chembio in the Supreme Court for the State of New York, County of Suffolk. The Chen complaint purports to assert a claim for breach of fiduciary duty against the defendants based on ostensibly false and misleading statements and omissions, interalia, concerning the Company's rapid COVID-19 antibody test. The Chen complaint goes on to allege that the misconduct asserted in the complaint gave rise to the filing of the consolidated securities litigation described above.

The plaintiffs in the Wong and Chen actions took part in the July 14, 2022 mediation described above, and the parties subsequently reached an agreement in principle on the terms of a proposed settlement of both actions, subject to execution of settlement papers and court approval. The proposed settlement contemplated the adoption of certain corporate governance measures that did not have to be implemented in the event of a change of control and did not entail any monetary compensation or payment other than the derivative plaintiffs' attorneys' fees, which the parties agreed would not exceed $595,000, and subject to Court approval.

On December 5, 2022, the parties to the Wong action advised the court that the parties had reached a settlement in principle of the claims in the Wong action as well as in the related Chen action and requested that the court stay the Wong action to allow the parties sufficient time to finish negotiating the settlement documentation and obtain settlement approval from the state court in the Chen action. The court granted the parties' request that same day.

On January 31, 2023, the Company announced that it entered into a definitive merger agreement with Biosynex SA.

On February 3, 2023, the Company submitted a letter to the United States District Court for the Eastern District of New York before which the Wong complaint is pending, informing the court of the proposed merger with Biosynex. In its letter, the Company advised the court that because the corporate governance enhancements central to the parties' settlement in principle will be mooted if the merger is consummated (in which case there will no longer be any Chembio public stockholders), the Company requested that the action should continue to be stayed until such time as it is known whether the merger with Biosynex is completed.

On February 6, 2023, counsel for the plaintiff in the Chen action sent a letter to K&L Gates, as counsel for the defendants, informing them of their intent to request the state court to lift the stay of the Chen action on an expedited basis for the purposes of allowing the plaintiff to engage in limited discovery, and suggesting that the parties speak to the mediator who had previously served the parties.

On February 7, 2023, K&L Gates sent counsel for the plaintiff in the Chen action a letter rejecting their request for discovery but agreeing to engage in a call with the mediator to further discuss the impact of the proposed Merger on the derivative litigation.

On February 13, 2023, the parties in the derivative litigation participated in a call with the mediator to discuss the impact of the proposed Merger on the settlement in principle and plaintiffs' standing in the event the Merger is consummated, as well as the discovery sought in the Chen action. While no resolution was reached on these issues during the call, the parties agreed to discuss the substance of their call and the mediator's suggestions with their clients, and counsel for Chen indicated that they would review the Schedule 14D-9, which we filed with the Securities and Exchange Commission on February 14, 2023 in connection with the Offer (as amended and supplemented, the "Schedule 14D-9") once filed to determine whether they would pursue the discovery for the Chen action set forth in their February 6 letter.

Pursuant to the court's February 11, 2023 order, the parties to the Wong action filed a joint status letter on February 17, 2023. In that joint status letter, the defendants advised the court that in the parties' February 13, 2023 call with the mediator, the parties discussed the impact of the Company's proposed merger with Parent on the settlement in principle of the litigation and on the plaintiffs' standing to pursue that litigation in the event the Merger is consummated, as well as the proposed discovery sought by counsel for plaintiff in the Chen action. The defendants also advised the court that no resolution of the issues was reached during the call with the mediator, but that counsel for the parties agreed to discuss the substance of the call and the mediator's suggestions with their clients, and that plaintiff's counsel in the Chen action had indicated that they would review the Schedule 14D-9 to determine whether they would pursue discovery in that litigation. Defendants also advised the court that defendants' position continues to be that the putative derivative litigation should be stayed until at least such time as it is known whether the Merger will be consummated and, in the event plaintiff in the Wong action intends to seek to lift the stay in that action, requested that the court schedule a conference to discuss any such request and, if appropriate, to discuss a briefing schedule on any motion to dismiss the case. Defendants also pointed out that the Company had made public disclosure of its consideration of strategic alternatives in its Form 10-Q filed on August 5, 2022, prior to the parties' entry into their memorandum of understanding dated August 15, 2022, and that the Schedule 14D-9 described in detail the timing of the Company's discussions with Parent regarding the particular transaction that is the subject of the Merger Agreement. Plaintiff Wong's counsel stated that Wong would like to pursue discovery from defendants to address plaintiff's asserted concerns regarding whether defendants intended to proceed with finalizing the settlement agreement over the past months and whether defendants had been planning the Merger for a long while. Plaintiff further asserted that defendants had received the benefit of a stay of proceedings in order to document a settlement, but were now continuing to seek a stay to see whether the Merger closes, resulting in Plaintiff's loss of standing to pursue the derivative claims. Plaintiff also contended that no stay was currently in place in the case, and requested that the court order defendants to respond to the complaint no later than March 10, 2023. Plaintiff further reserved her rights regarding any obligations that defendants may have pursuant to the memorandum of understanding executed on August 15, 2022.

On February 19, 2023, the court in the Wong action entered an order setting a status conference on March 2, 2023, directing the parties to be prepared to discuss the issues set forth in the joint status letter and whether the stay of the action should be continued. During the March 2, 2023 status conference, the parties advised the court of the status of settlement in light of the proposed Merger and took opposing positions regarding the appropriateness of the stay. The court directed the parties to submit, on or before March 8, 2023, simultaneous letter briefings as to whether the stay should remain in place.

On February 20, 2023, counsel for the plaintiff in the Chen case sent a letter to K&L Gates indicating that they had reviewed the Schedule 14D-9 and remained of the view that the Company is obligated to execute a settlement agreement in the case. Counsel for Chen also indicated that they were willing to continue discussions with the mediator in an attempt to reach an amicable resolution.

On March 8, 2023, the parties to the Wong action filed letter briefs addressing whether the December 5, 2022 stay of the Wong action should remain in place. On March 13, 2023, the court entered an order lifting the stay in the Wong action, directing the parties to meet, confer and submit a proposed discovery schedule to the court on or before March 20, 2023, and requiring that the defendants answer, move or otherwise respond to the complaint in the Wong action on or before April 13, 2023.

On March 17, 2023, the defendants in the Wong action filed a letter with the court advising the court that they intend to move to dismiss the complaint and requesting that the court stay discovery pursuant to the Private Securities Litigation Reform Act (“PSLRA”) pending a ruling on their anticipated motion to dismiss. Defendants further argued that discovery requested by plaintiff regarding the Merger and the defendants’ intent during settlement discussions is not relevant to any claims at issue in the case, and requested that the court adjourn the deadline to submit a discovery plan until after the motion to dismiss is decided. In response, plaintiff submitted a letter to the court in which she argued that the statutory stay does not apply to the discovery being sought or was waived. Plaintiff also submitted a proposed discovery plan for the court’s consideration. On March 18, 2023, the court entered an order denying the defendants’ request to adjourn the deadline to submit a proposed discovery plan and entered its own order requiring fact depositions to be completed on or before August 15, 2023. The court further noted that it will consider whether the statutory stay under the PSLRA applies at the time defendants file their motion to dismiss.

Merger Litigation

On February 17, 2023, a complaint was filed in the United States District Court, Southern District of New York, against the Company and the individual members of the Company Board and management, captioned Sholom Keller v. Chembio Diagnostics, Inc., Katherine L. Davis, John G. Potthoff, David W.K. Acheson, David W. Bespalko, Richard L. Eberly, Leslie Teso-Lichtman, and Lawrence J. Steenvoorden, Case No. 1:23-cv-01388 (the “New York Complaint”).

On March 8, 2023, a pro se complaint was filed in the United States District Court, District of Nevada, against the Company and the individual members of the Company Board and management, captioned David S. Gross v. Chembio Diagnostics, Inc., Katherine L. Davis, John G. Potthoff, David W.K. Acheson, David W. Bespalko, Richard L. Eberly, Leslie Teso-Lichtman, and Lawrence J. Steenvoorden, Case No. 3:23-cv-00093 (the "Nevada Complaint, and together with the New York Complaint, the "Complaints").

The Complaints asserts that the defendants violated Sections 14(d), 14(e), and 20(a) of the Exchange Act and certain rules and regulations promulgated thereunder by allegedly making false and misleading statements, or failing to disclose allegedly material facts necessary to make the statements made not misleading, relating to the Merger in the Company's Recommendation / Solicitation Statement on Schedule 14D-9 filed with the SEC on February 14, 2023 (as amended, the "Schedule 14D-9), including allegations relating to the background of the Merger, financial projections, and analyses of the Company's financial adviser, Craig-Hallum.

In addition to the Complaints referenced above, thirteen demand letters have been received from purported stockholders of the Company as of the date of this Annual Report, each challenging certain of the disclosures in the Schedule 14D-9. Additional complaints may be filed and/or demand letters may be received in connection with the Merger and the Transactions. If additional similar complaints are filed and/or demand letters received, absent new or different allegations that are material, the Company will not necessarily announce such additional complaints or demand letters.

The Company believes that the disclosures set forth in the Schedule 14D-9 comply fully with applicable laws and denies the allegations in the matters described above. However, in order to moot certain of the disclosure claims and avoid the costs, risks and uncertainties inherent in litigation, and provide additional information to its stockholders, the Company determined to voluntarily provide certain additional disclosures reflected in Amendment No. 1 to the Schedule 14D-9. Nothing in these supplemental disclosures, which also include certain supplemental disclosures unrelated to the New York Complaint and/or the demand letters, should be regarded as an indication that the Company or the Company's affiliates, management, directors or other representatives, or any recipient of this information, considered or now considers the information contained in the supplemental disclosures to be material; rather, the Company believes that the Schedule 14D-9 as filed on February 14, 2023 disclosed all necessary information and denies that any additional disclosures are or were required under any federal or state law.

Employee Litigation

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

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

On May 20, 2021, Chembio filed its answer and affirmative defenses denying the material allegations of Mr. Sperzel's complaint. All discovery in the case was completed in June 2022. On July 6, 2022, pursuant to local court rules, Chembio filed a formal notice with the District Court stating its intention to file a motion for summary judgment on all of Mr. Sperzel's claims, along with a statement of facts in support thereof. Mr. Sperzel's filed a responsive letter and factual statements on July 27, 2022, and Chembio filed a timely reply on August 10, 2022. On August 16, 2022, the Court held a pre-motion status conference, during which the Court directed the parties to confer regarding the renewal of settlement discussions. The parties subsequently engaged in a formal mediation conference before a neutral, private mediator on October 25, 2022, and have continued their settlement discussions into 2023. The Court has entered an Order providing for the filing of Chembio's summary judgment motion, any opposition, and reply, by May 4, 2023. At this stage of the litigation, the Company is not able to predict the probability of a favorable or unfavorable outcome.

Other

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

Nasdaq Communications

On April 5, 2022, the Company received notification from the Listing Qualifications Department of The Nasdaq Stock Market, or Nasdaq, stating that the Company did not comply with the minimum $1.00 bid price requirement for continued listing set forth in Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement"). In accordance with Nasdaq listing rules, the Company was afforded 180 calendar days (until October 3, 2022) to regain compliance with the Bid Price Requirement. On October 4, 2022, the Company received written notice from Nasdaq stating that, although the Company had not regained compliance with the Bid Price Requirement by October 3, 2022, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company is eligible for an additional 180 calendar day period, or until April 3, 2023, to regain compliance with the Bid Price Requirement. To regain compliance, the closing bid price of the Company's common stock must meet or exceed $1.00 per share for a minimum of ten consecutive business days during this additional 180-day period, all as described in more detail in the Current Reports on Form 8-K filed with the SEC on April 7, 2022 and October 4, 2022.

There can be no assurance that Chembio will be able to regain compliance with the Bid Price Requirement. The Company's inability to regain compliance with the Bid Price Requirement would, and the existence of the pending deficiency letter could, materially impair its ability to raise capital. Moreover, if Chembio were unable to regain compliance with the Bid Price Requirement, its common stock would likely then trade only in the over-the-counter market and the market liquidity of its common stock could be adversely affected and its market price could decrease. If Chembio's common stock were to trade on the over-the-counter market, selling Chembio's common stock could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and Chembio could face significant material adverse consequences, including: a limited availability of market quotations for its securities; reduced liquidity with respect to its securities; a determination that its shares are a "penny stock," which will require brokers trading in its securities to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for its securities; a reduced amount of news and analyst coverage; and a decreased ability to issue additional securities or obtain additional financing in the future. These factors could result in lower prices and larger spreads in the bid and ask prices for its common stock and would substantially impair its ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for Chembio.

NOTE 13 — LONG-TERM DEBT:

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

Principal outstanding under the Credit Agreement bears interest at a rate per annum equal to the sum of (a) the greater of the one-month London Interbank Offered Rate and 2.5% plus (b) 8.75%. At any time at which an event of default has occurred and is continuing, the interest rate will increase by 4.0%. Accrued interest is payable on a monthly basis. On December 31, 2022 the interest rate was 12.88%.

No principal repayments were due under the Credit Agreement prior to September 30, 2022. Chembio did not elect to prepay principal and an event of default identified in the Credit Agreement did not occur that would have accelerated principal payments. Principal installments in the amount of $300,000 are payable on the last day of each of the eleven months from September 2022 through July 2023, and all remaining principal is payable at maturity on September 3, 2023.

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, 2022, the loan balance, net of unamortized discounts and debt issuance costs, was $18.6 million, and Chembio was in compliance with its loan covenants.

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

Impairment, restructuring, severance and related costs include an impairment loss of $3.0 million during the first quarter of 2022 as a result of an impairment of goodwill due to the substantial decrease in our share price at March 31, 2022. The low price per share value at March 31, 2022 caused our book value to exceed our fair value. In addition, for the year ended December 31, 2022, $0.2 million was recorded which was related to severance charges. For the year ended 2021, the Company recorded an impairment loss of $7.0 million, of which $5.9 million was related to the write-off of intangible assets, net leasehold improvements, and net right-of-use assets for leases associated with our Malaysian operations, and $1.1 million was related to restructuring matters.

In order to address challenging economic conditions and implement its business strategy, in the first quarter of 2022 the Company continued to execute a program to reduce operating expenses and better align its costs with revenues, including by eliminating positions that were no longer aligned with its strategy, and recognized severance charges of $0.1 million.

The table below represents the total costs by category:

	For the year ended December 31, 2022	For the year ended December 31, 2021
Severance	**$ 202,621**	$ 83,087
Restructuring costs	-	1,083,951
Impairment	**3,033,565**	5,880,741
	$ 3,236,186	$ 7,047,779

NOTE 15 — SUBSEQUENT EVENTS:

The Company entered into an Agreement and Plan of Merger (the "Merger Agreement"), dated as of January 31, 2023, with Biosynex SA, a French société anonyme ("Biosynex"), and Project Merci Merger Sub, Inc., a Nevada corporation and wholly-owned indirect subsidiary of Biosynex (the "Purchaser"). Pursuant to the Merger Agreement, on February 14, 2023, the Purchaser commenced a tender offer (the "Offer") to purchase all of the issued and outstanding shares of the Company's common stock, par value $0.01 per share (the "Shares"), for a purchase price of $0.45 per share, net to the seller in cash, without interest and subject to any required tax withholding. On March 15, 2023, Biosynex announced an extension of the Offer until 6:00 p.m., New York City time, on March 28, 2023. Subsequently, on March 29,2023, Biosynex announced an extension of the Offer until 6:00 p.m., New York City time, on April 12, 2023. If the conditions to the Offer are satisfied and the Offer closes, Purchaser would acquire all remaining Chembio shares by a merger of Purchaser with and into Chembio (the "Merger"), with Chembio surviving the Merger as a wholly-owned indirect subsidiary of Biosynex. At the effective time of the Merger (the "Effective Time"), each Share issued and outstanding immediately prior to the Effective Time (including shares paid to holders of vested Chembio restricted stock units) will be converted into the right to receive $0.45 per share. Stock options that are outstanding immediately prior to the Effective Time will automatically terminate for no consideration.

If the conditions to the Offer are satisfied and the Offer closes, Purchaser would acquire all remaining Chembio shares by a merger of Purchaser with and into Chembio (the "Merger"), with Chembio surviving the Merger as a wholly-owned indirect subsidiary of Biosynex. At the effective time of the Merger (the "Effective Time"), each Share issued and outstanding immediately prior to the Effective Time (including shares paid to holders of vested Chembio restricted stock units) will be converted into the right to receive $0.45 per share. Stock options that are outstanding immediately prior to the Effective Time will automatically terminate for no consideration.

The Merger Agreement and the transactions contemplated thereby, including the Merger, were unanimously approved by the Company's Board of Directors. Completion of the Merger is subject to certain customary conditions as set forth in the Merger Agreement and the successful completion of the Offer. There can be no assurance that the Merger will be consummated on the terms described above or at all.

The foregoing description of the Merger Agreement and the transactions contemplated thereby, including the Offer, does not purport to be complete and is subject to, and qualified in its entirety by reference to, the full text of the Merger Agreement, which has been filed as Exhibit 2.1 to our Current Report on Form 8-K filed with the SEC on January 31, 2023.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

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

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

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

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

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

of our report dated March 29, 2023, 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, 2022.

/s/ Ernst & Young, LLP

Jericho, New York
March 29, 2023

Exhibit 31.1

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

I, Richard L. Eberly, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 29, 2023

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

Exhibit 31.2

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

I, Lawrence J. Steenvoorden, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 29, 2023

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

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, 2022, each of the undersigned Richard L. Eberly, the President & Chief Executive Officer of the Company, and Lawrence J. Steenvoorden, the Executive Vice President & Chief Financial Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of the undersigneds' knowledge and belief:

(1) This Form 10-K for the year ended December 31, 2022 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this Form 10-K for the year ended December 31, 2022 fairly presents, in all material respects, the financial condition and results of operations of Chembio Diagnostics, Inc. for the periods presented therein.

Date: March 29, 2023

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

Date: March 29, 2023

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